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Agricultural and veterinary chemicals

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The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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General information

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

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

Distribution and subscription

The APVMA Gazette is published in electronic format only and is available from the APVMA website.

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Privacy

For information on how the APVMA manages personal information when you contact us, see our Privacy Policy.

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Erratum notice

The Australian Pesticides and Veterinary Medicines Authority (APVMA) advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, No. APVMA 21, Tuesday 20 October 2026.

In the notice, under *Agvet chemical voluntary safety recall: COUNTER 150G Granular Soil Insecticide/Nematicide (20 kg)*, on page 57, the contact's name was incorrectly listed as Anuva Technologies.

The correct contact's name for Agvet chemical voluntary safety recall: COUNTER 150G Granular Soil Insecticide/Nematicide (20 kg) is AgNova Technologies Pty Ltd.

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.

The APVMA is implementing some changes to the way that we give this notice. While implementation occurs, there will be differences in how decisions appear in the tables below.

Table 1: Agricultural products based on existing active constituents

Application no.	153584
Chemical product name	Clipper Herbicide Blue
Distinguishing number of the chemical product	97649
Active constituent	100 g/kg flumioxazin (15 g/tablet)
Applicant name	Sumitomo Chemical Australia Pty. Limited
Date of registration and label approval	7 October 2026
Distinguishing number of label	97649/153584
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/kg flumioxazin tablet product and approval of label for the control of aquatic weeds in agricultural, non-agricultural, pasture, and natural aquatic systems including non-flowing freshwater bodies and the margins of slow-moving or quiescent streams, lakes, dams, and channels
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153504
Chemical product name	Genfarm Panzer 540 Herbicide B
Distinguishing number of the chemical product	97596
Active constituent	540 g/L glyphosate (present as the potassium salt)
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	12 October 2026
Distinguishing number of label	97596/153504
Description of the application and its purpose, including the intended use of the chemical product	Registration of Genfarm Panzer 540 Herbicide B and approval of label for the non-selective control of many annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153509
Chemical product name	Genfarm Panzer 540 Herbicide C
Distinguishing number of the chemical product	97597
Active constituent	540 g/L glyphosate (present as the potassium salt)
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	12 October 2026
Distinguishing number of label	97597/153509
Description of the application and its purpose, including the intended use of the chemical product	Registration of Genfarm Panzer 540 Herbicide C and approval of label for the non-selective control of many annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153516
Chemical product name	Genfarm Panzer 540 Herbicide D
Distinguishing number of the chemical product	97602
Active constituent	540 g/L glyphosate (present as the potassium salt)
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	12 October 2026
Distinguishing number of label	97602/153516
Description of the application and its purpose, including the intended use of the chemical product	Registration of Genfarm Panzer 540 Herbicide D and approval of label for the non-selective control of many annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153619
Chemical product name	Genfarm Clethodim 360 Selective Herbicide B
Distinguishing number of the chemical product	97669
Active constituent	360 g/L clethodim
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	12 October 2026
Distinguishing number of label	97669/153619
Description of the application and its purpose, including the intended use of the chemical product	Registration of Genfarm Clethodim 360 Selective Herbicide B and approval of label for the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes, and soybeans
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154279
Chemical product name	International VC Offshore Hard Racing Antifouling Dover White
Distinguishing number of the chemical product	98005
Active constituents	968 g/kg cuprous oxide, 479 g/kg xylene
Applicant name	Akzo Nobel Pty Limited
Date of registration and label approval	12 October 2026
Distinguishing number of label	98005/154279
Description of the application and its purpose, including the intended use of the chemical product	Registration of International VC Offshore Hard Racing Antifouling Dover White containing 968 g/kg cuprous oxide for use as a finish below the waterline on regularly maintained and cleaned racing craft to control short term fouling growth
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154387
Chemical product name	Titan Besuto 850 WG Herbicide C
Distinguishing number of the chemical product	98060
Active constituent	850 g/kg pyroxasulfone
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	12 October 2026
Distinguishing number of label	98060/154387
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 850 g/kg pyroxasulfone water dispersible granule product and approval of a label for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silvergrass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154428
Chemical product name	Titan Besuto 850 WG Herbicide B
Distinguishing number of the chemical product	98072
Active constituent	850 g/kg pyroxasulfone
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	12 October 2026
Distinguishing number of label	98072/154428
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 850 g/kg pyroxasulfone water dispersible granule product and approval of a label for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silvergrass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153456
Chemical product name	Glufoz-A 200 Herbicide
Distinguishing number of the chemical product	97573
Active constituent	200 g/L glufosinate-ammonium
Applicant name	Shandong Rainbow International Co Ltd
Date of registration and label approval	12 October 2026
Distinguishing number of label	97573/153456
Description of the application and its purpose, including the intended use of the chemical product	Registration of Glufoz-A 200 Herbicide and approval of label for the non-residual control of broadleaf and grass weeds in various situations
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153458
Chemical product name	Cerepin-A 100EC Selective Herbicide
Distinguishing number of the chemical product	97575
Active constituents	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
Applicant name	Shandong Rainbow International Co Ltd
Date of registration and label approval	12 October 2026
Distinguishing number of label	97575/153458
Description of the application and its purpose, including the intended use of the chemical product	Registration of Cerepin-A 100EC Selective Herbicide and approval of label for the for the control of key grass weeds and selective spray topping of wild oats in wheat and barley
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	149915
Chemical product name	Maxunitech Pyroxasulfone 850 WG
Distinguishing number of the chemical product	96576
Active constituent	850 g/kg pyroxasulfone
Applicant name	Max(Rudong) Chemicals Co., Ltd.
Date of registration and label approval	12 October 2026
Distinguishing number of label	96576/149915
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 850 g/kg pyroxasulfone water dispersible granule product for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153519
Chemical product name	Swan Pyroxasulfone 850 Herbicide
Distinguishing number of the chemical product	97605
Active constituent	850 g/kg pyroxasulfone
Applicant name	Swan Chemical Holdings Pty Ltd
Date of registration and label approval	13 October 2026
Distinguishing number of label	97605/153519
Description of the application and its purpose, including the intended use of the chemical product	Registration of Swan Pyroxasulfone 850 Herbicide and approval of label for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153501
Chemical product name	Zeemil 720 WG Systemic and Protective Fungicide FB
Distinguishing number of the chemical product	97594
Active constituents	640 g/kg mancozeb, 80 g/kg metalaxyl
Applicant name	UPL Australia Pty Ltd
Date of registration and label approval	13 October 2026
Distinguishing number of label	97594/153501
Description of the application and its purpose, including the intended use of the chemical product	Registration of a product containing 640 g/kg mancozeb and 80 g/kg metalaxyl product for control of downy mildew and certain other foliar diseases and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153603
Chemical product name	Excalia SC Fungicide
Distinguishing number of the chemical product	97660
Active constituent	400 g/L inpyrfluxam
Applicant name	Sumitomo Chemical Australia Pty Limited
Date of registration and label approval	13 October 2026
Distinguishing number of label	97660/153603
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 400 g/L inpyrfluxam suspension concentrate product for control of *rhizoctonia solani* in potato and yellow sigatoka in banana and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153831
Chemical product name	ADAMA LVE MCPA 570 Herbicide A
Distinguishing number of the chemical product	97792
Active constituent	570 g/L MCPA present as the 2-ethylhexyl ester
Applicant name	ADAMA Australia Pty Limited
Date of registration and label approval	13 October 2026
Distinguishing number of label	97792/153831
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 570 g/L MCPA present as the 2-ethylhexyl ester emulsifiable concentrate product and approval of label for selective control of certain weeds in agricultural crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154133
Chemical product name	Tenet 500 SC Herbicide - B
Distinguishing number of the chemical product	97909
Active constituent	500 g/L metazachlor
Applicant name	ADAMA Australia Pty Limited
Date of registration and label approval	13 October 2026
Distinguishing number of label	97909/154133
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L metazachlor suspension concentrate product for the control or suppression of a range of grass and broadleaf weeds in situations
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154705
Chemical product name	Apparent Machete 500 Herbicide B
Distinguishing number of the chemical product	98198
Active constituent	500 g/L 2,4-DB present as the dimethylamine salt
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	13 October 2026
Distinguishing number of label	98198/154705
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L 2,4-DB present as the dimethylamine salt product for the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153816
Chemical product name	Starling Fungicide B
Distinguishing number of the chemical product	97782
Active constituent	230 g/L fludioxonil
Applicant name	Grochem Australia Pty Ltd
Date of registration and label approval	13 October 2026
Distinguishing number of label	97782/153816
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 230 g/L fludioxonil suspension concentrate product for the control of certain post-harvest diseases in citrus, pome fruit, stone fruit and kiwi fruit
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154288
Chemical product name	Accensi Iprodione 365 SE Fungicide A
Distinguishing number of the chemical product	98012
Active constituent	365 g/L iprodione
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	13 October 2026
Distinguishing number of label	98012/154288
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 365 g/L iprodione suspo-emulsion formulation and approval of a label for the control of fungal diseases in recreational turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153541
Chemical product name	Rifaway Fire Ant Control Bait
Distinguishing number of the chemical product	97626
Active constituent	0.6 g/kg indoxacarb (75:25) (equivalent to 0.45 g/kg active S-isomer)
Applicant name	Syngenta Australia Pty Ltd
Date of registration and label approval	13 October 2026
Distinguishing number of label	97626/153541
Description of the application and its purpose, including the intended use of the chemical product	Registration and approval of a label for a 0.6 g/kg indoxacarb (75:25) (equivalent to 0.45 g/kg active S-isomer) ready-to-use bait product for the control of fire ants around buildings, gardens, grazing areas, lawns and public areas
Statement of the conditions of the registration that directly regulate the use of the product	Isomer Ratio The source of Indoxacarb constituent used must be of the S:R isomer ratio 75:25

Application no.	153428
Chemical product name	Amistar 250 Fungicide
Distinguishing number of the chemical product	97556
Active constituent	250 g/L azoxystrobin
Applicant name	Syngenta Australia Pty Ltd
Date of registration and label approval	13 October 2026
Distinguishing number of label	97556/153428
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L azoxystrobin suspension concentrate for the control of various diseases in certain vegetables, berries, field crops, tree and vine crops, and nursery stock
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153511
Chemical product name	Genfarm Panzer 540 K Herbicide B
Distinguishing number of the chemical product	97599
Active constituent	540 g/L glyphosate (present as the potassium salt)
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	13 October 2026
Distinguishing number of label	97599/153511
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 540 g/L glyphosate soluble concentrate as a non-selective herbicide for the control of many annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153686
Chemical product name	Genfarm Clopyralid 750 SG Herbicide B
Distinguishing number of the chemical product	97703
Active constituent	750 g/kg clopyralid present as the potassium salt
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	13 October 2026
Distinguishing number of label	97703/153686
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 750 g/kg clopyralid water soluble granules herbicide for control of a wide range of broadleaf weeds in wheat, barley, oats, triticale, canola, pastures and fallow land and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154416
Chemical product name	Accensi Flutriafol 500 SC Fungicide B
Distinguishing number of the chemical product	98068
Active constituent	500 g/L flutriafol
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	14 October 2026
Distinguishing number of label	98068/154416
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L flutriafol suspension concentrate product and approval of label for control of certain fungal disease on wheat, barley and canola when mixed with fertiliser
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154333
Chemical product name	Accensi TRI-MAX 480 EC Herbicide B
Distinguishing number of the chemical product	98039
Active constituent	480 g/L trifluralin
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	14 October 2026
Distinguishing number of label	98039/154333
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L trifluralin emulsifiable concentrate product for pre-emergence herbicide control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops and approval of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154130
Chemical product name	Genfarm Propyzamide 500 SC Herbicide B
Distinguishing number of the chemical product	97906
Active constituent	500 g/L propyzamide
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	14 October 2026
Distinguishing number of label	97906/154130
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L propyzamide suspension concentrate herbicide product and label approval for selective control of certain grasses and broadleaf weeds in lettuce, chicory, endive, radicchio and legume seed crops, pastures, pyrethrum crops, canola and mustard
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153679
Chemical product name	Genfarm Clopyralid 300 SL Herbicide B
Distinguishing number of the chemical product	97700
Active constituent	300 g/L clopyralid present as the triisopropanolamine salt
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	14 October 2026
Distinguishing number of label	97700/153679
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 300 g/L clopyralid soluble concentrate herbicide for the control of a wide range of broadleaf weeds in wheat, barley, triticale, oats, pastures, canola, fallow land, forests and industrial situations and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153512
Chemical product name	Antifouling Seaforce Active Plus Dark Red
Distinguishing number of the chemical product	97600
Active constituents	432 g/L copper present as cuprous oxide, 85 g/L zineb and 24 g/L copper pyrithione
Applicant name	Jotun Australia Pty Ltd
Date of registration and label approval	14 October 2026
Distinguishing number of label	97600/153512
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 432 g/L copper present as cuprous oxide, 85 g/L zineb and 24 g/L copper pyrithione antifouling paint product and approval of a label for control of marine growth below the waterline on vessels
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154117
Chemical product name	Genfarm Trifluralin 480 Selective Herbicide B
Distinguishing number of the chemical product	97895
Active constituent	480 g/L trifluralin
Applicant name	Nutrien AG Solutions Limited
Date of registration and label approval	14 October 2026
Distinguishing number of label	97895/154117
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L trifluralin emulsifiable concentrate product and approval of label for the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153629
Chemical product name	SeaQuantum Spectrum Blue
Distinguishing number of the chemical product	97676
Active constituents	449 g/L copper present as cuprous oxide, 61.6 g/L zineb and 23.9 g/L copper pyrithione
Applicant name	Jotun Australia Pty Ltd
Date of registration and label approval	14 October 2026
Distinguishing number of label	97676/153629
Description of the application and its purpose, including the intended use of the chemical product	Registration of 449 g/L copper present as cuprous oxide, 61.6 g/L zineb and 23.9 g/L copper pyrithione as an antifouling paint product and approval of the label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154217
Chemical product name	SeaQuantum Spectrum Black
Distinguishing number of the chemical product	97959
Active constituents	453 g/L copper present as cuprous oxide, 62.2 g/L zineb, 24.1 g/L copper pyrithione
Applicant name	Jotun Australia Pty Ltd
Date of registration and label approval	14 October 2026
Distinguishing number of label	97959/154217
Description of the application and its purpose, including the intended use of the chemical product	Registration of 453 g/L copper present as cuprous oxide, 62.2 g/L zineb and 24.1 g/L copper pyrithione as an antifouling paint product and approval of the label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154305
Chemical product name	Intersmooth 360 SPC Antifouling Dark Red
Distinguishing number of the chemical product	98021
Active constituents	626 g/L copper present as cuprous oxide, 66 g/L zinc pyrithione
Applicant name	Akzo Nobel Pty Limited
Date of registration and label approval	14 October 2026
Distinguishing number of label	98021/154305
Description of the application and its purpose, including the way the in which intended use of the chemical product	Registration of a 626 g/L copper present as cuprous oxide and 66 g/L zinc pyrithione antifouling paint product and approval of a label for the control marine growth below the waterline on vessels
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153836
Chemical product name	Celphide Fumigation Blanket 2
Distinguishing number of the chemical product	97795
Active constituent	330 g/kg phosphine (PH3) present as aluminium phosphide
Applicant name	Sumitomo Chemical Australia Pty. Limited
Date of registration and label approval	14 October 2026
Distinguishing number of label	97795/153836
Description of the application and its purpose, including the way the in which intended use of the chemical product	Registration of a 330 g/kg phosphine (PH3) present as aluminium phosphide blanket product and approval of label for control of insect pests of stored products in certain situations
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154117
Chemical product name	Genfarm Trifluralin 480 Selective Herbicide B
Distinguishing number of the chemical product	97895
Active constituent	480 g/L trifluralin
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	14 October 2026
Distinguishing number of label	97895/154117
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L trifluralin emulsifiable concentrate product and approval of label for the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154119
Chemical product name	Genfarm Trifluralin 480 Selective Herbicide C
Distinguishing number of the chemical product	97897
Active constituent	480 g/L trifluralin
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	15 October 2026
Distinguishing number of label	97897/154119
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L trifluralin emulsifiable concentrate product and approval of a label for the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155094
Chemical product name	Quali-Pro Twister Insecticide
Distinguishing number of the chemical product	98366
Active constituents	267 g/L indoxacarb (90:10) (equivalent to 240 g/L active S-isomer), 80 g/L novaluron
Applicant name	ADAMA Australia Pty Limited
Date of registration and label approval	15 October 2026
Distinguishing number of label	98366/155094
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for a 267 g/L indoxacarb (90:10) (equivalent to 240 g/L active S-isomer) plus 80 g/L novaluron suspension concentrate (SC) product for the control of african black beetle, argentine stem weevil, billbug, lepidoptera including cutworm, armyworm and sod webworm in turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154197
Chemical product name	Quali-Pro Twister Insecticide A
Distinguishing number of the chemical product	97944
Active constituents	320 g/L indoxacarb (75:25) (equivalent to 240 g/L active S-isomer), 80 g/L novaluron
Applicant name	ADAMA Australia Pty Limited
Date of registration and label approval	15 October 2026
Distinguishing number of label	97944/154197
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for a 320 g/L indoxacarb (75:25) (equivalent to 240 g/L active S-isomer) plus 80 g/L novaluron suspension concentrate (SC) product for the control of african black beetle, argentine stem weevil, billbug, lepidoptera including cutworm, armyworm and sod webworm in turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154097
Chemical product name	Hempel's Antifouling Olympic+ 72900-51110 Red
Distinguishing number of the chemical product	97880
Active constituents	331 g/L copper present as cuprous oxide, 121 g/L zineb
Applicant name	Hempel (Wattyl) Australia Pty Ltd
Date of registration and label approval	15 October 2026
Distinguishing number of label	97880/154097
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 331 g/L copper present as cuprous oxide, 121 g/L zineb antifouling paint product for the prevention of biofouling on ship hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154100
Chemical product name	Hempel's Antifouling Olympic+ 72900-30170 Blue
Distinguishing number of the chemical product	97881
Active constituents	330 g/L copper present as cuprous oxide, 121 g/L zineb
Applicant name	Hempel (Wattyl) Australia Pty Ltd
Date of registration and label approval	15 October 2026
Distinguishing number of label	97881/154100
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 330 g/L copper present as cuprous oxide, 121 g/L zineb antifouling paint product for the prevention of biofouling on ship hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154102
Chemical product name	Hempel's Antifouling Olympic+ 72900-19990 Black
Distinguishing number of the chemical product	97883
Active constituents	330 g/L copper present as cuprous oxide, 121 g/L zineb
Applicant name	Hempel (Wattyl) Australia Pty Ltd
Date of registration and label approval	15 October 2026
Distinguishing number of label	97883/154102
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 330 g/L copper present as cuprous oxide, 121 g/L zineb antifouling paint product for the prevention of biofouling on ship hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154313
Chemical product name	Brunnings Extra Strength Feed N Weed for Lawns B
Distinguishing number of the chemical product	98027
Active constituents	23 g/L MCPA present as the dimethylamine salt, 3.5 g/L dicamba present as the dimethylamine salt
Applicant name	Brunnings Garden Products Pty Ltd
Date of registration and label approval	15 October 2026
Distinguishing number of label	98027/154313
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 23 g/L MCPA present as the dimethylamine salt + 3.5 g/L dicamba present as the dimethylamine salt soluble concentrate for lawn feeding and selective kill of broadleaf weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154344
Chemical product name	Brunnings Bindii Kill for Lawns B
Distinguishing number of the chemical product	98048
Active constituents	15 g/L MCPA present as the dimethylamine salt, 2.3 g/L dicamba present as the dimethylamine salt
Applicant name	Brunnings Garden Products Pty Ltd
Date of registration and label approval	15 October 2026
Distinguishing number of label	98048/154344
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 15 g/L MCPA present as dimethylamine salt, 2.3g/L dicamba present as dimethylamine salt soluble concentrate (SL) product for the control of certain weeds in lawns and turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153390
Chemical product name	Touchdown Hitech 500 SL Herbicide
Distinguishing number of the chemical product	97540
Active constituent	500 g/L glyphosate present as the potassium salt
Applicant name	Syngenta Australia Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	97540/153390
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L glyphosate present as the potassium salt, soluble concentrate product for the control of a wide range of annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154193
Chemical product name	Antifouling Seaforce Active Black
Distinguishing number of the chemical product	97940
Active constituents	389.5 g/L copper present as cuprous oxide, 78.3 g/L zineb, 22.6 g/L copper pyrithione
Applicant name	Jotun Australia Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	97940 /154193
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 389.5 g/L copper present as cuprous oxide, 78.3 g/L zineb and 22.6 g/L copper pyrithione, as an antifouling paint product and approval of the label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154706
Chemical product name	Titan 2,4-DB 500 SC Herbicide B
Distinguishing number of the chemical product	98199
Active constituent	500 g/L 2,4-DB present as the dimethylamine salt
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	98199/154706
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L 2,4-DB present as the dimethylamine salt soluble concentrate product for the control of broadleaf weeds in seedling and established lucerne, medic and clover pastures, peanuts and cereal crops undersown with lucerne, medic or clover
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153525
Chemical product name	Antifouling Seaforce Active Blue
Distinguishing number of the chemical product	97611
Active constituents	383.8 g/L copper present as cuprous oxide, 77.1 g/L zineb, 22.3 g/L copper pyrithione
Applicant name	Jotun Australia Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	97611/153525
Description of the application and its purpose, including the intended use of the chemical product	Registration of 383.8 g/L copper present as cuprous oxide, 77.1 g/L zineb and 22.3 g/L copper pyrithione, as an antifouling paint product and approval of the label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155136
Chemical product name	DuPont Velpar K4 DF Herbicide A
Distinguishing number of the chemical product	98383
Active constituents	468 g/kg diuron, 132 g/kg hexazinone
Applicant name	Tessenderlo Kerley, Inc
Date of registration and label approval	16 October 2026
Distinguishing number of label	98383/155136
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 468.0 g/kg diuron and 132.0 g/kg hexazinone water dispersible granule (WG) product for the control of a wide range of annual and perennial grasses, broadleaved weeds and vines in established sugarcane and approval of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154254
Chemical product name	Albaugh Durango Ultra 540K SL Herbicide B
Distinguishing number of the chemical product	97980
Active constituent	540 g/L glyphosate present as the potassium salt
Applicant name	Albaugh Australia Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	97980/154254
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 540 g/L glyphosate present as the potassium salt soluble concentrate product for the control of a range of annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	151906
Chemical product name	Omkar Azoxystrobin 250 SC Fungicide
Distinguishing number of the chemical product	97112
Active constituent	250 g/L azoxystrobin
Applicant name	Omkar Agri Global Pvt. Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	97112/151906
Description of the application and its purpose, including the intended use of the chemical product	Registration and label approval of a 250 g/L azoxystrobin suspension concentrate product for the control of various diseases of grapes, potatoes, tomatoes, cucurbits, avocados, mangoes, passionfruit and poppies
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154345
Chemical product name	Brunnings Feed'N Weed B
Distinguishing number of the chemical product	98049
Active constituents	15 g/L MCPA present as the dimethylamine salt, 2.3 g/L dicamba present as the dimethylamine salt
Applicant name	Brunnings Garden Products Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	98049/154345
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 15 g/L MCPA present as dimethylamine salt, 2.3 g/L dicamba present as dimethylamine salt soluble concentrate product for control of broadleaf weeds in lawns
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154389
Chemical product name	Accensi Carbendazim 500 SC Fungicide
Distinguishing number of the chemical product	98062
Active constituent	500 g/L carbendazim
Applicant name	Australian Agribusiness (holdings) Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	98062/154389
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L carbendazim suspension concentrate product and approval of a label for the control of fungal diseases in various crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154390
Chemical product name	Accensi Carbendazim 500 SC Fungicide B
Distinguishing number of the chemical product	98063
Active constituent	500 g/L carbendazim
Applicant name	Australian Agribusiness (holdings) Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	98063/154390
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L carbendazim suspension concentrate, a broad-spectrum, systemic fungicide product, and approval of its label for the control of fungal diseases in various crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153543
Chemical product name	Antifouling Seaforce Active Dark Red
Distinguishing number of the chemical product	97628
Active constituents	380 g/L copper present as cuprous oxide, 78 g/L zineb, 22.6 g/L copper pyrithione
Applicant name	Jotun Australia Pty Ltd
Date of registration and label approval	16 October 2026
Distinguishing number of label	97628/153543
Description of the application and its purpose, including the intended use of the chemical product	Registration of 380 g/L copper present as cuprous oxide, 78 g/L zineb and 22.6 g/L copper pyrithione as an antifouling paint product and approval of the label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154299
Chemical product name	Accensi Glyphosate 540 Herbicide B
Distinguishing number of the chemical product	98017
Active constituents	540 g/L glyphosate present as the potassium salt
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	19 October 2026
Distinguishing number of label	98017/154299
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 540 g/L glyphosate soluble concentrate product for non-selective herbicide control of annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154214
Chemical product name	Farmalinx Rebel Herbicide B
Distinguishing number of the chemical product	97956
Active constituent	440 g/L 2,4-D acid
Applicant name	Farmalinx Pty Ltd
Date of registration and label approval	19 October 2026
Distinguishing number of label	97956/154214
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 440 g/L 2,4-D ACID emulsifiable concentrate product and approval of a label for selective control of various weeds in crops, pastures and non-agricultural areas
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	152747
Product name	WeedBan Fluroxypyr 400 EC Herbicide
Active constituent	400 g/L fluroxypyr as the methyl heptyl ester
Applicant name	Jiangsu Flag Chemical Industry Co Ltd
Applicant ACN	N/A
Date of registration	19 October 2026
Product registration no.	97329
Label approval no.	97329/152747
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 400 g/L fluroxypyr as the methyl heptyl ester 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 and winter cereals. Also, for the control of woody weeds in agricultural non-crop areas, commercial and industrial areas, forests, pastures and rights-of-way and approval of the product label

Application no.	153398
Chemical product name	Touchdown Hitech 500 Herbicide
Distinguishing number of the chemical product	97546
Active constituent	500 g/L glyphosate present as the potassium salt
Applicant name	Syngenta Australia Pty Ltd
Date of registration and label approval	19 October 2026
Distinguishing number of label	97546/153398
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L glyphosate present as the potassium salt, soluble concentrate for the control of a wide range of annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155037
Chemical product name	Carboline Sea-Barrier 1000 Antifouling Black
Distinguishing number of the chemical product	98321
Active constituents	332 g/L copper present as cuprous oxide, 44 g/L thiram
Applicant name	Resene Paints (Australia) Limited
Date of registration and label approval	19 October 2026
Distinguishing number of label	98321/155037
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 332 g/L copper present as cuprous oxide, 44 g/L thiram antifouling paint (PT) product and approval of a label for the control of marine growth below the waterline
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155054
Chemical product name	Carboline Sea-Barrier 1000 Antifouling Red
Distinguishing number of the chemical product	98337
Active constituents	332 g/L copper present as cuprous oxide, 44 g/L thiram
Applicant name	Resene Paints (Australia) Limited
Date of registration and label approval	19 October 2026
Distinguishing number of label	98337/155054
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 332 g/L copper present as cuprous oxide, 44 g/L thiram antifouling paint (PT) product and approval of a label for the control of marine growth below the waterline
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	152352
Product name	Omkar 24D LVE 680 Herbicide
Active constituent	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name	Omkar Agri Global Pvt. Ltd
Applicant ACN	N/A
Date of registration	19 October 2026
Product registration no.	97208
Label approval no.	97208/152352
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 680 g/L 2,4-D present as the 2-ethylhexyl ester product, formulated as an emulsifiable concentrate (EC) for selective control of various weeds in crops, pastures and non-agricultural areas

Application no.	153834
Chemical product name	Celphide Fumigation Tablets 2
Distinguishing number of the chemical product	97793
Active constituent	330 g/kg phosphine (PH3) present as aluminium phosphide
Applicant name	Sumitomo Chemical Australia Pty. Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	97793/153834
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 330 g/kg phosphine (PH3) present as aluminium phosphide tablet product for control of insect pests of stored products in certain situations and for control of rabbits in burrows and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153463
Chemical product name	Genfarm Paraquat 250 Herbicide C
Distinguishing number of the chemical product	97578
Active constituent	250 g/L paraquat present as paraquat dichloride
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	97578/153463
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L paraquat present as paraquat dichloride soluble concentrate product for the control of a certain range of grasses and broadleaf weeds
Statement of the conditions of the registration that directly regulate the use of the product	This product must be supplied in a container that is sealed with a fitting compatible with enclosed mixing and loading systems capable of preventing contact between the contents of the container and users of the product during loading of the chemical into the application mechanism

Application no.	153462
Chemical product name	Genfarm Paraquat 250 Herbicide B
Distinguishing number of the chemical product	97577
Active constituent	250 g/L paraquat present as paraquat dichloride
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	97577/153462
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L paraquat present as paraquat dichloride soluble concentrate product for the control of a certain range of grasses and broadleaf weeds
Statement of the conditions of the registration that directly regulate the use of the product	This product must be supplied in a container that is sealed with a fitting compatible with enclosed mixing and loading systems capable of preventing contact between the contents of the container and users of the product during loading of the chemical into the application mechanism

Application no.	154716
Chemical product name	Titan Glyphosate 540 K Salt Herbicide B
Distinguishing number of the chemical product	98208
Active constituent	540 g/L glyphosate present as the potassium salt
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label.	98208/154716
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 540 g/L glyphosate present as the potassium salt soluble concentrate (SL) non-selective herbicide for the control of many annual and perennial weeds and approval of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154251
Chemical product name	Albaugh ZIPMAL 960 EC Herbicide B
Distinguishing number of the chemical product	97979
Active constituent	960 g/L s-metolachlor
Applicant name	Albaugh Australia Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	97979/154251
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 960 g/L s-metolachlor, emulsifiable concentrate product for control of certain annual grasses and broadleaf weeds in certain crops, such as rhubarb, brassica leafy vegetables, mustard, spinach, silver beet, spring onions, shallots and culinary herbs
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154291
Chemical product name	Accensi Glyphosate 450 K-Salt Herbicide B
Distinguishing number of the chemical product	98015
Active constituent	450 g/L glyphosate present as the isopropylamine salt
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98015/154291
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for a 450 g/L glyphosate present as the isopropylamine salt non-selective soluble concentrate (SL) herbicide for control of grass and annual weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154298
Chemical product name	Accensi Glyphosate 450 K-salt Herbicide C
Distinguishing number of the chemical product	98016
Active constituent	450 g/L glyphosate present as the isopropylamine salt
Applicant name	Australian Agribusiness (holdings) Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98016/154298
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for a 450 g/L glyphosate present as the isopropylamine salt non-selective soluble concentrate (SL) herbicide for control of grass and annual weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154017
Chemical product name	Eraze 360 Bi-Aquatic Herbicide
Distinguishing number of the chemical product	97852
Active constituent	360 g/L glyphosate present as the isopropylamine salt
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	97852/154017
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 360 g/L glyphosate present as the isopropylamine salt aqueous concentrate herbicide and approval of a label. For non-selective control of annual and perennial weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153393
Chemical product name	Gramoxone 250 SL Herbicide
Distinguishing number of the chemical product	97543
Active constituent	250 g/L paraquat present as paraquat dichloride
Applicant name	Syngenta Australia Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	97543/153393
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L paraquat present as paraquat dichloride soluble concentrate product for control of certain range of grasses and broadleaf weeds
Statement of the conditions of the registration that directly regulate the use of the product	This product must be supplied in a container that is sealed with a fitting compatible with enclosed mixing and loading systems capable of preventing contact between the contents of the container and users of the product during loading of the chemical into the application mechanism

Application no.	153812
Chemical product name	Spirovia 240SC Insecticide B
Distinguishing number of the chemical product	97779
Active constituent	240 g/L spirotetramat
Applicant name	Grochem Australia Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	97779/153812
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L spirotetramat suspension concentrate product for the control of various insect pests in cotton and certain fruit and vegetable crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155022
Chemical product name	Luna Sensation Fungicide
Distinguishing number of the chemical product	98311
Active constituents	250 g/L fluopyram, 250 g/L trifloxystrobin
Applicant name	Bayer Cropscience Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98311/155022
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for a 250 g/L fluopyram and 250 g/L trifloxystrobin suspension concentrate product, for control of various diseases in almonds, various fruit crops, lettuce, green beans and pyrethrum
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154710
Chemical product name	Apparent 2,4-D Ester 680 Herbicide B
Distinguishing number of the chemical product	98203
Active constituent	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98203/154710
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for an agricultural chemical product containing 680 g/L 2,4-D present as the 2-ethylhexyl ester for the selective control of various weeds in crops, pastures and non-agricultural areas
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154708
Chemical product name	Apparent 2,4-D 625 Amine Herbicide B
Distinguishing number of the chemical product	98201
Active constituent	625 g/L 2,4-D present as the dimethylamine and diethanolamine salt
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98201/154708
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for an agricultural chemical product containing 625 g/L 2,4-D present as the dimethylamine and diethanolamine salts for the control of broadleafed weeds in fallow before direct drilling or sowing of cereals and pastures, and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153849
Chemical product name	Crop Doc 600 Fungicide B
Distinguishing number of the chemical product	97807
Active constituent	600 g/L phosphorous (phosphonic) acid present as mono (and) di potassium phosphite
Applicant name	Grochem Australia Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	97807 / 153849
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L phosphorous (phosphonic) acid present as mono (and) di potassium phosphite soluble concentrate formulation for the control of phytophthora diseases and downy mildew and approval of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153725
Chemical product name	Genfarm Clethodim 240EC Selective Herbicide B
Distinguishing number of the chemical product	97730
Active constituent	240 g/L clethodim
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	97730/153725
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L clethodim emulsifiable concentrate herbicide for the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155047
Chemical product name	Titian Carfentrazone 400 EC Herbicide B
Distinguishing number of the chemical product	98330
Active constituent	400 g/L carfentrazone-ethyl
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98330/155047
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 400 g/L carfentrazone-ethyl emulsifiable concentrate product, for improvement in the control of marshmallow and certain other broadleaf weeds prior to establishment of broadacre crops, fallows or forest plantations, in commercial, industrial and public service areas, around agricultural buildings and yards, in tree fruits, nuts, grape vines in tank mixture with knockdown herbicides; control of marshmallow and annual nettles in grass pastures and rough grass/turf areas; and control of volunteer cotton seedlings including Roundup Ready cotton and desiccation of cotton re-growth and approval of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154772
Chemical product name	Brunnings Extra Strength Feed N Weed for Lawns
Distinguishing number of the chemical product	98242
Active constituents	23 g/L MCPA present as the dimethylamine salt, 3.5 g/L dicamba present as the dimethylamine salt
Applicant name	Brunnings Garden Products Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98242/154772
Description of the application and its purpose, including the intended use of the chemical product	Registration of and label approval for a soluble concentrate product containing 23 g/L MCPA present as the dimethylamine salt and 3.5 g/L dicamba present as the dimethylamine salt for lawn feeding and selective kill of broadleaf weeds
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155414
Chemical product name	Nufarm Glyphosate 450SL Herbicide
Distinguishing number of the chemical product	98497
Active constituent	450 g/L glyphosate present as the monomethylamine, mono-ammonium and potassium salts
Applicant name	Nufarm Australia Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	98497/155414
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 450 g/L glyphosate present as the monomethylamine, mono-ammonium and potassium salts soluble concentrate product and approval of a label for use as a non-selective herbicide
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154812
Chemical product name	Brunnings Bindii Kill for Lawns
Distinguishing number of the chemical product	98253
Active constituents	15 g/L MCPA present as the dimethylamine salt, 2.3 g/L dicamba present as the dimethylamine salt
Applicant name	Brunnings Garden Products Pty Ltd
Date of registration and label approval	20 October 2026
Distinguishing number of label	98253/154812
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 15 g/L MCPA present as dimethylamine salt, 2.3 g/L dicamba present as dimethylamine salt soluble concentrate (SL) product for the control of certain weeds in lawns and turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155076
Chemical product name	Altex Yacht & Boat Paint No 5 Antifouling Classic Black
Distinguishing number of the chemical product	98357
Active constituents	640 g/L copper present as cuprous oxide, 44 g/L thiram
Applicant name	Resene Paints (Australia) Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	98357/155076
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 640 g/L copper present as cuprous oxide, 44 g/L thiram antifouling paint (PT) product and approval of a label for the control of marine growth below the waterline
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155077
Chemical product name	Altex Yacht & Boat Paint No 5 Antifouling Aurora Red
Distinguishing number of the chemical product	98358
Active constituents	640 g/L copper present as cuprous oxide, 44 g/L thiram
Applicant name	Resene Paints (Australia) Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	98358/155077
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 640 g/L copper present as cuprous oxide, 44 g/L thiram antifouling paint (PT) product and approval of a label for the control of marine growth below the waterline
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155078
Chemical product name	Altex Yacht & Boat Paint No 5 Antifouling Sea Green
Distinguishing number of the chemical product	98359
Active constituents	640 g/L copper present as cuprous oxide, 44 g/L thiram
Applicant name	Resene Paints (Australia) Limited
Date of registration and label approval	20 October 2026
Distinguishing number of label	98359/155078
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 640 g/L copper present as cuprous oxide, 44 g/L thiram antifouling paint (PT) product and approval of a label for the control of marine growth below the waterline
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153777
Chemical product name	Genfarm S-metolachlor 960 Herbicide B
Distinguishing number of the chemical product	97748
Active constituent	960 g/L S-metolachlor
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97748/153777
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 960 g/L S-metolachlor emulsifiable concentrate herbicide for the control of certain annual grasses and broadleaf weeds in certain crops and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153729
Chemical product name	Genfarm LV MCPA 570 Herbicide B
Distinguishing number of the chemical product	97732
Active constituent	570 g/L MCPA present as the 2-ethyl hexyl ester
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97732/153729
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 570 g/L MCPA present as the 2-ethyl hexyl ester emulsifiable concentrate herbicide for the selective control of certain weeds in agricultural crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154136
Chemical product name	Genfarm Flutriafol 500 SC Fungicide B
Distinguishing number of the chemical product	97912
Active constituent	500 g/L flutriafol
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97912/154136
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L flutriafol fungicide suspension concentrate and approval of label for the control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153776
Chemical product name	Genfarm S-metolachlor 960 Herbicide C
Distinguishing number of the chemical product	97747
Active constituent	960 g/L S-metolachlor
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97747/153776
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 960 g/L S-metolachlor emulsifiable concentrate herbicide for the control of certain annual grasses and broadleaf weeds in certain crops and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153777
Chemical product name	Genfarm S-metolachlor 960 Herbicide B
Distinguishing number of the chemical product	97748
Active constituent	960 g/L S-metolachlor
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97748/153777
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 960 g/L S-metolachlor emulsifiable concentrate herbicide for the control of certain annual grasses and broadleaf weeds in certain crops and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153444
Chemical product name	BASF Lexicon Intrinsic Brand Fungicide
Distinguishing number of the chemical product	97566
Active constituents	333 g/L pyraclostrobin, 167 g/L fluxapyroxad
Applicant name	BASF Australia Ltd
Date of registration and label approval	21 October 2026
Distinguishing number of label	97566/153444
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 333 g/L pyraclostrobin and 167g/L fluxapyroxad suspension concentrate (SC) product and approval of a label for use as a broad-spectrum preventative and curative disease treatment for turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153781
Chemical product name	Genfarm Pyrox 850 WG Herbicide B
Distinguishing number of the chemical product	97752
Active constituent	850 g/kg pyroxasulfone
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97752/153781
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg pyroxasulfone water dispersible granule (WG) product and approval of a label for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153779
Chemical product name	Genfarm Pyrox 850 WG Herbicide C
Distinguishing number of the chemical product	97750
Active constituent	850 g/kg pyroxasulfone
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97750/153779
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg pyroxasulfone water dispersible granule (WG) product and approval of a label for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154709
Chemical product name	Titan LV Ester 680 Herbicide B
Distinguishing number of the chemical product	98202
Active constituents	680 g/L 2,4-D 2-ethylhexyl ester
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	21 October 2026
Distinguishing number of label	98202/154709
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 680 g/L 2,4-D 2-ethylhexyl ester product for the control of broadleaf weeds in seedling and established Lucerne, medic and clover pastures, peanuts and cereal crops undersown with Lucerne, medic or clover
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	152926
Product name	Swan Azoxystrobin + Metalaxyl-M Fungicide
Active constituents	312 g/L azoxystrobin, 119 g/L metalaxyl-m
Applicant name	Swan Chemical Holdings Pty Ltd
Applicant ACN	669 863 067
Date of registration	21 October 2026
Product registration no.	97385
Label approval no.	97385/152926
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 312 g/L azoxystrobin and 119 g/L metalaxyl-m product, formulated as a suspoemulsion (SE) for the control of rhizoctonia, pythium, leaf rust and net blotch in barley, control of rhizoctonia, pythium and stripe rust in wheat, and suppression of powdery mildew in barley and yellow spot in wheat

Application no.	154535
Chemical product name	BASF Lexicon Intrinsic Brand Fungicide 02
Distinguishing number of the chemical product	98123
Active constituents	333 g/L pyraclostrobin, 167 g/L fluxapyroxad
Applicant name	BASF Australia Ltd
Date of registration and label approval	21 October 2026
Distinguishing number of label	98123/154535
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 333 g/L pyraclostrobin and 167 g/L fluxapyroxad suspension concentrate (SC) product and approval of a label for use as a broad-spectrum preventative and curative disease treatment for turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153610
Chemical product name	Genfarm Spirotetramat 240 SC Insecticide B
Distinguishing number of the chemical product	97664
Active constituent	240 g/L spirotetramat
Applicant name	Nutrien Ag Solutions Limited
Date of registration and label approval	21 October 2026
Distinguishing number of label	97664/153610
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L spirotetramat suspension concentrate insecticide product for the control of various insect pests in cotton and certain fruit and vegetable crops and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154249
Chemical product name	Kelpie Rico HPS 540 Herbicide
Distinguishing number of the chemical product	97977
Active constituent	540 g/L glyphosate present as the potassium salt
Applicant name	Sinochem International Australia Pty. Ltd.
Date of registration and label approval	21 October 2026
Distinguishing number of label	97977/154249
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 540 g/L glyphosate present as the potassium salt soluble concentrate (SL) product for non-selective herbicide for the control of many annual and perennial weed and approval of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154060
Chemical product name	Determite Ultra Low Odour Timber Framing Insecticide RTU 2
Distinguishing number of the chemical product	97874
Active constituent	5 g/L bifenthrin
Applicant name	Koppers Performance Chemicals Australia Pty Ltd
Date of registration and label approval	21 October 2026
Distinguishing number of label	97874/154060
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 5 g/L bifenthrin emulsion product and approval of label for the protection of timber and timber-based products from damage by borers and termites
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154566
Chemical product name	Kusabi Fungicide
Distinguishing number of the chemical product	98140
Active constituent	300 g/L pyriofenone
Applicant name	Ishihara Sangyo Kaisha, Ltd
Date of registration and label approval	21 October 2026
Distinguishing number of label	98140/154566
Description of the application and its purpose, including the intended use of the chemical product	Registration of 300 g/L pyriofenone suspension concentrate (SC) product and approval of a label for the control of powdery mildew in cucurbits and grapes
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154996
Chemical product name	Apparent Trifluralin 480 Herbicide B
Distinguishing number of the chemical product	98296
Active constituent	480 g/L trifluralin
Applicant name	Titan Ag Pty Ltd
Date of registration and label approval	21 October 2026
Distinguishing number of label	98296/154996
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L trifluralin emulsifiable concentrate (EC) product and approval of a label for pre-emergence control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops as listed in the Directions for Use table
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154569
Chemical product name	Segway Fungicide
Distinguishing number of the chemical product	98142
Active constituent	400 g/L cyazofamid
Applicant name	Ishihara Sangyo Kaisha, Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	98142/154569
Description of the application and its purpose, including the intended use of the chemical product	Registration of and approval of a label for a 400 g/L cyazofamid suspension concentrate (SC) product for the control of various fungal diseases in turf
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154414
Chemical product name	Accensi Paraquat 250 Herbicide C
Distinguishing number of the chemical product	98066
Active constituent	250g/L paraquat present as paraquat dichloride
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	98066/154414
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L paraquat present as paraquat dichloride soluble concentrate product for control of certain range of grasses and broadleaf weeds
Statement of the conditions of the registration that directly regulate the use of the product	This product must be supplied in a container that is sealed with a fitting compatible with enclosed mixing and loading systems capable of preventing contact between the contents of the container and users of the product during loading of the chemical into the application mechanism

Application no.	155074
Chemical product name	Altex Yacht & Boat Paint No 5 Antifouling Navy Blue
Distinguishing number of the chemical product	98355
Active constituents	640 g/L copper present as cuprous oxide, 44 g/L thiram
Applicant name	Resene Paints (Australia) Limited
Date of registration and label approval	22 October 2026
Distinguishing number of label	98355/155074
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 640 g/L copper present as cuprous oxide, 44 g/L thiram antifouling paint (PT) product and approval of a label for the control of marine growth below the waterline
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155072
Chemical product name	Altex Yacht & Boat Paint No 5 Antifouling Seaport Blue
Distinguishing number of the chemical product	98353
Active constituents	640 g/L copper present as cuprous oxide, 44 g/L thiram
Applicant name	Resene Paints (Australia) Limited
Date of registration and label approval	22 October 2026
Distinguishing number of label	98353/155072
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 640 g/L copper present as cuprous oxide, 44 g/L thiram antifouling paint (PT) product and approval of a label for the control of marine growth below the waterline
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153846
Chemical product name	CropSure Captan 800 Fungicide
Distinguishing number of the chemical product	97805
Active constituent	800 g/kg captan
Applicant name	CropSure Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97805/153846
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 800 g/kg captan product for the control of certain diseases in a range of fruit crops, almonds, pistachios, turf and ornamentals and registration of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155594
Chemical product name	CropSure Captan 800WG Fungicide
Distinguishing number of the chemical product	98541
Active constituent	800 g/kg captan
Applicant name	CropSure Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	98541/155594
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 800 g/kg captan product for the control of certain diseases in a range of fruit crops, almonds, pistachios, turf and ornamentals and registration of a label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154138
Chemical product name	Transocean Cleanship Antifouling 291 Black
Distinguishing number of the chemical product	97913
Active constituents	503 g/L copper present as cuprous oxide, 72.5 g/L diuron
Applicant name	Wagon Paints Australia Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97913/154138
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 503 g/L copper present as cuprous oxide, 72.5 g/L diuron antifouling paint product and approval of a label for the prevention of marine growth on vessel hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154140
Chemical product name	Transocean Cleanship Antifouling 291 Blue
Distinguishing number of the chemical product	97914
Active constituents	501 g/L copper present as cuprous oxide, 72.2 g/L diuron
Applicant name	Wagon Paints Australia Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97914/154140
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 501 g/L copper present as cuprous oxide, 72.2 g/L diuron antifouling paint product and approval of a label for the prevention of marine growth on vessel hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154144
Chemical product name	Transocean Cleanship Antifouling 291 Red
Distinguishing number of the chemical product	97917
Active constituents	506 g/L copper present as cuprous oxide, 73 g/L diuron
Applicant name	Wagon Paints Australia Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97917/154144
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 506 g/L copper present as cuprous oxide, 73 g/L diuron antifouling paint product and approval of a label for the prevention of marine growth on vessel hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154101
Chemical product name	Transocean Optima Antifouling 2.32 Pink
Distinguishing number of the chemical product	97882
Active constituent	416 g/L copper present as cuprous oxide
Applicant name	Wagon Paints Australia Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97882 / 154101
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 416 g/L copper present as cuprous oxide antifouling paint and approval of a label for the prevention of marine biofouling on ship hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154106
Chemical product name	Transocean Optima Antifouling 2.32 Blue
Distinguishing number of the chemical product	97885
Active constituent	413 g/L copper present as cuprous oxide
Applicant name	Wagon Paints Australia Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97885/154106
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 413 g/L copper present as cuprous oxide antifouling paint product and approval of a label for the prevention of marine biofouling on vessel hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154109
Chemical product name	Transocean Optima Antifouling 2.32 Black
Distinguishing number of the chemical product	97888
Active constituent	407 g/L copper present as cuprous oxide
Applicant name	Wagon Paints Australia Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97888/154109
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 407 g/L copper present as cuprous oxide antifouling paint product and approval of a label for the prevention of marine biofouling on vessel hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154112
Chemical product name	Transocean Optima Antifouling 2.32 Redbrown
Distinguishing number of the chemical product	97891
Active constituent	417 g/L copper present as cuprous oxide
Applicant name	Wagon Paints Australia Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97891/154112
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 417 g/L copper present as cuprous oxide antifouling paint product and approval of a label for the prevention of marine biofouling on vessel hulls
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	154323
Product name	Yates Home Pest Auto-Armour Super Barrier Spray
Active constituents	20 g/kg propoxur, 10 g/kg piperonyl butoxide, 2 g/kg tetramethrin
Applicant name	Sundew Solutions Pty Ltd
Applicant ACN	135 400 261
Date of registration	22 October 2026
Product registration no.	98034
Label approval no.	98034/154323
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 g/kg propoxur, 10 g/kg piperonyl butoxide, 2 g/kg tetramethrin product, formulated as an aerosol (AE) for prevention and control of spiders, cobwebs, ants and cockroaches in vehicles

Application no.	153893
Chemical product name	EnviroSoap Insecticidal A Spray
Distinguishing number of the chemical product	97834
Active constituent	8.5 g/L potassium salts of fatty acids
Applicant name	Australian Adjuvants Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97834/153893
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 8.5 g/L potassium salts of fatty acids ready-to-use formulation product and approval of a label for control of insect pests on indoor and outdoor plants, fruit and nut trees and vegetables in the home garden and home nurseries
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155398
Chemical product name	EnviroSoap Insecticidal Spray
Distinguishing number of the chemical product	98491
Active constituent	8.5 g/L potassium salts of fatty acids
Applicant name	Australian Adjuvants Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	98491/155398
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 8.5 g/L potassium salts of fatty acids ready-to-use formulation product and approval of a label for control of insect pests on indoor and outdoor plants, fruit and nut trees and vegetables in the home garden and home nurseries
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	153896
Chemical product name	EnviroSoap Insecticidal Concentrate A Spray
Distinguishing number of the chemical product	97837
Active constituent	285 g/L potassium salts of fatty acids
Applicant name	Australian Adjuvants Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	97837/153896
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 285 g/L potassium salts of fatty acids soluble concentrate product and approval of a label for the control of insect pests on indoor plants, fruit trees, vegetables, nut crops and nurseries
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155395
Chemical product name	EnviroSoap Insecticidal Concentrate Spray
Distinguishing number of the chemical product	98490
Active constituent	285 g/L potassium salts of fatty acids
Applicant name	Australian Adjuvants Pty Ltd
Date of registration and label approval	22 October 2026
Distinguishing number of label	98490/155395
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 285 g/L potassium salts of fatty acids soluble concentrate product and approval of a label for the control of insect pests on indoor plants, fruit trees, vegetables, nut crops and nurseries
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155169
Chemical product name	FMC Magister Herbicide
Distinguishing number of the chemical product	98399
Active constituent	480 g/L clomazone
Applicant name	FMC Australasia Pty Ltd
Date of registration and label approval	23 October 2026
Distinguishing number of label	98399/155169
Description of the application and its purpose, including the intended use of the chemical product	Registration of FMC Magister Herbicide and approval of label for the control of certain annual grasses in rice as per the directions for use table
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155247
Chemical product name	Amgrow Chemspray Weed Control Kleen Lawn Selective Lawn Weeder B
Distinguishing number of the chemical product	98435
Active constituents	240 g/L mecoprop present as a dimethylamine salt, 40 g/L dicamba present as a dimethylamine salt
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Date of registration and label approval	23 October 2026
Distinguishing number of label	98435/155247
Description of the application and its purpose, including the intended use of the chemical product	Registration of a product containing 40 g/L dicamba and 240 g/L mecoprop, both present as the dimethylamine salts, and approval of the associated label for the control of clover and broadleaf weeds in couch, bent and kikuyu lawns in the home garden
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	155032
Chemical product name	Sumiblast Crack and Crevice Residual Aerosol
Distinguishing number of the chemical product	98319
Active constituents	2.5 g/kg cyphenothrin, 2.5 g/kg d-tetramethrin
Applicant name	Sumitomo Chemical Australia Pty. Limited
Date of registration and label approval	23 October 2026
Distinguishing number of label	98319/155032
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 2.5 g/kg cyphenothrin and 2.5 g/kg d-tetramethrin aerosol product and approval of a label for knockdown and residual control of household insects such as ants, carpet beetles, cockroaches, fleas, flies, millipedes, mosquitoes, adult moth and moth larvae, silver fish, slaters, spiders, and wasps
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Application no.	152411
Product name	Argus 100 Insect Growth Regulator
Active constituent	100 g/L pyriproxyfen
Applicant name	Shanghai Broco Chemicals Co., Ltd.
Applicant ACN	N/A
Date of registration	23 October 2026
Product registration no.	97230
Label approval no.	97230/152411
Description of the application and its purpose, including the intended use of the chemical product	Registration of 100 g/L pyriproxyfen emulsifiable concentrate product for the control of silverleaf whitefly (*Bemisia tabaci* Biotype B) in cotton, rockmelon and capsicum, the control of silverleaf whitefly (*Bemisia tabaci* Biotype B) and greenhouse whitefly in tomatoes, and the control of various scale in citrus, mangoes and olives

Application no.	152208
Product name	Weed Weapon Preventer Herbicide
Active constituents	10 g/kg pendimethalin, 7.5g/kg dimethenamind-p
Applicant name	Animal Control Technologies (Australia) Pty Ltd
Applicant ACN	137 868 449
Date of registration	23 October 2026
Product registration no.	97186
Label approval no.	97186/152208
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 g/kg pendimethalin and 7.5 g/kg dimethenamind-p product, formulated as a granular formulation (GR) for pre-emergent weed control of broadleaf and grassy weeds associated with ornamental plants in containers and in-ground and in warm season turf

Application no.	152210
Product name	Weed Weapon Super Control Herbicide
Active constituent	240 g/L imazapyr present as isopropylamine salt
Applicant name	Animal Control Technologies (Australia) Pty Ltd
Applicant ACN	137 868 449
Date of registration	23 October 2026
Product registration no.	97188
Label approval no.	97188/152210
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L imazapyr present as isopropylamine salt product, formulated as a soluble concentrate (SL) for the control of various annual and perennial weeds in non-crop situations

Application no.	152212
Product name	Genfarm Lambda-Cyhalothrin 250 CS Insecticide
Active constituent	250 g/L lambda-cyhalothrin
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	23 October 2026
Product registration no.	97189
Label approval no.	97189/152212
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L lambda-cyhalothrin product, formulated as a capsule suspension (CS) for the control of certain insect pests in cotton, barley, wheat and various field crops

Application no.	152746
Product name	Smart CTPR Insecticide
Active constituent	600 g/L chlorantraniliprole
Applicant name	Crop Smart Pty Ltd
Applicant ACN	093 927 961
Date of registration	23 October 2026
Product registration no.	97328
Label approval no.	97328/152746
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L chlorantraniliprole product, formulated as a suspension concentrate (SC) for the control of lepidopteran species of insect pests in cotton and pulse crops

Application no.	152671
Product name	Exit-R Herbicide
Active constituent	850 g/kg pyroxasulfone
Applicant name	PKB Intensive Animal Services Pty Ltd
Applicant ACN	078 031 115
Date of registration	23 October 2026
Product registration no.	97300
Label approval no.	97300/152671
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg pyroxasulfone product, formulated as a water dispersible granule (WG) for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops

Application no.	154308
Chemical product name	GP Regain 200 SD Herbicide
Distinguishing number of the chemical product	98024
Active constituent	200 g/kg tebuthiuron
Applicant name	Granular Products Assets Pty Ltd
Date of registration and label approval	23 October 2026
Distinguishing number of label	98024/154308
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/kg tebuthiuron granule formulation, product for control of brigalow regrowth, prickly acacia, parkinsonia, mimosa pigra and certain problem woody weeds on grazing lands by hand, aerial and ground application and approval of label
Statement of the conditions of the registration that directly regulate the use of the product	No conditions apply that directly regulate use of the product

Table 2: Variations of registration – agricultural chemical products

Application no.	155621
Product name	Ateka 480 SC Insecticide
Active constituent	480 g/L spirotetramat
Applicant name	ADAMA Australia Pty Limited
Applicant ACN	050 328 973
Date of variation	29 September 2026
Product registration no.	95641
Label approval no.	95641/155621
Description of the application and its purpose, including the intended use of the chemical product	Variation to remove the use of the chemical product in turf from the instructions

Application no.	155664
Product name	Signature Xtra Stressgard Systemic Turf Fungicide
Active constituent	600 g/kg fosetyl-aluminium
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	86770
Label approval no.	86770/155664
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155665
Product name	Spearhead Selective Herbicide
Active constituents	300 g/L MCPA present as the potassium salt, 20 g/L clopyralid present as the olamine salt, 15 g/L diflufenican
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	53833
Label approval no.	53833/155665
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions and safety directions appearing on a label to reflect the current labelling standard

Application no.	155652
Product name	Ligna No-Rot Gel Wood Preservative
Active constituents	52 g/L boron (B) present as disodium octaborate tetrahydrate,12 g/L benzalkonium chloride
Applicant name	Preschem Pty. Ltd.
Applicant ACN	006 867 929
Date of variation	1 October 2026
Product registration no.	97974
Label approval no.	97974/155652
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 ‘No-Rot Gel Insecticide/Fungicide’ to ‘Ligna No-Rot Gel Wood Preservative’

Application no.	155653
Product name	Indofil Manfil 800 WP Fungicide
Active constituent	800 g/kg mancozeb
Applicant name	Indofil Industries Australia Pty. Ltd.
Applicant ACN	681 530 521
Date of variation	1 October 2026
Product registration no.	51793
Label approval no.	51793/155653
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 ‘Rotam Winner Mancozeb WP Agricultural Fungicide’ to ‘Indofil Manfil 800 WP Fungicide’

Application no.	155654
Product name	Indofil Manfil 750 WG Fungicide
Active constituent	750 g/kg mancozeb
Applicant name	Indofil Industries Australia Pty. Ltd.
Applicant ACN	681 530 521
Date of variation	1 October 2026
Product registration no.	59516
Label approval no.	59516/155654
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 'Runge Agrichems Manfil Mancozeb 750 WG Agricultural Fungicide' to 'Indofil Manfil 750 WG Fungicide'

Application no.	155658
Product name	Destiny Selective Turf Herbicide
Active constituent	100 g/kg iodosulfuron-methyl-sodium
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	56801
Label approval no.	56801/155658
Description of the application and its purpose, including the intended use of the chemical product	Variation to the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155659
Product name	Esplanade Herbicide
Active constituent	500 g/L indaziflam
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	86235
Label approval no.	86235/155659
Description of the application and its purpose, including the intended use of the chemical product	Variation to the first aid instructions and safety directions appearing on a label to reflect the current FAISD handbook

Application no.	155660
Product name	K-Obiol EC Combi Synergised Grain Protectant
Active constituents	400 g/L piperonyl butoxide, 50 g/L deltamethrin
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	66921
Label approval no.	66921/155660
Description of the application and its purpose, including the intended use of the chemical product	To vary the first aid instructions and safety directions appearing on a label to reflect the current FAISD handbook

Application no.	155661
Product name	Kordon Termite System
Active constituent	4 g/kg deltamethrin (equivalent to 2 g/m^2 deltamethrin)
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	60759
Label approval no.	60759/155661
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155662
Product name	Reserve Stressgard Turf Fungicide
Active constituent	720 g/L chlorothalonil
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	81269
Label approval no.	81269/155662
Description of the application and its purpose, including the intended use of the chemical product	Variation to the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155666
Product name	Temprid 75 Residual Insecticide
Active constituents	50 g/L imidacloprid, 25 g/L beta-cyfluthrin
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	64371
Label approval no.	64371/155666
Description of the application and its purpose, including the intended use of the chemical product	Variation to the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155668
Product name	Tribute Selective Turf Herbicide
Active constituent	22.5 g/L foramsulfuron
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	1 October 2026
Product registration no.	63240
Label approval no.	63240/155668
Description of the application and its purpose, including the intended use of the chemical product	Variation to the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155715
Product name	Coopex Insecticidal Dusting Powder Industrial Strength
Active constituent	10 g/kg permethrin (25:75)
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	33210
Label approval no.	33210/155715
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155718
Product name	Indemnify Turf Nematicide
Active constituent	400 g/L fluopyram
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	84365
Label approval no.	84365/155718
Description of the application and its purpose, including the intended use of the chemical product	Variation to the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155779
Product name	Perigen Defence Residual Insecticide
Active constituent	500 g/L permethrin (25:75 cis:trans)
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	57184
Label approval no.	57184/155779
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155783
Product name	Termistop Termite Barrier
Active constituent	4 g/kg deltamethrin (equivalent to 2 g/ m^2 deltamethrin)
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	89939
Label approval no.	89939/155783
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155785
Product name	Termishield Termite Barrier
Active constituent	4 g/kg deltamethrin (equivalent to 2 g/m^2 deltamethrin)
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	89942
Label approval no.	89942/155785
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155786
Product name	Termiweb Termite Barrier
Active constituent	4 g/kg deltamethrin (equivalent to 2 g/m^2 deltamethrin)
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	89938
Label approval no.	89938/155786
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155787
Product name	Dedicate Forte Stressgard Turf Fungicide
Active constituent	240 g/L tebuconazole
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	89422
Label approval no.	89422/155787
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	155719
Product name	Dedicate Turf and Ornamental Fungicide
Active constituents	200 g/L tebuconazole, 100 g/L trifloxystrobin
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	2 October 2026
Product registration no.	62638
Label approval no.	62638/155719
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions AND safety directions appearing on a label to reflect the current FAISD handbook. To update the storage and disposal statements to be in line with current labelling code requirements

Application no.	N/A – Variation under s29A
Product name	Genfarm Clethodim 360 Selective Herbicide
Active constituent	360 g/L clethodim
Applicant name	APVMA initiated variation
Date of variation	12 October 2026
Product registration no.	81849
Label approval no.	81849/118432V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product and label approval and label particulars to update the label for the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes, and soybeans

Application no.	N/A – Variation under s29A
Product name	Genfarm Clopyralid 750 SG Herbicide
Active constituent	750 g/kg clopyralid present as the potassium salt
Applicant name	APVMA initiated variation
Date of variation	14 October 2026
Product registration no.	59960
Label approval no.	59960/128450V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation to the particulars of registration and label approval to add spray drift restrained

Application no.	N/A – Variation under s29A
Product name	Genfarm Propyzamide 500SC Herbicide
Active constituent	500 g/L propyzamide
Applicant name	APVMA initiated variation
Date of variation	14 October 2026
Product registration no.	66867
Label approval no.	66867/134425V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of registration particulars and label particulars and label approval to update the constituent statements and remove references to Label A and Label B from the label

Application no.	143852
Chemical product name	Exirel Insecticide
Distinguishing number of the chemical product	64103
Active constituent	100 g/L cyantraniliprole
Applicant name	FMC Australasia Pty Ltd
Date of variation	15 October 2026
Distinguishing number of label	64103/143852
Description of the application and its purpose, including the way the in which intended use of the chemical product	Variation of registration particulars and particulars of label and label approval to add new crops (avocado, macadamia, mango) and pests, as well as add tank mix use with Parachute Paraffinic Spraying Oil

Application no.	N/A – Variation under s29A
Product name	Antifouling Seaforce Active Plus Light Red
Active constituents	432 g/L copper as cuprous oxide, 85 g/L zineb, 24 g/L copper pyrithione
Applicant name	APVMA initiated variation
Date of variation	16 October 2026
Product registration no.	87840
Label approval no.	87840/119538V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product and label approval to update the product distinguishing name

Application no.	N/A – Variation under s29A
Product name	ADAMA LVE MCPA 570 Herbicide
Active constituent	570g/L MCPA present as the 2-ethyl hexyl ester
Applicant name	APVMA initiated variation
Date of variation	16 October 2026
Product registration no.	65745
Label approval no.	65745/100686V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars and label particulars of registered chemical product to update the mode of action and correct the product name on the label to ADAMA LVE MCPA 570 Herbicide

Application no.	N/A – Variation under s29A
Product name	Farmalinx Rebel Herbicide
Active constituent	440 g/L 2,4-D acid
Applicant name	APVMA initiated variation
Date of variation	19 October 2026
Product registration no.	84093
Label approval no.	84093/132846V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product and label approval and label particulars to update the constituent and solvent statements, and remove references to label A and label B

Application no.	N/A – Variation under s29A
Product name	Kelpie Cleth-D 240 EC Herbicide
Active constituent	240 g/L clethodim
Applicant name	APVMA initiated variation
Date of variation	19 October 2026
Product registration no.	81059
Label approval no.	81059/102251V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product and label approval to update the constituent statement for Kelpie Cleth-D 240 EC Herbicide for the control of certain grass weeds in various crops as per the Directions for Use

Application no	N/A – Variation under s29A
Product name	Tenet 500 SC Herbicide A
Active constituent	500 g/L metazachlor
Applicant name	APVMA initiated variation
Date of variation	19 October 2026
Product registration no	89948
Label approval no	89948/130591V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Tenet 500 SC Herbicide A is for the control or suppression of a range of grass and broadleaf weeds in Canola Variation of relevant particulars of registered chemical product and label approval and label particulars to update the product name to Tenet 500 SC Herbicide A

Application no.	N/A – Variation under s29A
Product name	Genfarm Trifluralin 480 Selective Herbicide
Active constituent	480 g/L trifluralin
Applicant name	APVMA initiated variation
Date of variation	19 October 2026
Product registration no.	60425
Label approval no.	60425/137412V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of registration particulars and label particulars and label approval to update constituent statements to remove references to Label A, B, C, D, E, F, and G

Application no.	N/A – Variation under s29A
Product name	Albaugh Durango Ultra 540K SL Herbicide
Active constituent	540 g/L glyphosate present as the potassium salt
Applicant name	APVMA initiated variation
Date of variation	20 October 2026
Product registration no.	94473
Label approval no.	94473/145550V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product and label approval to update label constituent statement and remove references to label A and label B

Application no.	N/A – Variation under s29A
Product name	Genfarm Clethodim 240EC Selective Herbicide
Active constituent	240 g/L clethodim
Applicant name	APVMA initiated variation
Date of variation	21 October 2026
Product registration no.	60542
Label approval no.	60542/118054V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product to update the label

Application no.	N/A – Variation under s29A
Product name	Genfarm Panzer 540 K Herbicide
Active constituent/s	540 g/L glyphosate (present as the potassium salt)
Applicant name	APVMA initiated variation
Date of variation	21 October 2026
Product registration no.	64995
Label approval no.	64995/125228V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product containing 540 g/L glyphosate in a soluble concentrate for the non-selective control of many annual and perennial weeds and label approval to update the formulation details

Application no.	N/A – Variation under s29A
Product name	Titan Glyphosate 540 K Salt Herbicide
Active constituent	540 g/L glyphosate present as the potassium salt
Applicant name	APVMA initiated variation
Date of variation	22 October 2026
Product registration no.	65104
Label approval no.	65104/113665V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Variation of relevant particulars of registered chemical product and label approval to update the constituent statement to 540 g/L glyphosate present as the potassium salt soluble concentrate (SL) non-selective herbicide for the control of many annual and perennial weeds

Application no.	N/A – Variation under s29A
Product name	DuPont Velpar K4 DF Herbicide
Active constituent	468 g/kg diuron, 132 g/kg hexazinone
Applicant name	APVMA initiated variation
Date of variation	22 October 2026
Product registration no.	45909
Label approval no.	45909/1112V
Description of the application and its purpose, including the intended use of the chemical product and the nature of and reasons for the variation	Amend the register of a 468.0 g/kg diuron and 132.0 g/kg hexazinone water dispersible granule (WG) product for the control of a wide range of annual and perennial grasses, broadleaved weeds and vines in established sugarcane and approval of a label

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.	153036
Product name	Headway Amoxiclav 50 mg Tablets
Active constituents	40 mg/tablet amoxycillin as amoxycillin trihydrate, 10 mg/tablet clavulanic acid as diluted potassium clavulanate
Applicant name	Headway Investments Pty Ltd
Applicant ACN	655 095 855
Date of registration	20 October 2026
Product registration no.	97401
Label approval no.	97401/153036
Description of the application and its purpose, including the intended use of the chemical product	Registration and the approval of a label of a Headway 50 mg tablet product for use in dogs and cats for bacterial infections

Application no.	154005
Product name	Bainbridge Wormer for Small Animals
Active constituent	40 mg/mL piperazine (as the citrate)
Applicant name	Bainbridge Pty Ltd
Applicant ACN	097 002 205
Date of registration	22 October 2026
Product registration no.	97842
Label approval no.	97842/154005
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 mg/mL piperazine (as the citrate) Oral Solution/Suspension product and approval of a label for removal of round worms in guinea pigs, rabbits and rats

Table 4: Variations of registration – veterinary chemical products

Application no.	155918
Product name	Coxidin 400 Microgranulate Monensin Feed Additive
Active constituent/s	400 g/kg monensin (as monensin sodium)
Applicant name	Huvepharma EOOD
Applicant ACN	N/A
Date of variation	16 October 2026
Product registration no.	62232
Label approval no.	62232/15591
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 'Coxidin 400 Monensin Feed Additive' to 'Coxidin 400 Microgranulate Monensin Feed Additive'

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.	150793
Active constituent	Fluopyram
Applicant name	Foison Scitech Co., Limited
Applicant ACN	N/A
Date of approval	14 October 2026
Approval no.	96830
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluopyram for use in agricultural chemical products

Application no.	150806
Active constituent	Cyantraniliprole
Applicant name	Foison Scitech Co., Limited
Applicant ACN	N/A
Date of approval	14 October 2026
Approval no.	96841
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyantraniliprole for use in agricultural chemical products

Application no.	150986
Active constituent	Saflufenacil
Applicant name	Zhejiang Zhongshan Chemical Industry Group Co., Ltd
Applicant ACN	N/A
Date of approval	14 October 2026
Approval no.	96865
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent saflufenacil for use in agricultural chemical products

Application no.	151260
Active constituent	Metsulfuron-methyl
Applicant name	Sichuan Leshan Fuhua Tongda Agro-Chemical Tech. Co. Ltd
Applicant ACN	N/A
Date of approval	14 October 2026
Approval no.	96922
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent metsulfuron-methyl for use in agricultural chemical products

Application no.	151475
Active constituent	Saflufenacil
Applicant name	Shaoxing Shangyu Xin Yinbang Biochemical Co., Ltd.
Applicant ACN	N/A
Date of approval	15 October 2026
Approval no.	97003
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent saflufenacil for use in agricultural chemical products

Application no.	151698
Active constituent	Oxamyl
Applicant name	Agoceania Pty Ltd
Applicant ACN	649 344 141
Date of approval	15 October 2026
Approval no.	97073
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent oxamyl for use in agricultural chemical products

Application no.	152388
Active constituent	Pyraclostrobin
Applicant name	Shaanxi Mei Bang Pharmaceutical Group Co Ltd
Applicant ACN	N/A
Date of approval	15 October 2026
Approval no.	97224
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyraclostrobin for use in agricultural chemical products

Application no.	152386
Active constituent	Sulfoxaflor
Applicant name	Shaanxi Mei Bang Pharmaceutical Group Co Ltd
Applicant ACN	N/A
Date of approval	16 October 2026
Approval no.	97222
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent sulfoxaflor for use in agricultural chemical products

Application no.	152387
Active constituent	Fluxapyroxad
Applicant name	Shaanxi Mei Bang Pharmaceutical Group Co Ltd
Applicant ACN	N/A
Date of approval	16 October 2026
Approval no.	97223
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluxapyroxad for use in agricultural chemical products

Application no.	152391
Active constituent	Sulfoxaflor
Applicant name	Chia Yi Chemical Industry Co., Ltd.
Applicant ACN	N/A
Date of approval	19 October 2026
Approval no.	97227
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent sulfoxaflor for use in agricultural chemical products

Application no.	152389
Active constituent	Flonicamid
Applicant name	Shaanxi Mei Bang Pharmaceutical Group Co Ltd
Applicant ACN	N/A
Date of approval	21 October 2026
Approval no.	97225
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent flonicamid for use in agricultural chemical products

Application no.	151991
Active constituent	Indaziflam
Applicant name	Liao Ning Cynda Group
Applicant ACN	N/A
Date of approval	21 October 2026
Approval no.	97143
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent indaziflam for use in agricultural chemical products

Application no.	151223
Active constituent	Pyrasulfotole
Applicant name	Safex Chemicals Australia Pty Ltd
Applicant ACN	668 261 569
Date of approval	22 October 2026
Approval no.	96912
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyrasulfotole for use in agricultural chemical products

Application no.	151321
Active constituent	Emamectin benzoate
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of approval	22 October 2026
Approval no.	96951
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent emamectin benzoate for use in agricultural chemical products

Application no.	152587
Active constituent	Imidacloprid
Applicant name	Jiangsu Agrochem Laboratory Co Ltd
Applicant ACN	N/A
Date of approval	22 October 2026
Approval no.	97282
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imidacloprid for use in agricultural chemical products

Application no.	150978
Active constituent	Dodine
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of approval	22 October 2026
Approval no.	96862
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent dodine for use in agricultural chemical products

Application no.	150724
Active constituent	Pyroxasulfone
Applicant name	Jiangsu Yangnong Chemical Co. Ltd
Applicant ACN	N/A
Date of approval	22 October 2026
Approval no.	96801
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyroxasulfone for use in agricultural chemical products

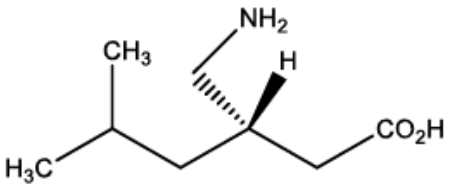
New veterinary chemical product: Bonqat 50 mg/mL Oral Solution for Cats, containing a new active constituent

The APVMA has before it an application for the approval of a new active constituent, **pregabalin**, from Mavlab Animal Health Pty Ltd, an application for the registration of a new product containing this new active constituent, Bonqat 50 mg/mL Oral Solution for Cats, for short term alleviation of acute anxiety and fear in cats associated with transportation and veterinary visits, in conjunction with approval of the active constituent, pregabalin.

Active constituent particulars

The APVMA has evaluated the safety of the new active constituent pregabalin.

Table 6: Particulars of the active constituent pregabalin

Common name	Pregabalin
Applicant company	Mavlab Animal Health Pty Ltd
IUPAC name	(3*S*)-3-(Aminomethyl)-5-methylhexanoic acid
CAS name	(3*S*)-3-(Aminomethyl)-5-methylhexanoic acid
CAS registry number	148553-50-8
Minimum purity	98.0-102.0% (anhydrous substance)
Molecular formula	$C_8H_{17}NO_2$
Molecular weight	159.229 $g.mol^{-1}$
Structure	
Chemical family	Gamma-amino acid
Mode of action	Pregabalin reduces neuronal hyperexcitability by binding to the $\alpha_2\delta$ subunit of presynaptic voltage-gated calcium channels, which decreases the release of excitatory neurotransmitters.

Summary of the APVMA's evaluation of pregabalin active constituent

A summary of the APVMA's evaluation of **pregabalin** in accordance with the requirements of section 14(1)(b) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

1. The APVMA has evaluated the chemistry aspects of pregabalin (identification, physicochemical properties, stability, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

2. The APVMA has considered the toxicological aspects of pregabalin and concluded that there are no toxicological concerns regarding the approval of this active constituent. No ADI or ARfD was established, as it is currently only intended for non-food producing uses. Pregabalin is currently listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The APVMA proposes to be satisfied under sections 5A(2) of the Agvet Code.

Bonqat 50 mg/mL Oral Solution for Cats containing pregabalin

The APVMA has under consideration an application to register a new product, **Bonqat 50 mg/mL Oral Solution for Cats,** containing the new active, **pregabalin**.

Table 7: Particulars of the product

Proposed product name/s	Bonqat 50 mg/mL Oral Solution for Cats
Applicant company	Mavlab Animal Health Pty Ltd
Name of active constituent	Pregabalin
Signal heading	Schedule 4
Formulation type	Oral solution
Summary of proposed use	For short term alleviation of acute anxiety and fear in cats associated with transportation and veterinary visits.
Dose rate	The effective dose is 5.0 mg/kg body weight (0.1 mL/kg). The product is administered orally 1.5 hours before veterinary visits. If the cat weighs more than 10 kg, the total dose will need to be calculated and given in 2 separate doses as the syringe holds maximally only 1.0 mL of solution (50 mg/mL).
Pack sizes	2 mL
Withholding period	N/A

A summary of the APVMA's evaluation of **Bonqat 50 mg/mL Oral Solution for Cats** in accordance with the requirements of section 14(1)(c) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994:*

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

i. The APVMA is satisfied that proposed use of Bonqat 50 mg/mL Oral Solution for Cats would not be an undue hazard to the safety of people exposed to it during its handling and use. Assessment included, 4 new Organisation for Economic Co-operation and Development (OECD) test guideline compliant studies which assessed acute skin and eye irritation, skin sensitisation and percutaneous absorption of pregabalin in the Bonqat (liquid) formulation. Additionally, a new reverse mutation assay and micronucleus study with pure pregabalin was also submitted, in addition to providing extensive summaries of toxicological and pharmacokinetic (PK) studies. The pharmacokinetics of pregabalin were evaluated in studies in rats, mice, cats, dogs, monkeys and humans. Based on the results of these studies the APVMA determined that:

   a. The product is unlikely to be a skin or eye irritant. The likely route of incidental exposure to Bonqat liquid by users (i.e. veterinarian or pet owners) is confined to short-term (minimal) skin contact from administering the liquid. Since the dermal absorption of pregabalin is slow and likely to be minimal, it is recommended that hands should be washed after dosing is complete. If accidental skin contact is made to a treated cat's excreta or vomit, immediate hand washing is recommended. In the unlikely event that poisoning occurs, the label first aid instructions advise immediate 'contact a doctor or the Poisons Information Centre. Phone Australia 13 11 26'.

   b. There was no evidence of carcinogenic activity of pregabalin in rats after long term continuous exposure in feed. Species specific increase in the incidence of haemangiosarcoma was observed in mice at relatively high systemic exposures (based on a blood level comparison of pharmacokinetic parameters with those of humans) and this was not observed in rats. The potential carcinogenic risk of pregabalin exposure in humans is considered to be small.

c. Genotoxicity assays (Ames test and human lymphocyte micronucleus assay) were negative. Based on public literature, pregabalin was not genotoxic based on an extensive battery of in vivo and in vitro tests in bacterial and mammalian systems (bacterial mutagenicity, structural chromosomal aberrations [SCA], in vitro mammalian cell mutagenicity, in vivo micronucleus [MN] in rats and unscheduled DNA synthesis [UDS] in mice).

d. The reproductive, prenatal and postnatal toxicity studies of pregabalin were performed in rats; and embryo-foetal developmental studies were available in mice, rats and rabbits. The doses at which reproductive and developmental effects were observed were significantly higher doses (≥ 20 times the human dose equivalent based on a body surface area comparison).

   In pregnant rats, excessive embryo-foetal mortality and enhanced ossification were seen at exposure to high oral pregabalin doses approximately 8 times the human equivalent dose. However, no major malformations were observed. Therefore, pregabalin is not considered to be teratogenic.

e. Neurological effects of pregabalin on rats, mice and squirrel monkeys have shown to reduce spontaneous locomotor activity and/or cause ataxia at significantly higher doses.

f. Frequent repeated exposure to pregabalin is not expected, as the product is to be used in cats prior to veterinary visits. The clinical safety and efficacy of repeated administration and long-term use have not been established in cats. In human studies the pregabalin elimination half-life is approximately 6 h and steady state is achieved within 1 to 2 days of repeated administration.

g. Accidental exposure to children is risk mitigated by product packaging containing child-resistant cap in addition to the bottles which are in use will have the syringe plug-in inserted, making removal of the product without the special syringe even more difficult. The product information will carry the standard statements: 'Keep out of reach of children' and additional user safety information.

h. Pregabalin has been added in the Schedule 4 and Appendix K Clause 1 substance of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), Health, 2026). This is considered appropriate for the proposed use of this veterinary medicine. None of the excipients in the product are listed or require listing in the SUSMP. Based on the active constituent inclusion in the SUSMP, Bonqat 50 mg/mL Oral Solution for Cats will have an entry in the Handbook of First Aid Instructions and Safety Directions for Agricultural and Veterinary Chemicals (FAISD) and Additional user safety Instructions.

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

Signal Heading

- *PRESCRIPTION ANIMAL REMEDY*
- *KEEP OUT OF REACH OF CHILDREN*
- *FOR ANIMAL TREATMENT ONLY*
- *READ SAFETY DIRECTIONS BEFORE OPENING OR USING*

Claims

- *For use by or under direction of a veterinarian*

Directions for use

- *Use as directed by prescribing veterinarian*

First aid instructions

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

Safety directions

- *Wash hands after use.*

Additional User Safety

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

- *Exposure to pregabalin may cause adverse effects such as dizziness, tiredness, ataxia, blurred vision and headache.*
- *Avoid skin, eye or mucosal contact. Thoroughly wash hands immediately after administration of the veterinary medicinal product.*
- *In case of accidental eye or mucosal contact, flush with water. Seek medical advice if symptoms (dizziness, tiredness, ataxia or blurred vision) occur.*
- *In case of accidental skin contact with the product, wash with soap and water. Remove contaminated clothing.*
- *In case accidental skin contact is made to a treated cat's excreta or vomit, wash immediately with soap and water.*
- *In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive as tiredness may occur.*

j. After consideration of the toxicological profile and likely human exposure associated with the use Bonqat 50 mg/mL Oral Solution for Cats, the APVMA concludes that the human health risks are acceptable and the safety criteria of section 5A of the Agvet Code are met when used in accordance with the directions for use (DFU).

ii. The APVMA is satisfied that the proposed use of Bonqat 50 mg/mL Oral Solution for Cats will not be an undue hazard to the safety of people using anything containing its **residues.**

a. The product is for use in companion animals (cats) only. Bonqat 50 mg/mL Oral Solution for Cats is therefore, unlikely to enter the food chain.

iii. The APVMA is satisfied that the proposed use of Bonqat 50 mg/mL Oral Solution for Cats containing the active constituent pregabalin is not likely to have an unintended effect that is harmful to plants or the **environment** if used according to the product label directions.

a. Environmental risks of Bonqat 50 mg/mL Oral Solution for Cats (containing 50 mg/mL pregabalin) were assessed according to the VICH [1]Phase I decision tree. The assessment determined that the amount of pregabalin introduced to the environment is expected to be negligible based on its uses in non-food animals (cats). Therefore, the assessment stopped in VICH phase I, and no further assessment was required.

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

[1] Veterinary International Cooperation on Harmonisation (VICH)

Disposal

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

iv. The APVMA is satisfied that the proposed use of Bonqat 50 mg/mL Oral Solution for Cats is not likely to have an unintended effect that is harmful to **target animals (cats)** if used according to the product label directions.

a. Target Animal Safety (TAS) was investigated one pivotal GLP-compliant safety study that was conducted in 32 healthy cats (four study groups with 4 males and 4 females per group), age 7 months, weight range 2.7 – 5.2 kg. Bonqat was administered at 1x, 3x and 5x the proposed recommended treatment dose for 6 days. Four non-clinical studies were provided to investigate target animal safety of the product, in addition to the safety data obtained from the clinical efficacy trials and dose determination study.

b. Margin of safety study

- Pivotal safety study showed signs of limited usage of hind limbs, uncoordinated behaviour (severity up to moderate), abnormal gait, decreased activity(lethargy), lying on side, and/or sedated appearance (grade 1; i.e. mild signs of depression, drowsiness or ataxia). At higher doses, dose-dependent increases in the frequency and severity of adverse effects were observed. The signs in relation to motor coordination (abnormal gait, limited usage of hind limbs/paws, uncoordinated behaviour (ataxia)), somnolence (decreased activity (lethargy), closed eyes, lying on side, dilated pupils, decreased body temperature(hypothermia) and depression), vomiting and salivation at greater frequency, severity and duration than the adverse reactions observed at the recommended dose. On rare occasions loss of consciousness was seen at the 5-fold dose.

Target Animal Efficacy Field studies

- Nonclinical and field study data has shown clinical signs primarily related to central nervous system signs (lethargy, mild sedation, mild ataxia, decreased activity, abnormal movement, mydriasis). Other possible treatment related signs included nausea (salivation, vomiting), reduction in heart rate and a decrease in body temperature.
- Muscle tremor, dilated pupils, loss of appetite, weight loss and reduced number of white blood cells have been reported uncommonly in clinical studies.

c. The use of Bonqat 50 mg/mL Oral Solution for Cats has neither been studied during pregnancy, lactation or in animals intended for breeding.

d. Studies in range of species including rats, monkeys and humans indicated that principal route of elimination of pregabalin is via urine. This has not been studied in cats. Most of the pregabalin found in urine is unmetabolized. Main metabolite of pregabalin in cat was found to be glucose or galactose conjugate.

e. Precaution is advised in cats with renal impairment, liver, or cardiovascular disease.

f. As the product has sedation as a side effect, the owner is required to inform the attending veterinarian regarding the use of the product, to avoid confusions on clinical evaluations or planning procedures involving anaesthesia.

g. The APVMA has therefore, concluded that the administration of Bonqat 50 mg/mL Oral Solution for Cats is generally well tolerated at 5 mg/kg bw single dose for one day prior transportation/planned veterinary visit. Appropriate statements have been included on the label to mitigate the risks identified as follows:

Contraindications

- *Not to be used in cats that are hypersensitive to the active substance.*

Precautions

- *The cat's health status needs always to be assessed by the veterinarian before prescribing the veterinary medicinal product. The animal owner should be advised by the prescribing veterinarian to always inform the attending veterinarian if the veterinary medicinal product has been administered to the cat prior to the veterinary visit.*
- *If the cat spits part of the dose, vomits after treatment, or in case of excessive salivation, do not give another dose.*
- *The clinical safety and efficacy of repeated administration and long-term use have not been established.*
- *The safety of the veterinary medicinal product has not been established in cats weighing less than 2 kg, younger than 5 months and older than 15 years. Use only according to the benefit-risk assessment by the responsible veterinarian.*
- *The safety of the veterinary medicinal product has only been established in healthy animals or those with mild systemic illness. It has not been established in animals with moderate or severe systemic disease e.g. moderate or severe renal, liver, or cardiovascular disease. Use only according to the benefit-risk assessment by the responsible veterinarian.*
- *Use with caution in cats with known or suspected renal impairment, as reduced renal function may increase systemic exposure to pregabalin and the risk of toxicity.*
- *The veterinary medicinal product may cause slight decrease in heart rate, respiratory rate and body temperature. As a decrease of body temperature can occur after the administration, the treated animal should be kept warm at a suitable ambient temperature.*
- *If pupils are dilated following product administration, avoid exposing the cat to direct sunlight until the pupils return to normal.*
- *Monitor the cat carefully for any symptoms of sleepiness and respiratory depression if the veterinarian informs that another medicine causing central nervous system depression has been used concomitantly with the veterinary medicinal product.*
- *The effects of the veterinary medicinal product last for a median duration of 7 hours at the recommended dose. If the cat appears drowsy, disoriented, unsteady, or exhibits other signs of exaggerated pharmacological effects following administration of Bonqat, keep the cat indoors in a quiet, secure environment to minimise the risk of accidental injury until normal behaviour and coordination have returned. Do not offer food or water until the cat has fully recovered from these effects.*
- *Pregnancy, lactation and breeding:*

  Laboratory studies in rats and rabbits have shown evidence of embryofoetotoxic and maternotoxic effects when pregabalin is administered repeatedly at very high doses (≥ 250- fold the recommended dose for cats). The safety of the veterinary medicinal product has not been established in pregnant, lactating and breeding cats. Use only according to the benefit-risk assessment by the responsible veterinarian.
- *Interactions:*

  The use of other central nervous system depressants is expected to potentiate the effects of pregabalin and therefore an appropriate dose adjustment should be made by the prescribing veterinarian.

Side effects

- *Signs of sedation (characterised by lethargy, difficulties in perception of the position and, abnormal movement of the body and problems with balance(ataxia)) and vomiting have been observed commonly in clinical studies. Muscle tremor, dilated pupils, loss of appetite, weight loss and reduced number of white blood cells have been reported uncommonly in clinical studies. Salivation has been reported rarely in clinical studies. Typically, clinical signs are mild and transient.*
- *The frequency of adverse reactions is defined using the following convention:*
  - *very common (more than 1 in 10 animals treated displaying adverse reaction(s))*
  - *common (more than 1 but less than 10 animals in 100 animals treated)*
  - *uncommon (more than 1 but less than 10 animals in 1,000 animals treated)*
  - *rare (more than 1 but less than 10 animals in 10,000 animals treated)*
  - *very rare (less than 1 animal in 10,000 animals treated, including isolated reports).*
- *If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.*
- *Overdose (symptoms, emergency procedures, antidotes):*

  Safety following repeated administration of Bonqat once daily for 6 consecutive days and at up to 5 times the recommended treatment dose was investigated in an overdose study. Overdose (3- and 5-fold higher than the recommended dose) can cause signs related to motor coordination (abnormal gait, limited usage of hind limbs/paws, uncoordinated behaviour (ataxia)), somnolence (decreased activity (lethargy), closed eyes, lying on side, dilated pupils, decreased body temperature(hypothermia) and depression), vomiting and salivation at greater frequency, severity and duration than the adverse reactions observed at the recommended dose. On rare occasions loss of consciousness was seen at the 5-fold dose.

General directions

Observations from safety studies

- *In a margin of safety study, 32 healthy, 7‑month‑old domestic shorthair cats (4 males and 4 females per group; weight range 2.7-5.2 kg) were administered either Bonqat or a negative control. Bonqat was administered once daily by oral administration for 6 consecutive days at dose rates of 5, 15, or 25 mg/kg/day.*
- *At the recommended dose of 5 mg/kg, clinical signs consistent with sedation were observed. These included reduced use of the hind limbs, incoordination (up to moderate severity), abnormal gait, decreased activity (lethargy), lying on the side, and/or a sedated appearance (Grade 1; mild depression, drowsiness, or ataxia) in male cats on Day 1.*
- *Sedation was assessed using a 4-point scale (0 = not sedated; 3 = deep sedation). At higher doses (15 and 25 mg/kg/day), dose-related increases in the frequency and severity of adverse effects were observed. Clinical signs included reduced use of the hind limbs or paws, incoordination, abnormal gait, lethargy, lying on the side, bradycardia, partially to completely closed eyes, a sedated appearance, mydriasis (dilated pupils), quiet but alert behaviour, reduced mental alertness, and hypothermia (cold to touch). Sedation scores increased to Grade 3 (depressed, drowsy, and sleepy). One cat receiving 25 mg/kg experienced transient loss of consciousness and recovered without treatment. In addition,*
- *Slight to severe salivation was observed immediately after dosing on multiple treatment days and was considered related to the taste of the test product.*

- *Clinical signs were observed primarily on the first day of dosing and generally persisted for longer at higher dose levels. Most signs resolved within 8 to 12 hours after dosing.*

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

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

The submission included 5 pharmacological studies in the target species(cats). Dose determination was supported by pharmacokinetic/pharmacodynamic (PK/PD) calculations and safety evaluations. Two studies investigated the effect of food on PK parameters. Two dose-confirmation studies were also provided: a pilot-scale, multi-site field efficacy study and a pivotal field efficacy and safety study. These studies also evaluated the usability of the product. Published literature was provided as additional supporting evidence. A summary of the efficacy studies and the assessment findings is provided below:

a. Pharmacodynamics

Pregabalin binds to the auxiliary subunit (alpha2-delta protein) of voltage-gated calcium channels in the central nervous system, reducing presynaptic calcium influx into neurons and thereby decreasing the release of various neurotransmitters (glutamate and monoaminergic neurotransmitters) contributing to its anxiolytic effect.

b. Pharmacokinetics

Absorption

Pregabalin is rapidly absorbed after oral administration in cats. The C_{max} in plasma was 10.1 μg/mL and occurred at 0.5 - 1.0 hours after administration of 5 mg/kg bodyweight into the mouth of cats in fasted state. The area under plasma concentration-time curve (AUC_{0-24h}) in fasted state was 129 μg*h/mL. The mean absolute oral bioavailability of pregabalin was 94.3%. After re-dosing of 5 mg/kg at 24 hours, the exposure, in terms of C_{max}, AUC_{0-24h}, and $t_{1/2}$, was comparable with the exposure following single dosing. No significant differences were noted in overall absorption, expressed as plasma C_{max} and

AUC, after administration of pregabalin into the mouth under different feeding regimes.

Distribution

Pregabalin has a relatively large volume of distribution. After intravenous bolus administration, the volume of distribution at the steady state (V_{ss}) was 0.41 L/kg. Pregabalin is not known to bind to plasma proteins in mice, rats, monkeys or humans. This has not been studied in cats.

Metabolism and excretion

Pregabalin is quite slowly eliminated from the body of cats. Total plasma clearance was 0.03 L/h/kg. The mean half-life of elimination from the circulation was 12.3 hours after intravenous administration of 2.5 mg/kg and 14.7 hours after oral administration of 5 mg/kg.

Elimination of the parent compound as well as the methylation metabolite from circulation occurs almost exclusively by renal excretion in rats, monkeys and humans. In dogs, approximately 45% of the pregabalin dose is excreted in urine as *N*-methyl metabolite. This has not been studied in cats.

c. Dose finding

Dose determination was based on PK/PD calculations. Based on PK/PD studies, 2.5 mg/kg and 5 mg/kg bw doses were considered appropriate dose regimens to be tested under field conditions to determine an anxiolytic dose with only mild signs of sedation.

In a pilot and pivotal field studies involving cats with diagnosed anxiety, safety and efficacy of the use of proposed 5 mg/kg dose rate was assessed.

d. Field studies

- Pilot multi-site field study:

A GCP-compliant Placebo controlled cross over study with 4 treatment days, examined the anxiolytic effects of different doses of pregabalin in 13 client owned cats in Finland. The Owner's assessment of the effect of the treatment determined based on a number of different numerical rating scoring systems was used as the primary efficacy measurement in this study.

The study was low powered and was not possible to draw firm conclusions regarding efficacy of a specific dose.

- Pivotal multi-site field study:

A parallel-group, multicentre study was conducted in 20 veterinary practices in Europe, using client owned cats with a history of being anxious and/or fearful when transported by car and during veterinary visits. This randomised, blinded, GCP-compliant study containing 2 stages, investigated the anxiolytic effects of a single dose of 2.5 mg/kg bw or 5 mg/kg bw of pregabalin compared to a placebo. Doses were administered approximately 1.5 hours before the cat was put into the carrier and starting of the transportation to the visits.

A total of 238 cats with a history of anxiety and/or fear associated with car transportation and veterinary visits were allocated to groups that received either Bonqat orally at dose rates of 5 mg/kg (n=108) or 2.5 mg/kg (n=29) or a placebo (n=101). The cats were between 5 months and 15 years of age and weighed 1.8 to 10.3 kg.

Treatment success was defined using 2 primary effectiveness endpoints. These were the owner's assessment of the treatment effect based on the cat's anxiety and/or fear during transportation in a car and the veterinarian's assessment of the treatment effect based on the cat's anxiety and/or fear during physical examination at the clinic. These endpoints were rated using the scale: 1- Excellent, 2- Good, 3- Fair, 4- Poor, 5- Very Poor.

In the 5 mg/kg group, 51.4% cat owners assessed the treatment response as excellent or good during transportation compared with 26.7% of owners of placebo-treated cats.

During veterinary examination, 55.2% of Bonqat treated cats were rated by veterinarians as having a good or excellent response, compared with 29.7% of placebo-treated cats. Statistically significant treatment responses were demonstrated for both primary efficacy variables at the 5mg/kg dose compared with the placebo (generalised linear mixed model, $p < 0.0010$), although treatment was not successful in all cats. In contrast, the 2.5 mg/kg dose group did not differ significantly from the placebo for either primary efficacy variable.

e. Feeding

In one study conducted with 4 cats, administration of the 39-76% of the daily food allowance one hour before dosing resulted in a delayed time to reach maximum plasma concentration (T_{max} 2-4 h) and decreased C_{max} (5.9 µg/mL) relative to fasting conditions. In a separate study conducted with another 4 cats which received 10-50% of their daily food intake at varying frequencies under different feeding regimes, no significant differences were noted in overall absorption of pregabalin, expressed as plasma C_{max} and AUC, following oral administration of the product.
Overall absorption (expressed as AUC) remained comparable between fed and fasted state.

f. Usability

The pilot efficacy study demonstrated that administration of a human registered product was difficult. In the pivotal field study, a formulation developed for the cats with reduced dose volume had improved usability with 79% of the owners assessing that it was easy or very easy to administer the product. The product is to be administered orally to the cat at 0.1 mL/kg by using the syringe provided with the product. Mixing with a small amount of food can be attempted, noting that large amounts of food may delay the onset of effect.
The APVMA has therefore, concluded that Bonqat 50 mg/mL Oral Solution for Cats is, would be effective for short-term alleviation of acute anxiety and fear in cats associated with transportation and veterinary visits with following statements imposed on the label:

Claims

- *For short-term alleviation of acute anxiety and fear in cats associated with transportation and veterinary visits.*

Dosage and Administration

- *Store the opened bottle refrigerated at 2° C to 8° C. Use the contents within 6 months of first opening the container. Discard any unused portion thereafter. During the 6 months in-use period, the product may be stored temporarily at temperatures up to 25° C for a cumulative period not exceeding 1 month.*
- *The recommended dose is a single dose of 5 mg/kg (0.1 mL/kg) bodyweight.*
- *Give Bonqat approximately 1.5 hours before the start of the transportation/planned veterinary visit.*
- *Administer the product orally.*
- *Use the oral syringe provided in the package for administration of the veterinary medicinal product. If the cat weighs more than 10 kg, the total dose will need to be calculated and given in 2 separate doses as the syringe holds maximally only 1.0 mL of solution.*
- *The veterinary medicinal product can be administered either directly into the mouth or mixed with a small amount of food. Large amounts of food may delay the onset of effect.*

General Directions

Mechanism of action

- *Pregabalin binds to the auxiliary subunit (alpha2-delta protein) of voltage-gated calcium channels in the central nervous system, reducing presynaptic calcium influx into neurons and thereby decreasing the release of various neurotransmitters (glutamate and monoaminergic neurotransmitters) contributing to its anxiolytic effect.*
- *Demonstrated efficacy in field studies.*

The effectiveness of Bonqat was evaluated in a multi-centre field study conducted in Europe. A total of 238 cats with a history of anxiety and/or fear associated with car transportation and veterinary visits were allocated to groups that received either Bonqat orally at dose rates of 5 mg/kg (n=108) or 2.5 mg/kg (n=29) or a placebo (n=101). Doses were administered approximately 1.5 hours before the cat was put into the carrier and transported to the veterinary clinic. The cats were between 5 months and 15 years of age and weighed 1.8 to 10.3 kg.

Treatment success was defined using 2 primary effectiveness endpoints. These were the owner's assessment of the treatment effect based on the cat's anxiety and/or fear during transportation in a car and the veterinarian's assessment of the treatment effect based on the cat's anxiety and/or fear during physical examination at the clinic. These endpoints were rated using the scale: 1- Excellent, 2- Good, 3- Fair, 4- Poor, 5- Very Poor.

In the 5 mg/kg group, 51.4% cat owners assessed the treatment response as excellent or good during transportation compared with 26.7% of owners of placebo-treated cats.

During veterinary examination, 55.2% of Bonqat treated cats were rated by veterinarians as having a good or excellent response, compared with 29.7% of placebo-treated cats. Statistically significant treatment responses were demonstrated for both primary efficacy variables at the 5mg/kg dose compared with the placebo (generalised linear mixed model, $p < 0.0010$), although treatment was not successful in all cats. In contrast, the 2.5 mg/kg dose group did not differ significantly from the placebo for either primary efficacy variable

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

iii. The APVMA is satisfied that the proposed use of Bonqat 50 mg/mL Oral Solution for Cats would not adversely affect **trade** between Australia and places outside Australia as the product is for use in cats, which are not food-producing animals, and which do not produce any major Australian export commodities.

Making a submission

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

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **Bonqat 50 mg/mL Oral Solution for Cats** should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

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

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

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

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

Email: casemanagement@apvma.gov.au

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

Privacy

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

New veterinary chemical product: Fatrovax RHD Vaccine for Rabbits, containing 2 new active constituents

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it, applications for the approval of 2 new active constituents, **Recombinant Rabbit Haemorrhagic Disease virus 1 (RHDV1) VP1a virus-like particles** and **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles**, and an application for the registration of a new product containing the new active constituents, **Fatrovax RHD Vaccine for Rabbits**.

The new product contains the 2 recombinant proteins **RHDV1 VP1a** and **RHDV2 VP1ab**, which auto-assemble into virus-like particles (VLPs). The proteins are produced using recombinant baculoviruses grown in *Trichoplusia ni* pupae. The product is presented as a suspension for injection containing 5 μg (≥1 relative potency (RP)) of each active constituent per 0.5 mL dose, together with aluminium hydroxide as an adjuvant, and thiomersal as a preservative.

The product is intended for active immunisation of rabbits from 30 days of age to reduce mortality, infection, clinical signs and organ lesions caused by rabbit haemorrhagic disease virus 1 (RHDV1) and rabbit haemorrhagic disease virus type 2 (RHDV2). The proposed dose is 0.5 mL administered by subcutaneous injection. The onset of immunity is 7 days after vaccination and the duration of immunity is 12 months.

Active constituent particulars – Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles

As part of the application to register **Fatrovax RHD Vaccine for Rabbits** containing the new actives, the APVMA has evaluated the safety of the new active constituent **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles.**

Table 8: Particulars of the active constituent Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles

Common name	Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles
Applicant company	FATRO S.P.A.
Brief description of active (GMO, recombinant, live, inactivated)	Recombinant protein that auto-assembles into virus-like particles. The sequences of the VP1 major capsid protein and the VP2 minor structural protein are derived from the Rabbit Haemorrhagic Disease Virus (RHDV) strain Ast89, isolated in 1989 in Spain.
Mode of action	Active immunisation of rabbits against rabbit haemorrhagic disease caused by RHDV1 through the recombinant capsid protein presented as virus-like particles.

Summary of the APVMA's evaluation of the Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles active constituent

A summary of the APVMA's evaluation of the **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles** active constituent in accordance with the requirements of section 14(1)(b) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

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

   i. The APVMA is satisfied with the chemistry and manufacturing aspects of the active constituent **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles** and has determined that the active constituent is manufactured to an acceptable standard.

      a. RHDV1 VP1a is produced using a recombinant baculovirus expressing the VP1 capsid protein. The recombinant baculovirus is propagated in *Trichoplusia ni* pupae. Following harvest, the recombinant protein is extracted, purified by filtration, ammonium sulphate precipitation and diafiltration, and subjected to sterilising filtration. This is a purified recombinant protein only and does not contain viable genetically modified organisms (GMOs), recombinant baculovirus, or replicating genetic material. Accordingly, while the manufacturing process utilises GM technology, the active is not considered a GMO.

      b. The assessment considered the manufacture and control of the starting materials, including the viral master seed and working seed, cell master and working seed and *Trichoplusia ni* pupae. Appropriate information was provided on the construction and testing of the recombinant baculoviruses, and justification for the extraneous-agent testing was considered acceptable given the synthetic construction and propagation in chemically defined media.

      c. Appropriate in-process controls are applied during manufacture, including testing for sterility, absence of mycoplasma, identity, protein concentration, yield, purity and baculovirus inactivation. Validation data demonstrated that the manufacturing process adequately inactivates the recombinant baculovirus.

      d. The shelf life of the active was established by stability studies in accordance with APVMA guidance for veterinary vaccines.

   ii. The APVMA is satisfied that the toxicological and human health aspects of the active constituent **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles** are acceptable.

      a. Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) has been established as the active constituent is an immunobiological active intended for use in a companion animal (rabbits).

      b. As Recombinant Rabbit haemorrhagic disease virus 1 (RHDV1) VP1a virus-like particles is a recombinant protein that forms non-infectious virus-like particles for use as a veterinary vaccine antigen, scheduling under the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) is not considered necessary.

c. The active constituent is a recombinant capsid protein presented as virus-like particles and does not contain live RHDV1. The recombinant baculovirus used in manufacture is inactivated and removed during processing. Accordingly, the product is not expected to pose a zoonotic risk to users.

d. There are no objections on toxicological grounds to the approval of the active constituent **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles**

2) The APVMA proposes to be satisfied under section 5A (1) of the Agvet Code that **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a active constituent virus-like particles** would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; would not be likely to have an effect that is harmful to human beings; and would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

Active constituent particulars – Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles

As part of the application to register **Fatrovax RHD Vaccine for Rabbits** containing the new actives, the APVMA has evaluated the safety of the new active constituent **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles.**

Table 9: Particulars of the active constituent Recombinant Rabbit haemorrhagic disease virus type 2 (RHDV2) VP1ab virus-like particles

Common name	Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles
Applicant company	FATRO S.P.A.
Brief description of active (GMO, recombinant, live, inactivated)	Recombinant protein that auto-assembles into virus-like particles. The construct is a chimeric capsid protein (VP1ab) combining the N-terminal sequence of classical RHDV strain Ast89 with the main capsid sequence of RHDV2 strain N11 (isolated in Spain in 2011).
Mode of action	Active immunisation against rabbit haemorrhagic disease caused by RHDV2 through the recombinant VP1 capsid protein presented as virus-like particles.

Summary of the APVMA's evaluation of Recombinant Rabbit Haemorrhagic Disease Vvirus type 2 (RHDV2) VP1ab virus-like particles active constituent

A summary of the APVMA's evaluation of **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles** active constituent in accordance with the requirements of section 14(1)(b) of the Agvet Code:

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

   i. The APVMA is satisfied with the chemistry aspects of the active constituent **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles** and has determined that the active constituent is manufactured to an acceptable standard.

      a. RHDV2 VP1ab is a recombinant capsid protein produced using recombinant baculovirus grown in *Trichoplusia ni* pupae. The recombinant baculovirus is propagated in *Trichoplusia ni* pupae. Following harvest, the recombinant protein is extracted, purified by filtration, ammonium sulphate precipitation and diafiltration, and subjected to sterilising filtration. This is a purified recombinant protein only and does not contain viable genetically modified organisms (GMOs), recombinant baculovirus, or replicating genetic material. Accordingly, while the manufacturing process utilises GM technology, the active is not considered a GMO.

      b. The assessment considered the manufacture and control of the starting materials, including the viral master seed and working seed, cell master and working seed and *Trichoplusia ni* pupae. Appropriate information was provided on the construction and testing of the recombinant baculoviruses, and justification for the extraneous-agent testing was considered acceptable given the synthetic construction and propagation in chemically defined media.

      c. Appropriate in-process controls are applied during production, including testing for sterility, absence of mycoplasma, identity, protein concentration, yield, purity and recombinant baculovirus inactivation. Validation studies were provided to support the manufacturing controls.

      d. The shelf life of active was established by stability studies in accordance with APVMA guidance for veterinary vaccines.

   ii. The APVMA is satisfied that the toxicological and human health aspects of the active constituent **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles** are acceptable.

      a. Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) has been established as the active constituent is an immunobiological active intended for use in a companion animal.

      b. As Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles is a recombinant protein that forms non-infectious virus-like particles for use as a veterinary vaccine antigen, scheduling under the SUSMP is not considered necessary.

      c. The active constituent is a recombinant capsid protein presented as virus-like particles and does not contain live RHDV2. The recombinant baculovirus used in manufacture is inactivated and removed during processing. Accordingly, the product is not expected to pose a zoonotic risk to users.

      d. There are no objections on toxicological grounds to the approval of the active constituent **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles.**

2) The APVMA proposes to be satisfied under section 5A (1) of the Agvet Code that **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles** active constituent would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; would not be likely to have an effect that is harmful to human beings; and would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

Fatrovax RHD Vaccine for Rabbits containing active constituents Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a and Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles

In addition to the applications to approve the new active constituents **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles** and **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles**, the APVMA has under consideration an application to register **Fatrovax RHD Vaccine for Rabbits**, a new product containing these 2 active constituents.

Table 10: Particulars of the product

Proposed product name	Fatrovax RHD Vaccine for Rabbits
Applicant company	FATRO S.P.A
Name of active constituents and constituent statements	Each dose (0.5 mL) contains: Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a* ≥1 RP** Rabbit Haemorrhagic Disease Virus 2 (RHDV2) VP1ab* ≥1 RP** *recombinant capsid protein ** Relative potency: ELISA by comparison with a reference serum in vaccinated mice Also contains per dose (0.5 mL): 0.83 mg Aluminium (as Aluminium hydroxide) (Adjuvant) 0.05 mg Thiomersal (Preservative)
Signal heading	FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
Formulation type	Suspension for injection
Summary of proposed use	**Fatrovax RHD Vaccine for Rabbits** contains 2 recombinant proteins, Rabbit haemorrhagic disease virus 1 (RHDV1) VP1a and Rabbit haemorrhagic disease virus type 2 (RHDV2) VP1ab, which auto-assemble into virus-like particles (VLPs). Each 0.5 mL dose contains 5 μg RHDV1 VP1a (≥1 RP) and 5 μg RHDV2 VP1ab (≥1 RP). The product contains aluminium hydroxide as an adjuvant and thiomersal as a preservative. **Fatrovax RHD Vaccine for Rabbits** is for the active immunisation of rabbits from 30 days of age to reduce mortality, infection, clinical signs and organ lesions of rabbit haemorrhagic disease caused by RHDV1 and RHDV2. Onset of immunity: 1 week (7 days) after vaccination. **Duration of immunity**: 1 year. The recommended dose is 0.5 mL administered by subcutaneous injection.
Pack sizes	Type I glass syringes: 0.5 mL single dose and 5 × 0.5 mL single-dose syringes. Polypropylene bottles: 25 mL (50 doses) and 100 mL (200 doses).
Withholding period	N/A, as the product is for use in companion rabbits only.

A summary of the APVMA's evaluation of **Fatrovax RHD Vaccine for Rabbits** in accordance with the requirements of section 14(1)(c) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

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

i. The APVMA is satisfied that the proposed use of **Fatrovax RHD Vaccine for Rabbits** would not be an undue hazard to the **safety of people exposed to it during its handling and use.**

a. None of the active constituents or other ingredients in Fatrovax RHD Vaccine for Rabbits are included in a Schedule of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

b. The vaccine is supplied as a sterile suspension for injection and contains 2 recombinant viral proteins, **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a** and **Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles,** which self-assemble into virus-like particles. The vaccine does not contain live rabbit haemorrhagic disease virus and is incapable of replication.

c. The vaccine is administered as a single 0.5 mL dose by subcutaneous injection. The product is intended to be used for the vaccination of companion rabbits and therefore exposure is expected to be limited to veterinarians, trained animal health professionals and animal handlers administering the product.

d. The formulation contains 0.83 mg Aluminium (as Aluminium hydroxide) as an adjuvant and 0.05 mg Thiomersal as a preservative The principal user safety risk is accidental self-injection during administration of the vaccine.

e. As the product is administered by subcutaneous injection and contains an aluminium hydroxide adjuvant, appropriate user safety statements have been included on the label to minimise the risk associated with accidental self-injection.

f. To mitigate potential risks, the following signal headings, first aid instructions, and additional user safety directions statements are to appear on the product labels:

Signal Heading
FOR ANIMAL TREATMENT ONLY
READ SAFETY DIRECTIONS

Safety Directions
Wash hands after use.

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

Additional User Safety
Take care to avoid self-injection. In the event of self-administration, seek medical attention if you are concerned. Show the package leaflet or label to the medical practitioner.

g. After consideration of the toxicological profile and likely human exposure associated with the use of Fatrovax RHD Vaccine for Rabbits, the APVMA concludes that the human health risks are acceptable and the safety criteria of section 5A of the Agvet Code are met when used in accordance with the directions for use.

ii. The APVMA is satisfied that the proposed use of **Fatrovax RHD Vaccine for Rabbits** would not be an undue hazard to the safety of people using anything containing its **residues.**

a. Residues data were not required because the product is intended solely for use in companion rabbits and is not intended for administration to food-producing animals.

b. The following statement must be included on the label under **Restraints:**
DO NOT USE *in rabbits that may be processed for human consumption.*

c. Given the product is intended solely for use in companion rabbits and is not intended for use in food-producing animals, the APVMA is satisfied that the proposed use of the product meets the safety criteria in section 5A of the Agvet Code, as it would not be an undue hazard to the safety of people using anything containing its residues and would not be likely to have an effect that is harmful to human beings.

iii. The APVMA is satisfied that the proposed use of **Fatrovax RHD Vaccine for Rabbits** is not likely to have an unintended effect that is harmful to the **environment** if used according to the product label directions.

a. The environmental risks associated with **Fatrovax RHD Vaccine for Rabbits,** containing the active constituents **Recombinant Rabbit Haemorrhagic Disease Virus 1 (RHDV1) VP1a virus-like particles** and **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles,** were assessed.

b. The environment assessment concluded that environmental exposure associated with the proposed use of the product is expected to be limited and that the risk to the environment is negligible. This conclusion was based on the nature of the active constituents, the manufacturing process and the proposed use pattern, which involves administration as a single 0.5 mL subcutaneous injection to individual companion rabbits, with total volumes of less than 1 L proposed for use in Australia.

c. The following mitigation/labelling statement is recommended, based on the outcome of the risk assessment and general labelling requirements:

Disposal

25 and 100 mL pack size
Dispose of unused product and containers in accordance with the approved product label.

0.5 mL prefilled syringe
Discarded needles should be placed in an appropriately designated sharps container.

d. On the basis of the environmental assessment, the APVMA is satisfied that the proposed use of Fatrovax RHD Vaccine for Rabbits meets the safety criteria in paragraph 5A(1)(c) of the Agvet Code, as it would not be likely to have an unintended effect that is harmful to the environment when used in accordance with the proposed label directions.

iv. The APVMA is satisfied that the proposed use of **Fatrovax RHD Vaccine for Rabbits** would not be likely to have an unintended effect that is harmful to **target animals (companion rabbits)** if used according to the product label directions.

i. The following target animal safety information for the proposed product was provided:

(a) A laboratory safety study was conducted to evaluate the safety of a 2-fold overdose and repeated administration of the vaccine.

(b) A reproductive safety study was conducted in pregnant rabbits.

(c) A field safety study was conducted in young rabbits under field conditions.

(d) Safety observations were collected during the pivotal efficacy studies, including studies supporting the onset and duration of immunity claims.

(e) Adverse events and clinical observations recorded during the efficacy studies were evaluated as part of the overall target animal safety assessment.

(f) Post-registration pharmacovigilance data and adverse event reports from overseas use of the product were reviewed to support the target animal safety assessment.

ii. A **laboratory safety study** was conducted in 15 unvaccinated 28-day-old Netherland Dwarf rabbits. Ten (10) rabbits received the vaccine and 5 received saline control. The vaccinated animals received a 2-fold overdose as the first 0.5 mL dose, followed 26 days later by a repeat 0.5 mL dose. Following the first vaccination, no clinical signs were observed. Two vaccinated rabbits developed transient local reactions. One developed redness and swelling followed by a non-painful nodule, which resolved by day 11; another developed a non-painful nodule that resolved within 9 days of appearing. No vaccinated animal had a temperature increase greater than 2.0 ° C and there was no significant difference in average weight gain between vaccinated and control animals. Following the repeat dose, no clinical signs or local reactions were observed. The study supported the safety of a 2-fold overdose and repeated administration in rabbits of the minimum vaccination age.

iii. A **reproductive safety and repeated-dose study** was conducted in 60 pregnant New Zealand White does, comprising 4 groups of 15 animals. Vaccinated animals received the vaccine at either 10 or 22 days of gestation, with the latter group receiving a repeat dose 6 weeks after the first vaccination. No compromised health associated with vaccination was observed and there were no statistically significant differences between vaccinated and control groups in pregnancy length, number of animals born, number stillborn or average weight per rabbit in each litter. The study concluded that there were no adverse effects on reproductive function in vaccinated females or on the health status of their offspring attributable to the vaccine, supporting use during pregnancy. Following repeat administration, four (4) vaccinated rabbits had temperature increases greater than 0.5 ° C above baseline, but none exceeded 1 ° C, and 2 animals developed small injection-site nodules of less than 1 cm.

iv. A **field safety study** was conducted in 15 just-weaned rabbits, 27 to 34 days of age, comprising 6 males and 9 females of crossbreeds of dwarf rabbits. Each rabbit received a single 0.5 mL dose administered subcutaneously. The study was conducted under field conditions in individual owners' homes and was submitted to confirm the laboratory safety findings following administration of the recommended dose. Observations following vaccination identified no unexpected adverse reactions and no safety concerns of clinical significance. The study confirmed the acceptable safety profile of the vaccine when administered at the recommended dose under field conditions.

v. Safety observations were collected during the **pivotal efficacy studies** supporting the onset and duration of immunity claims. Vaccinated rabbits were monitored for local and systemic adverse reactions following vaccination. The vaccine was generally well tolerated, with reported findings limited to transient increases in body temperature and small injection-site reactions that resolved without treatment. No vaccine-related serious adverse events were reported.

vi. **Safety observations recorded during challenge studies** conducted in support of efficacy were also evaluated as part of the target animal safety assessment. The studies did not identify any unexpected

adverse reactions associated with vaccination and provided additional evidence supporting the safety of the vaccine when administered according to the proposed label directions.

vii. **Pharmacovigilance data** from overseas commercial use of the product were reviewed. The post-registration safety information provided additional evidence that the vaccine has an acceptable safety profile under field conditions and did not identify any new or unexpected safety concerns relevant to the proposed Australian use pattern.

viii. Summary:

(a) Overall, the laboratory studies demonstrated that the vaccine was generally well tolerated following administration of the recommended dose, a 2-fold overdose and repeated administration. The principal treatment-related findings were **transient local injection-site reactions and transient increases in body temperature**, with no significant effects on weight gain identified in the overdose/repeat-dose study.

(b) The reproductive safety study supported the safety of vaccination during pregnancy. Although some reproductive events occurred during the study, including dead litters in 2 vaccinated does, there was no statistically significant difference between the vaccinated and control groups for the reproductive parameters examined, and the study concluded that no adverse effects on reproductive function or offspring attributable to the vaccine were detected.

(c) The field study provided additional safety information following administration of a single recommended 0.5 mL dose by the subcutaneous route to young rabbits under field conditions. No unexpected adverse reactions or clinically significant safety concerns were identified. The findings were consistent with the laboratory safety and reproductive safety studies and provided confirmation that the vaccine has an acceptable safety profile when used in accordance with the proposed label directions under normal field conditions.

(d) Safety observations and adverse event monitoring undertaken during the pivotal efficacy studies, including studies supporting the onset and duration of immunity claims, were consistent with the findings of the dedicated target animal safety studies. The vaccine was generally well tolerated, and no additional safety concerns were identified.

(e) Safety observations recorded during challenge studies conducted in support of efficacy similarly did not identify any unexpected adverse reactions or evidence of vaccine-associated disease, providing further support for the safety of the vaccine when administered according to the proposed label directions.

(f) Pharmacovigilance data and adverse event reports from overseas commercial use were reviewed as part of the overall weight of evidence. These data did not identify any new or unexpected adverse events beyond those already described on the product label and did not raise any safety concerns that would alter the conclusions of the pre-registration target animal safety studies.

(g) Taken together, the laboratory safety, reproductive safety and field safety studies, together with safety observations from the pivotal efficacy and challenge studies and post-registration pharmacovigilance data, support the conclusion that **Fatrovax RHD Vaccine**

for Rabbits has an acceptable target animal safety profile and can be safely administered to rabbits, including pregnant animals, in accordance with the proposed label directions.

ix. The following statements must be included on the label to mitigate the risks identified:

Precautions

Vaccinate only healthy rabbits.

Use with caution in young animals as the possible interference of Maternally Derived Antibodies cannot be excluded at the recommended age for vaccination.

Use with caution as the effect on reproductive performance in male rabbits was not evaluated.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product should therefore be made on a case-by-case basis.

This product must not be mixed with other veterinary medicinal products.

Side Effects

A small painless palpable nodule (maximum 5.2 mm diameter) may be very commonly observed at the injection site, resolving within 12 days. A transient temperature increase up to 1.65 ° C can very commonly occur in the first week following vaccination.

Overdosage: In dwarf rabbits, small transient nodules at the injection site were commonly noted following administration of a 2X dose that completely disappeared in the first two weeks.

x. On the basis of the submitted target animal safety studies, supporting efficacy studies and post-registration pharmacovigilance data, the APVMA has concluded that **Fatrovax RHD Vaccine for Rabbits** is generally well tolerated and has an acceptable safety profile when administered according to the recommended vaccination schedule and route. Accordingly, the APVMA is satisfied that the proposed use of the product meets the safety criteria in paragraph 5A(1)(c) of the Agvet Code, as it would not be likely to have an unintended effect that is harmful to animals when used in accordance with the proposed label directions.

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

i. In relation to its assessment of efficacy, the APVMA is satisfied that data from trials supporting the efficacy of **Fatrovax RHD Vaccine for Rabbits** adequately demonstrate that, if used according to the product label directions, the product is effective for its proposed uses.

ii. The following information and study reports were provided to support the application:

- Dose determination studies.

- Onset of immunity studies for RHDV1 and RHDV2.
- Duration of immunity studies.
- A study investigating maternally derived antibodies (MDA).
- A scientific justification addressing the relevance of the vaccine antigens to RHDV strains circulating in Australia.

iii. **Australian relevance:** The applicant provided evidence addressing the relevance of RHDV1 and RHDV2 to the Australian situation. Sequence comparison of the RHDV2 VP1ab gene with 176 Australian RHDV2 isolates demonstrated 98.3% to 99.06% identity. The RHDV2 challenge strain Gal08/13 showed 98.37% to 98.91% homology with the same Australian isolates. The assessment concluded that the high homology supports the relevance of the vaccine antigen to Australian circulating strains.

iv. The efficacy studies were assessed against the requirements of Ph. Eur. Monograph 2325, Rabbit Haemorrhagic Disease Vaccine (Inactivated). While the proposed vaccine contains virus-like particles rather than inactivated RHD virus, the monograph was considered appropriate for assessment of efficacy.

v. **Challenge models:** The efficacy studies used RHDV challenge strains Ast89 and Te5/88 and RHDV2 challenge strains Gal08/13 and Ve/2019. The Ast89 strain was isolated in Spain in 1989 and is considered a reference RHDV strain, while Gal08/13 was isolated in Spain in 2013.

vi. **Efficacy parameters:** The efficacy studies assessed virus-neutralising antibody titres, viral load, clinical signs and mortality over the post-challenge observation period. These parameters were considered appropriate for evaluating reduced mortality, infection, clinical signs and organ lesions caused by rabbit haemorrhagic disease and were consistent with Ph. Eur. Monograph 2325.

vii. **Dose determination:** Two dose-determination studies investigated different antigen concentrations and subcutaneous and intradermal administration using RHDV and RHDV2 challenge models. The applicant justified the subcutaneous route as more suitable for young rabbits, and the submitted studies demonstrated efficacy of a formulation containing 5 µg of each antigen against both RHDV and RHDV2.

viii. **Onset of immunity (OOI)**

(a) **RHDV2:** Study 04CO-4LAB1 included 36 unvaccinated 30-day-old New Zealand White rabbits, divided into 3 groups of 12. The group relevant to the proposed use received a single 0.5 mL subcutaneous dose containing 5 µg RHDV1 and 5 µg RHDV2 and was challenged with RHDV2 strain Gal08/13 7 days after vaccination. The vaccinated group had 100% survival compared with 0% survival in the control group, and RHDV2 genome was not detected in liver samples from vaccinated rabbits. The study supported an onset of immunity of 7 days following vaccination against RHDV2.

(b) **RHDV1:** Study 04CO-34LAB2 included 34 unvaccinated New Zealand White rabbits and evaluated efficacy against challenge with RHDV strain Ast89 following a single 0.5 mL subcutaneous vaccination. Two vaccinated groups were included in the study. The first group was vaccinated at 30 days of age and challenged 28 days later, at approximately 58 days of age when rabbits are susceptible to RHDV1 infection. This group demonstrated 100% survival following challenge. The second group was vaccinated at 51 days of age and challenged 7 days later, also at approximately 58 days of age, and demonstrated

91.6% survival (11/12).

Young rabbits exhibit natural resistance to classical RHDV1 infection up to approximately 6–8 weeks of age. Consequently, a challenge conducted 7 days after vaccination in 30-day-old rabbits would not have provided a suitable assessment of vaccine-induced protection. The study instead demonstrated that rabbits vaccinated at the minimum intended age were protected when challenged at a susceptible age and that protective immunity developed within 7 days of vaccination in susceptible rabbits. Collectively, these findings demonstrated the efficacy of the RHDV1 VP1a antigen when administered as a single subcutaneous dose and were considered sufficient to support an onset of immunity of 7 days following vaccination against RHDV1.

(c) **Conclusion:** The efficacy assessment concluded that the available data supported an onset of immunity of 7 days following a single subcutaneous vaccination against both RHDV1 and RHDV2.

ix. **Duration of immunity (DOI)**

(a) Three studies were submitted to investigate duration of immunity. A 6-month challenge study included 46 healthy, unvaccinated New Zealand White rabbits aged 28–29 days. Rabbits received a single 0.5 mL subcutaneous dose of a minimum-release potency batch. At challenge, vaccinated rabbits demonstrated 100% protection against RHDV and 90% protection against RHDV2. The study supported a duration of immunity of 6 months.

(b) A separate longitudinal serology study involving 23 rabbits monitored antibody responses for 12 months. However, because no correlation between the measured ELISA titres and protection against RHDV or RHDV2 was established, this study was not considered supportive by itself of a 12-month duration of immunity.

(c) The pivotal 12-month challenge study involved 44 healthy unvaccinated New Zealand White rabbits aged 28–30 days. Vaccinated rabbits received a single 0.5 mL subcutaneous dose of Fatrovax RHD Vaccine for Rabbits. At 12 months, selected vaccinated and control animals were challenged separately with RHDV2 and RHDV.

(d) Following RHDV2 challenge, vaccinated animals had 90% survival, compared with 100% mortality in controls. Following RHDV challenge, vaccinated animals had 100% survival, compared with 100% mortality in controls. The study demonstrated a 12-month duration of immunity against both RHDV1 and RHDV2.

(e) Overall, the APVMA assessment concluded that a 12-month duration of immunity is supported for both RHDV1 VP1a and RHDV2 VP1ab following a single subcutaneous vaccination.

x. **Maternally derived antibodies (MDA)**

(a) One study involving 150 rabbits aged 32–34 days at vaccination was submitted to evaluate interference from maternally derived antibodies. However, only a maximum of approximately one-third of animals expected to have maternal antibodies had detectable antibodies when tested one week before vaccination, and the presence of MDA was not established at the actual time of vaccination.

(b) The assessment therefore concluded that the study did not demonstrate efficacy in the presence of maternally derived antibodies, and possible MDA interference cannot be excluded at the recommended age for vaccination. This limitation will be reflected in the product label.

xi. **Interactions with other immunobiologicals:** No studies were submitted to investigate the safety or efficacy of Fatrovax RHD Vaccine for Rabbits when administered concurrently or mixed with other veterinary immunological products. Therefore, no conclusions can be drawn regarding the safety or efficacy of concomitant use with other veterinary immunological products.

xii. **Field studies and pharmacovigilance**

(a) No field efficacy studies were submitted. Reliance on laboratory efficacy studies without field efficacy data was considered acceptable where the product is restricted to **companion animals only,** supplemented by overseas pharmacovigilance information.

(b) Pharmacovigilance information was provided for several periods following overseas registration, with no suspected adverse reactions reported in the data reviewed. These post-registration data provided additional support for the overall weight of evidence, did not identify any new or unexpected adverse events beyond those already described on the product label, and did not raise any safety concerns that would alter the conclusions of the pre-registration target animal safety studies.

xiii. **Overall conclusion on efficacy and label claims**

(a) The submitted studies support the efficacy of the RHDV1 VP1a and RHDV2 VP1ab antigens against RHDV strains relevant to Australia.

i. An **onset of immunity of 7 days** following a single subcutaneous vaccination is supported.

ii. A **duration of immunity of 12 months** is supported against both RHDV1 and RHDV2.

iii. The possible interference of maternally derived antibodies **cannot be excluded** at the recommended age for vaccination.

iv. In the absence of field efficacy studies, the assessment supports use of the product in **companion rabbits only**.

xiv. To mitigate the identified risks and address the data limitations discussed above, the following directions for use statements must be included on the product label:

Claims
For active immunisation of companion rabbits from the age of 30 days to reduce mortality, infection, clinical signs and organ lesions of rabbit haemorrhagic disease caused by RHDV1 and RHDV2.

Onset of immunity: 1 week (7 days) after vaccination.
Duration of immunity: 1 year.

Dosage and Administration
For use by or under the direction of a veterinarian.

Before use allow the vaccine to reach room temperature (15°C – 25°C).

Shake well before use to resuspend the sediment.

Use immediately after broaching.

Administer one 0.5 mL dose by subcutaneous injection.

Vaccination schedule: Administer the first dose (0.5 mL) at 30 days of age.
Revaccination: every 12 months.

Vaccination using the single-dose presentation (0.5 mL)
The pre-filled glass syringes needs to be attached to the needle included in the packaging.
Administer one dose by subcutaneous injection.

Vaccination using multi-dose presentations (50 doses (25 mL) or 200 doses (100 mL))
Administer one dose of 0.5 ml per animal by subcutaneous injection.

General Directions
Fatrovax is intended to stimulate active immunity against Rabbit Haemorrhagic Disease Virus (RHDV; classical strain) and Rabbit Haemorrhagic Disease Virus 2 (RHDV2; variant strain).

The active substances of the vaccine are 2 recombinant proteins: Rabbit Haemorrhagic Disease Virus VP1a (capsid protein VP1 and VP2 of strain Ast89) and Rabbit Haemorrhagic Disease Virus 2 VP1ab (chimera of strains Ast89 and N11), that auto-assemble into Virus-Like Particles (VLPs).

xv. On the basis of the submitted efficacy studies, supporting scientific justification addressing Australian relevance and post-registration information, the APVMA is satisfied that **Fatrovax RHD Vaccine for Rabbits** meets the efficacy criteria in section 5B of the Agvet Code. The APVMA has concluded that the product would be effective for the active immunisation of companion rabbits from 30 days of age to reduce mortality, infection, clinical signs and organ lesions of rabbit haemorrhagic disease caused by RHDV1 and RHDV2, with an onset of immunity of 7 days and a duration of immunity of 1 year when used in accordance with the proposed label directions.

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

i. The APVMA is satisfied that the proposed use of **Fatrovax RHD Vaccine for Rabbits** would not adversely affect trade between Australia and places outside Australia, as the assessment supports use of the product in companion rabbits only.

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **Recombinant Rabbit Haemorrhagic Disease virus 1 (RHDV1) VP1a virus-like particles** and **Recombinant Rabbit Haemorrhagic Disease Virus type 2 (RHDV2) VP1ab virus-like particles** should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based. The technical report confirms that approval is sought for both new active constituents.

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

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

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

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

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

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

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

Email: casemanagement@apvma.gov.au

Post:

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

Privacy

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

Agvet chemical voluntary recall: Linco-Spec Injection

Product name: Linco-Spec Injection

APVMA registration number: 86913

APVMA approved label number: 117018

Batch numbers: VLS9335, VLS9460, VLS9730, VLS9844, VLS9907

Sold by: Veterinary retailers/wholesalers nationally between 18 February 2020 to 21 October 2026

On 21 October 2026, Abbey Laboratories Pty Ltd (ABN: 96 156 000 430) 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 voluntary recall has been initiated as the product from above-mentioned batches has been identified as with low active potency/efficacy than the APVMA-approved release specification.

Hazard

Animals treated at the label dose will receive less active than intended. This may result in reduced efficacy or treatment failure.

What to do if in possession of this chemical product

Cease use of Linco-Spec Injection from above-mentioned batches immediately. Quarantine all the stock on hand of the recalled product and contact Abbey Laboratories to arrange return and credit.

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:

Abbey Laboratories

Phone: (02) 8088 0720
Email: anitha.l@abbeylabs.com.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 11:

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

Approval or registration number	Name	Type of approval or registration	Holder	Reason for cancellation (if relevant pursuant to s45A(3))	Date of cancellation
44090	Metribuzin	Active	Bayer Crop Science Pty Ltd	Not applicable	26 October 2026
61231	Flubendiamide	Active	Bayer Crop Science Pty Ltd	Not applicable	26 October 2026

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

Instructions

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

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

Possession or custody

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

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 11 according to its label instructions, including any conditions relating to shelf life or expiry date, for one year 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 11, for one year after the date of cancellation.

Contraventions

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

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

APVMA contact

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

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

More information

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