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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

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Agricultural chemical products and approved labels

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

Table 1: Agricultural products based on existing active constituents

Application no.	145702
Product name	Golden Farmstead Glufosinate 200 Herbicide
Active constituent	200 g/L glufosinate-ammonium
Applicant name	Golden Farmstead Pty Ltd
Applicant ACN	675 182 484
Date of registration	14 January 2025
Product registration no.	95446
Label approval no.	95446/145702
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L glufosinate-ammonium soluble concentrate (SL) for the non-residual control of broadleaf and grass weeds in various situations

Application no.	135426
Product name	Menno Florades Disinfectant
Active constituent	90 g/L benzoic acid
Applicant name	Menno Chemie-Vertrieb GMBH
Applicant ACN	N/A
Date of registration	14 January 2025
Product registration no.	92415
Label approval no.	92415/135426
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 90 g/L benzoic acid in a soluble concentrate (SL) formulation for use as a hard surface and tool disinfectant in agricultural and horticultural situations against fungi (including spore forms), bacteria, viruses and viroid’s

Application no.	141714
Product name	Tanalith Eμ 26 Wood Preservative Concentrate
Active constituents	390 g/L copper (Cu) present as copper carbonate, 15.6 g/L tebuconazole
Applicant name	Arch Wood Protection (Aust) Pty Limited
Applicant ACN	003 780 872
Date of registration	15 January 2025
Product registration no.	94157
Label approval no.	94157/141714
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 390 g/L copper (present as 696 g/L copper carbonate), and 15.6 L tebuconazole suspension concentrate (SC) wood preservative for the protection against fungal decay, powder beetles, furniture beetles and termites

Application no.	146318
Product name	Agro-Essence Clopyralid 600 Herbicide
Active constituent	600 g/L clopyralid present as the acid and triisopropanolamine salt
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	15 January 2025
Product registration no.	95549
Label approval no.	95549/146318
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L clopyralid, present as the acid and triisopropanolamine salt, soluble concentrate product, for the control of broadleaf weeds in wheat, barley, triticale, oats, pastures, canola, fallow land, forests and industrial situations

Application no.	145924
Product name	Sabakem Propiconazole 550
Active constituent	550 g/L propiconazole
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of registration	16 January 2025
Product registration no.	95516
Label approval no.	95516/145924
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new agricultural product containing 550 g/L propiconazole for the control of certain fungal diseases of bananas, oats, peanuts, perennial ryegrass, pineapples, stone fruit, sugar cane, wheat and other crops in certain states as specified in the directions for use, and for the control of dollar spot in bent and Queensland blue couch, and spring dead spot in couch as specified in the directions for use for turf

Application no.	146316
Product name	ProForce Pistol 600 Fungicide
Active constituent	600 g/L thiram
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	16 January 2025
Product registration no.	95548
Label approval no.	95548/146316
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L thiram suspension concentrate product for the control of fungal diseases of turf and seed treatment

Application no.	146551
Product name	Imtrade Militia 550 SC Miticide
Active constituent	550 g/L fenbutatin oxide
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	17 January 2025
Product registration no.	95629
Label approval no.	95629/146551
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 550 g/L fenbutatin oxide suspension concentrate product for the control of certain mites in fruit, hops and ornamentals as specified in the directions for use table

Application no.	139970
Product name	SALTRO Pro Fungicide Seed Treatment
Active constituents	200 g/L pydiflumetofen, 75 g/L metalaxyl-M, 25 g/L fludioxonil
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of registration	17 January 2025
Product registration no.	93620
Label approval no.	93620/139970
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L pydiflumetofen, 75 g/L metalaxyl-M and 25 g/L fludioxonil suspension concentrate for seed treatment (FS) product for use against blackleg and downy mildew canola

Application no.	140816
Product name	BARRICADE Pre-Emergent Herbicide HG
Active constituent	480 g/L prodiamine
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of registration	17 January 2025
Product registration no.	93901
Label approval no.	93901/140816
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L prodiamine suspension concentrate product for control of grass and some broadleaf weeds prior to germination in established lawns and turf, garden beds and potted plants in the home garden

Application no.	145721
Product name	Smart Fluroxypyr EC 400 Herbicide
Active constituent	400 g/L fluroxypyr (present as the methyl heptyl ester)
Applicant name	Crop Smart Pty Ltd
Applicant ACN	093 927 961
Date of registration	20 January 2025
Product registration no.	95456
Label approval no.	95456/145721
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 400 g/L fluroxypyr (present as the methyl heptyl ester) emulsifiable concentrate (EC) product for the control of broadleaf weeds in fallow, lucerne, maize, millets, pastures, sorghum, sugar cane, sweet corn, winter cereals and woody weeds in agricultural non-crop areas, commercial and industrial areas, pastures, and rights-of-way

Application no.	141712
Product name	X-Pand Gibberellic Acid Growth Regulant
Active constituent	133 g/L gibberellic acid
Applicant name	Stoller Australia Pty. Limited
Applicant ACN	065 320 747
Date of registration	20 January 2025
Product registration no.	94155
Label approval no.	94155/141712
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 133 g/L gibberrellic acid soluble concentrate for foliar spray application to certain varieties of grapes, citrus and prunes to promote desirable harvest effects and to stimulate production of winter dormant grass-dominant pastures for high intensity grazing such as dairy pasture or sheep lambing paddocks

Application no.	143762
Product name	Albaugh TRAPIS 500 WG Herbicide
Active constituent	500 g/kg flumioxazin
Applicant name	Albaugh Australia Pty Ltd
Applicant ACN	676 890 994
Date of registration	21 January 2025
Product registration no.	94820
Label approval no.	94820/143762
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/kg flumioxazin, water dispersible granule product for pre-emergent weed control in wheat, faba bean, chickpea, field pea, along fence lines and non-crop boundary areas; and to improve brown-out and weed control with knockdown herbicides

Application no.	146525
Product name	Quantum Glyphosate 450 SL Herbicide
Active constituent	450 g/L glyphosate present as the isopropylamine salt
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of registration	22 January 2025
Product registration no.	95615
Label approval no.	95615/146525
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 450 g/L glyphosate soluble concentrate product for use as a non-selective herbicide for the control of a wide range of annual, perennial, and woody weeds as per the directions for use

Application no.	146397
Product name	F.S.A. Mantis Herbicide
Active constituents	90 g/L mefenpyr-diethyl, 30 g/L mesosulfuron-methyl
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	23 January 2025
Product registration no.	95573
Label approval no.	95573/146397
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 30 g/L mesosulfuron-methyl and 90 g/L mefenpyrdiethyl oil-based suspension concentrate for the post-emergent control of wild oats and annual Phalaris, and suppression of brome grass, barley grass and annual ryegrass in wheat, as per the directions for use table

Application no.	145284
Product name	Genfarm Fludi-Cyprodinil WG Fungicide
Active constituents	375 g/kg cyprodinil, 250 g/kg fludioxonil
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	23 January 2025
Product registration no.	95320
Label approval no.	95320/145284
Description of the application and its purpose, including the intended use of the chemical product	Registration of a water dispersible granule (WG) fungicide containing 375 g/kg cyprodinil and 250 g/kg fludioxonil for the control of various fungal diseases in alliums, apples, capsicum, cucumber, cut flowers, garlic, grapes, green beans, green peas, leafy vegetables, lettuce, nursery stock, ornamentals, pyrethrum and strawberries

Application no.	144555
Product name	Imtrade Sheriff Veriphy EC Herbicide
Active constituents	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	24 January 2025
Product registration no.	95048
Label approval no.	95048/144555
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 25 g/L cloquintocet-mexyl and 100 g/L pinoxaden emulsifiable concentrate product for the control of key grass weeds and selective spray topping of wild oats in wheat and barley as specified in the directions for use table

Table 2: Variations of registration – agricultural chemical products

Application no.	147022
Product name	Grazon Extra Herbicide
Active constituents	300 g/L triclopyr present as the butoxyethyl ester, 100 g/L picloram present as the hexyloxypropylamine salt, 8 g/L aminopyralid present as hexyloxypropylamine salt
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	3 January 2024
Product registration no.	60830
Label approval no.	60830/147022
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 remove uses for controlled droplet application (CDA) and high volume low concentrate (HVLC) application from the instructions. To update the safety directions in line with the current FAISD Handbook

Application no.	147071
Product name	Kelpie PROSULF 800 Herbicide
Active constituent	800 g/L prosulfocarb
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	9 January 2025
Product registration no.	86887
Label approval no.	86887/147071
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 'Ezycrop Prosulfocarb 800 Herbicide' to 'Kelpie PROSULF 800 Herbicide'

Application no.	145590
Product name	Farmalinx Swysh 400 EC Herbicide
Active constituent	400 g/L fluroxypyr present as the methyl heptyl ester
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	13 January 2025
Product registration no.	89664
Label approval no.	89664/145590
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of product registration and label approval to increase the range of packs to include a 1000 L

Application no.	141574
Product name	HITMAN Organic Insecticide & Fungicide
Active constituent	285 g/L potassium salts of fatty acids
Applicant name	Victorian Chemical Company Proprietary Limited
Applicant ACN	004 188 863
Date of variation	13 January 2025
Product registration no.	58472
Label approval no.	58472/141574
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars, to include suppression of botrytis in grapevines

Application no.	147098
Product name	TrikoPik HERBICIDE
Active constituents	300 g/L triclopyr present as the butoxyethyl ester, 100 g/L picloram present as hexyloxypropylamine salt
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	13 January 2025
Product registration no.	69378
Label approval no.	69378/147098
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 'Rainbow Triclopyr/Picloram Herbicide' to 'TrikoPik HERBICIDE'

Application no.	142387
Product name	Termidor Residual Termiticide and Insecticide
Active constituent	100 g/L fipronil
Applicant name	BASF Australia Ltd.
Applicant ACN	008 437 867
Date of variation	14 January 2025
Product registration no.	54624
Label approval no.	54624/142387
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of label, to vary product registration and label approval to include a rate range for specific pests

Application no.	142680
Product name	Titan Butafenacil 200 EC Herbicide
Active constituents	200 g/L butafenacil
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	14 January 2025
Product registration no.	90360
Label approval no.	90360/142680
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label to add uses for the control of a range of grass and broadleaf weeds in fallow or prior to the establishment of cereals, canola and pulses

Application no.	142606
Product name	Roadblock Spider & Ant Automotive Treatment
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 variation	14 January 2025
Product registration no.	92950
Label approval no.	92950/142606
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label to add claims for control of cockroaches and other ants

Application no.	147107
Product name	Ant and Roach Gel
Active constituent	0.6 g/kg fipronil
Applicant name	Lifeguard Sciences (Pty) Ltd
Applicant ACN	N/A
Date of variation	14 January 2025
Product registration no.	90826
Label approval no.	90826/147107
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 ‘Ant and cockroach bait syringe’ to ‘Ant and Roach Gel’

Application no.	147111
Product name	Kingstar 250 Fungicide
Active constituent	250 g/L azoxystrobin
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	14 January 2025
Product registration no.	67741
Label approval no.	67741/147111
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 ‘Rainbow Azoxystrobin 250 SC’ to ‘Kingstar 250 Fungicide’

Application no.	145548
Product name	Foison Clopyralid 300 SL Herbicide
Active constituent	300 g/L clopyralid present as the triisopropanolamine salt
Applicant name	Foison Scitech Co., Limited
Applicant ACN	N/A
Date of variation	16 January 2025
Product registration no.	89077
Label approval no.	89077/145548
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to amend the pack size

Application no.	147138
Product name	Abamite Insecticide / Miticide
Active constituent	18 g/L abamectin
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	16 January 2025
Product registration no.	65750
Label approval no.	65750/147138
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 ‘Rainbow Abamectin Insecticide / Miticide’ to ‘Abamite Insecticide / Miticide’

Application no.	145735
Product name	Titan Abamectin 18 Insecticide/Miticide
Active constituents	18 g/L abamectin
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	20 January 2025
Product registration no.	65889
Label approval no.	65889/145735
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label approval to correct the erroneous rate on citrus for control of mites

Application no.	145575
Product name	Glufonium 200 SL Herbicide
Active constituent	200 g/L glufosinate-ammonium
Applicant name	Sinon Australia Pty Limited
Applicant ACN	102 741 024
Date of variation	20 January 2025
Product registration no.	83334
Label approval no.	83334/145575
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label approval to add uses in blueberries, black currant, beans, pyrethrum, duboisia, date palms, green tea, native foods, sugarcane, fence lines, summer fallows, oil tea tree, nursery stock, foliage and cut flowers

Application no.	145552
Product name	Ultraphos Phosphine Fumigant
Active constituents	990 g/kg phosphine
Applicant name	Specialty Gases Pty Ltd
Applicant ACN	161 156 403
Date of variation	21 January 2025
Product registration no.	68499
Label approval no.	68499/145552
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add a commodities column, increase the maximum application rate for certain pests and situations, as well as updating the restraints, general instructions, precautions, and storage and disposal sections

Application no.	145555
Product name	Globachem Abamectin 18 EC Insecticide
Active constituent	18 g/L abamectin
Applicant name	Globachem n.v.
Applicant ACN	N/A
Date of variation	21 January 2025
Product registration no.	94817
Label approval no.	94817/145555
Description of the application and its purpose, including the intended use of the chemical product	Variation to correct the rate in the control of mites in citrus to be 250 mL summer oil per 100 L

Application no.	147165
Product name	Yates Organic Garden Pest Killer
Active constituent	400 g/L Clitoria ternatea extract
Applicant name	DuluxGroup (Australia) Pty Ltd
Applicant ACN	000 049 427
Date of variation	21 January 2025
Product registration no.	94412
Label approval no.	94412/147165
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 'Yates Nature's Way Bee Safe Pest Control Multi-purpose' to Yates Organic Garden Pest Killer'

Application no.	143712
Product name	Mateno Complete Herbicide
Active constituents	400 g/L aclonifen, 100 g/L pyroxasulfone, 66 g/L diflufenican
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of variation	23 January 2025
Product registration no.	89959
Label approval no.	89959/143712
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, and particulars of label, to update the safety directions

Application no.	N/A – variation under section 29A of the AgVet Code
Product name	Dual Gold Herbicide
Active constituent	960 g/L S-metolachlor
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	23 January 2025
Product registration no.	50477
Label approval no.	50477/133889
Description of the application and its purpose, including the intended use of the chemical product	Variation of label particulars only to remove hydrocarbon solvent statements

Application no.	145634
Product name	Accensi Triadimenol 150 C Flowable Seed Dressing
Active constituents	150 g/L triadimenol, 4 g/L cypermethrin
Applicant name	Australian Agribusiness (Holdings) Pty Ltd
Applicant ACN	135 355 958
Date of variation	24 January 2025
Product registration no.	63620
Label approval no.	63620/145634
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and label to extend net contents up to 1000 L

Application no.	145551
Product name	Sabakem Prazon 400EC Selective Herbicide
Active constituent	300 g/L triclopyr present as the butoxyethyl ester, 100 g/L picloram present as the hexyloxypropylamine salt
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of variation	24 January 2025
Product registration no.	69889
Label approval no.	69889/145551
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add a new pack size

Table 3: Label approval – agricultural chemical products

Application no.	146574
Product name	Farmalinx Scanner 500 SC Herbicide
Active constituent	500 g/L ethofumesate
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	21 January 2025
Product registration no.	69025
Label approval no.	69025/146574
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the registered product ‘Farmalinx Scanner 500 SC Herbicide’ with the label name ‘ProForce Array 500 SC Herbicide’

Application no.	146407
Product name	Farmalinx Aqua-Noxy Herbicide
Active constituent	300 g/L 2,4-D
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	21 January 2025
Product registration no.	95228
Label approval no.	95228/146407
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Farmalinx Aqua-Noxy Herbicide' with the label name 'ProForce Scuba 300 Herbicide'

Application no.	146432
Product name	Farmalinx Abazine Miticide
Active constituents	187.5 g/L clofentezine, 18 g/L abamectin
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	21 January 2025
Product registration no.	87784
Label approval no.	87784/146432
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Farmalinx Abazine Miticide' with the label name 'Novagreen Pursuit Miticide'

Veterinary chemical products and approved labels

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

Table 4: Veterinary products based on existing active constituents

Application no.	145563
Product name	Headway Selamectin Spot-On for Cats
Active constituent	60 mg/mL selamectin
Applicant name	Headway Investments Pty Ltd
Applicant ACN	655 095 855
Date of registration	13 January 2025
Product registration no.	95417
Label approval no.	95417/145563
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 60 mg/mL selamectin spot on product for cats and rabbits

Application no.	145718
Product name	VETSENSE Abamec LV Pour-On for Cattle
Active constituent	10 g/L abamectin
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of registration	22 January 2025
Product registration no.	95453
Label approval no.	95453/145718
Description of the application and its purpose, including the intended use of the chemical product	Registration of a pour-on solution of 10 g/L abamectin for the treatment and control of abamectin sensitive internal and external parasites of beef and dairy cattle

Table 5: Variations of registration – veterinary chemical products

Application no.	145573
Product name	Ketoprofen V Injection for Cattle and Horses
Active constituent	100 mg/mL ketoprofen
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of variation	20 January 2025
Product registration no.	82151
Label approval no.	82151/145573
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the product registration and label approval by aligning the label with the Veterinary Labelling Code

Approved active constituents

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

Table 6: Approved active constituents

Application no.	136530
Active constituent	Palmitoylethanolamide manufacturing concentrate
Applicant name	Pharmako Biotechnologies Pty Limited
Applicant ACN	605 139 688
Date of approval	15 January 2025
Approval no.	92752
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent palmitoylethanolamide manufacturing concentrate for use in veterinary chemical products

Application no.	144641
Active constituent	Aluminium phosphide
Applicant name	National Fumigants Pty Ltd
Applicant ACN	090 505 785
Date of approval	15 January 2025
Approval no.	95091
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent aluminium phosphide for use in agricultural chemical products

Application no.	142951
Active constituent	Copper pyrithione
Applicant name	Kolon Life Science, Inc
Applicant ACN	N/A
Date of approval	16 January 2025
Approval no.	94615
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent copper pyrithione for use in agricultural chemical products

Application no.	144835
Active constituent	Fluopyram
Applicant name	Thai Harvest Limited
Applicant ACN	N/A
Date of approval	20 January 2025
Approval no.	95163
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.	145373
Active constituent	Levamisole hydrochloride
Applicant name	Aura Laboratories Limited
Applicant ACN	N/A
Date of approval	20 January 2025
Approval no.	95367
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent levamisole hydrochloride for use in veterinary chemical products

Application no.	143952
Active constituent	Pentobarbital sodium
Applicant name	Probus Pharmaceuticals Pty Ltd
Applicant ACN	638 193 674
Date of approval	21 January 2025
Approval no.	94888
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pentobarbital sodium for use in veterinary chemical products

Application no.	145374
Active constituent	Oxyclozanide
Applicant name	Aura Laboratories Limited
Applicant ACN	N/A
Date of approval	21 January 2025
Approval no.	95368
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent oxyclozanide for use in veterinary chemical products

Application no.	142930
Active constituent	Doramectin
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of approval	22 January 2025
Approval no.	94604
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent doramectin for use in veterinary chemical products

Application no.	144399
Active constituent	Chlorantraniliprole
Applicant name	Agoceania Pty Ltd
Applicant ACN	649 344 141
Date of approval	22 January 2025
Approval no.	94988
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlorantraniliprole for use in agricultural chemical products

Application no.	144896
Active constituent	Bixafen
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of approval	22 January 2025
Approval no.	95195
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bixafen for use in agricultural chemical products

Application no.	144976
Active constituent	Topramezone
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	22 January 2025
Approval no.	95206
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent topramezone for use in agricultural chemical products

Application no.	144423
Active constituent	Hydrocortisone aceponate
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of approval	23 January 2025
Approval no.	94999
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent hydrocortisone aceponate for use in veterinary chemical products

Application no.	144781
Active constituent	Florasulam
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of approval	24 January 2025
Approval no.	95138
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent florasulam for use in agricultural chemical products

Application no.	145757
Active constituent	Hydroxocobalamin acetate
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of approval	24 January 2025
Approval no.	95470
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent hydroxocobalamin acetate for use in veterinary chemical products

Table 7: Variations of active constituent

Application no.	145644
Active constituent	Clenbuterol hydrochloride
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	21 January 2025
Approval no.	83441
Description of the application and its purpose, including the intended use of the active constituent	Variation to remove a manufacturing site for the existing approval

Application no.	145733
Active constituent	Meloxicam
Applicant name	Le Vet Beheer B. V.
Applicant ACN	N/A
Date of variation	23 January 2025
Approval no.	87888
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars of an approved active constituent

New veterinary chemical products containing a new veterinary active constituent

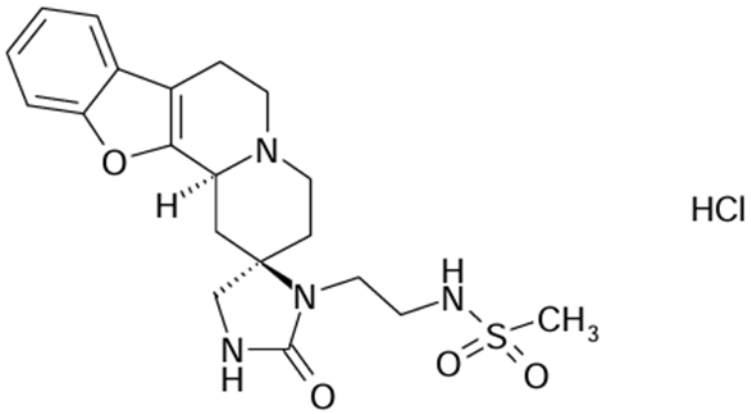
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the registration of a new product, *Zenalpha Injection for Dogs*, containing a new active constituent, vatinoxan hydrochloride and an existing active constituent, medetomidine hydrochloride.

Dechra Regulatory B.V. is seeking the registration of the *Zenalpha Injection for Dogs* containing 10 mg/mL vatinoxan hydrochloride and 0.5 mg/mL medetomidine hydrochloride for use as a sedative and analgesic in dogs, in conjunction with approval of vatinoxan hydrochloride as a new active constituent and new sources of an existing active constituent medetomidine hydrochloride.

Vatinoxan hydrochloride

As part of the application to register the product containing vatinoxan hydrochloride, the APVMA has evaluated the safety of the new active constituent, vatinoxan hydrochloride.

Table 8: Particulars of the active constituent

Common name	Vatinoxan hydrochloride
IUPAC name	N-[2-[(2R,12bS)-2'-oxospiro[1,3,4,6,7,12b-hexahydro-[1]benzofuro[2,3-a]quinolizine-2,5'-imidazolidine]-1'-yl]ethyl]methanesulfonamide;hydrochloride
CAS name	N-(2-((2R,12bS)-2'-oxo-1,3,4,6,7,12b-hexahydrospiro[benzofuro[2,3-a] quinolizine-2,4'-imidazolidine]-3'-yl) ethyl) methane sulfonamide hydrochloride
CAS registry number	130466-38-5
Manufacturer's codes	T1146, Periati HCl
Purity	98.0-102.0% (anhydrous basis)
Molecular formula	$C_{20}H_{26}N_4O_4S$, HCl
Molecular weight	454.97 g/mol
Structure	
Mode of action	A peripherally selective α2-adrenoceptor antagonist which attaches to and blocks α2-adrenoceptors in the heart and blood vessels

Summary of the APVMA's evaluation of vatinoxan hydrochloride active constituent

The APVMA has evaluated the chemistry aspects of vatinoxan hydrochloride (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, batch analysis results, and analytical methods) and found them to be acceptable.

The APVMA has considered the toxicological aspects of vatinoxan hydrochloride and concluded that there are no toxicological concerns regarding the approval of this active constituent. Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) is required because the active constituent is not proposed for use in food-producing animals. No impurities of toxicological concern were identified in the health assessment.

As a proposed prescription veterinary medicine, vatinoxan hydrochloride has been included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The APVMA proposes to be satisfied under sections 5A(1)(a),(b) and (c) of the Agvet Code that vatinoxan hydrochloride 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, or things, or to the environment.

Zenalpha Injection for Dogs, containing a new active constituent, vatinoxan hydrochloride and an existing active constituent medetomidine hydrochloride.

In addition to the application to approve the new active constituent vatinoxan hydrochloride, the APVMA has under consideration an application to register a new product *Zenalpha Injection for Dogs*, a sedative and analgesic in dogs to facilitate clinical examinations, clinical procedures, and minor surgical procedures, containing the new active constituent, vatinoxan hydrochloride and an existing active constituent medetomidine hydrochloride.

Table 9: Particulars of the product/s

Proposed product name/s	Zenalpha Injection for Dogs
Applicant company	DECHRA REGULATORY B.V.
Name of active constituents	Vatinoxan hydrochloride Medetomidine hydrochloride
Signal heading	Schedule 4
Summary of proposed use	A sedative and analgesic in dogs to facilitate clinical examinations, clinical procedures, and minor surgical procedures. The product is for use by veterinarians and will be administered by intramuscular injection at a dose of 1 mg medetomidine hydrochloride and 20 mg vatinoxan hydrochloride (equivalent to 2 mL solution) per square metre of body surface area.
Pack sizes	10 mL
Withholding period	n/a

A summary of the APVMA's evaluation of *Zenalpha Injection for Dogs* 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 *Zenalpha Injection for Dogs* would not be an **undue hazard to the safety of people** exposed to it during its handling and use.

   a. The product is intended to be used as a sedative and analgesic in dogs to facilitate clinical examinations, clinical procedures, and minor surgical procedures.

   b. To support the approval of the new active constituent and registration of the proposed product, supporting documentation were submitted consisting of unpublished and published studies on vatinoxan, medetomidine/dexmedetomidine or various combinations of these actives, including published summary reports from the European Medicines Agency (EMA). The APVMA sourced additional information including published summary reports from the European Chemicals Agency (ECHA), EMA and the US Food and Drug Administration (FDA).

   c. The applicant submitted three acute toxicity studies on vatinoxan: one by the oral route (rat) and two by the intravenous route (mouse and rat). Vatinoxan has low acute oral toxicity in the rat.

   d. In a 28-day repeat dose dietary study in rats with vatinoxan, the key adverse effect observed was soft stools in male rats at 60 mg/kg bw/d. The No Observed Adverse Effect Level (NOAEL) was 20 mg/kg bw/d. No neurotoxicity, immunotoxicity, developmental, reproductive or carcinogenicity studies were provided. The justification provided for these data gaps is based on the proposed single dose use in animals; no proposed use in food-producing animals; and the known developmental and reproductive toxicity effects of the second active constituent (medetomidine) in the product. The draft label includes a warning that safety has not been

established in dogs during pregnancy or lactation, however similar warning is required for the workers administering the product. Vatinoxan hydrochloride was non-genotoxic in *in vitro* and *in vivo* studies.

e. Acute skin and eye irritation studies and a skin sensitisation study were submitted for a developmental formulation containing 0.5 mg/mL medetomidine and 15 mg/mL vatinoxan (1:30). The APVMA also estimated the acute toxicity of *Zenalpha Injection for Dogs* (0.5 mg/mL medetomidine and 10 mg/mL vatinoxan, 1:20) based on the ingredients in the formulation. Overall, based on the information provided and mixture estimates, *Zenalpha Injection for Dogs* is considered to have low acute oral, dermal and inhalation toxicity. It is likely to be a slight skin and eye irritant but not a skin sensitiser therefore, appropriate safety directions are required on the label.

f. A semi-quantitative/qualitative assessment of the risks of accidental exposure via accidental self-injection (considered worst case) was undertaken. This was compared to both the applicant's and EMA's risk assessments. Although conservative accidental exposure levels are calculated to be higher than doses which do not result in adverse or pharmacological effects in humans, the risk can be mitigated by label directions, along with an understanding of the low probability of exposure from prescribed professional use and short duration of action of the pharmacological effects. It is also noted that the risks from medetomidine exposure from *Zenalpha Injection for Dogs* are no greater than currently registered veterinary medicines containing medetomidine or dexmedetomidine.

g. To mitigate potential risks involving human exposure, the following signal headings, first aid instructions, and safety directions statements are to appear on the product label.

Poisons Standard and Signal Heading

Medetomidine hydrochloride is listed in **Schedule 4** of the SUSMP with no exceptions. Vatinoxan hydrochloride was not listed in the SUSMP. For the purpose of registration of *Zenalpha Injection for Dogs* for use as a veterinary sedative and analgesic, the APVMA's proposal was considered and approved that vatinoxan hydrochloride to be listed in **Schedule 4** of the SUSMP, based on its use and toxicological profile. The Schedule 4 Poison thereby requires '**PRESCRIPTION ANIMAL REMEDY'** and '**KEEP OUT OF REACH OF CHILDREN**' signal headers on the label.

First aid instructions (FAI)

'If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766.'

Safety directions

'May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.'

The safety directions will be listed in the FAISD handbook - APVMA 2025 (Handbook of first aid instructions, safety directions, warning statements and general safety precautions for agricultural and veterinary chemicals) and will be required on the product label.

Additional user safety

'Avoid accidental self-injection, or skin, eye, or mucosal contact. Accidental exposure may cause sedation and changes in blood pressure.

In case of accidental self-injection or ingestion, seek medical advice immediately and show the product leaflet or packaging to the doctor. DO NOT DRIVE.

In case of skin or mucosal contact, wash the area thoroughly with water and remove contaminated clothing. If in eyes, wash out immediately with water. If symptoms occur, contact a doctor.

Pregnant women should exercise special caution to avoid exposure. Uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Notes to doctor: The veterinary product contains medetomidine, an alpha-2 adrenoceptor agonist, in combination with vatinoxan, a peripherally selective alpha-2 adrenoceptor antagonist. Symptoms after absorption may include dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia.'

Warning Statements

None. See Additional User Safety for other statements.

Restraints/Restrictions

DO NOT USE in food producing species of animals.

Re-entry or Re-handling Statement

Not required.

h. After consideration of the toxicological profile and likely human exposure associated with the use of *Zenalpha Injection for Dogs*, the APVMA concludes that the human health risks are acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994 as amended) for the proposed administration method, provided the recommendations are noted and where relevant, incorporated on the product label, as above.

ii. The APVMA is satisfied that the proposed use of *Zenalpha Injection for Dogs*, containing a new active constituent, vatinoxan hydrochloride and an existing active constituent medetomidine hydrochloride would not be likely to have an unintended effect that is harmful to **the environment,** if used according to the product label directions.

a. It is assumed that assessments of veterinary medicinal products that end at VICH Phase-I will have limited use and limited environmental exposure and consequently have limited environmental effects. *Zenalpha Injection for Dogs* will only be used in non-food animals (dogs) and therefore the assessment ends at Phase I. The APVMA is therefore satisfied that environmental risks of the proposed use of *Zenalpha Injection for Dogs* are acceptable.

b. Based on the outcome of this assessment, no environmental protection statements are required. The following disposal statement is recommended as per the Vet Labelling Code.

DISPOSAL

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

iii. The APVMA is satisfied that the proposed use of *Zenalpha Injection for Dogs*, containing a new active constituent, vatinoxan hydrochloride and an existing active constituent medetomidine hydrochloride would **not be likely to have an unintended effect that is harmful to the target animals** if used according to the product label directions.

a. The submission comprised of a range of laboratory model, pharmacological, dose determination, dose confirmation, margin of safety – dose rate studies and confirmatory field/clinical trials.

b. *Zenalpha* contains two actives, medetomidine hydrochloride (0.5 mg/mL), an alpha (α)2- adrenoreceptor agonist, and vatinoxan hydrochloride (10 mg/mL), an α2- adrenoreceptor antagonist. Medetomidine is a commonly used sedative in veterinary species, while vatinoxan blocks the peripherally-induced adverse effects of medetomidine while not affecting the centrally mediated sedation since it does not cross the blood brain barrier.

c. A study was undertaken to investigate cardiac output and the cardiovascular effects of medetomidine hydrochloride 0.5 mg/mL, vatinoxan hydrochloride 10 mg/mL (dose rate 1 mg/m^2 medetomidine and 20 mg/m^2 vatinoxan intramuscular (IM) or medetomidine (1 mg/m^2) alone in dogs. The dose rate and the method of administration were consistent with the recommendations for the proposed use of Zenalpha. The dogs were monitored for Heart Rate (HR), Cardiac Output (CO), Cardiac Index (CI), Stroke Volume

(SV), Stroke Volume Index (SVI), left ventricular rate pressure product, systemic vascular resistance (SVR) index, oxygen delivery, oxygen consumption and oxygen extraction. Medetomidine and vatinoxan had better cardiovascular parameters than medetomidine alone demonstrating the *Zenalpha* combination to be safer.

d. A study with instrumented dogs to measure blood pressures (BP), heart rate (HR), respiratory rate (RR) and electrocardiogram (ECG) reported that the test formulation, the same final formulation as Zenalpha, appeared safe in dogs.

e. A Target Animal Safety (TAS) study administered treatments of 1X (medetomidine 1.0 mg/m2 and vatinoxan 20 mg/m2), 3X and 5X daily for 4 days intravenous. There was a dose-and time-dependent expression and resolution of sedation, hypotension, hypothermia, and initial sinus bradycardia and later sinus tachycardia. An additional study administered medetomidine and vatinoxan (IM) to six dogs, although the concentration of vatinoxan was higher (30 mg/m^2 vatinoxan IM). There was good local tolerability. The changes in clinical and physical observations, including ECG changes, are to be outlined on the label.

f. A field safety and efficacy trial was conducted for a fixed *Zenalpha* combination of vatinoxan/medetomidine, when used as a sedative in dogs older than 16 weeks of age of various breeds and sex, and required a procedure considered to be non-painful or mildly painful. The dose rate and the method of administration were consistent with the recommendations for the proposed use i.e. 1 mg/m^2 medetomidine and 20 mg/m^2 vatinoxan IM. It was concluded that that the combination was safer than dexmedetomidine (the active enantiomer of medetomidine) alone and cardiovascular changes were less pronounced.

g. *Zenalpha* is not to be used in animals with severe systemic disease, shock, hypovolemia, or cardiovascular disease, or respiratory disorders and also in animals with hypoglycaemia or are at risk of developing hypoglycaemia. In the absence of available safety data, treatment of puppies less than 4.5 months of age should be based on a benefit-risk assessment by the responsible veterinarian. The safety of *Zenalpha* has not been established in dogs during pregnancy or lactation or in dogs intended for breeding. The use of the veterinary medicinal product is therefore not recommended in pregnant or lactating animals. Side effects of hypothermia, bradycardia, and tachycardia and reduced respiratory rate were very commonly observed in safety and clinical studies. Diarrhoea/colitis and muscle tremor were also observed. All these side effects will be listed on the label.

2) The APVMA has evaluated the application, 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 demonstrated that if used according to the product label directions, the product is effective for its proposed uses.

ii. Efficacy of the product is supported by both product specific studies and published literature. The submission consisted of a range of pharmacological studies, dose confirmation studies and confirmatory field/clinical trials.

a. There are several injectable medetomidine-containing products currently registered for use in dogs and cats in Australia (1 mg/mL). In addition, the related active dexmedetomidine hydrochloride (the active enantiomer in medetomidine), is available in injectable formulations for use as a sedative and analgesic in dogs and cats.

b. Vatinoxan (the new active constituent) is an α2-adrenoreceptor antagonist which is rapidly absorbed from the injection site following IM dosing in dogs with pharmacokinetics which are very similar to intravenous (IV) administration. Scientific literature suggests that a ratio of 1:20 (medetomidine:vatinoxan) is the most effective for this combination, with vatinoxan generally having a dose-dependent antagonistic

effect on the peripheral adverse effects of medetomidine. The presence of vatinoxan results in an earlier, and possibly more intense, sedation of shorter duration. Vatinoxan reduces the analgesic action of opioids co-administered with medetomidine but will enhance the efficacy of reversal of the sedative effect by atipamezole.

iii. Unlike other medetomidine products registered in the Australian market, *Zenalpha* is dosed on a mg/ m^2 body surface area basis, not a mg/kg basis. In practice, this is approximated by a conversion table which allows a mg/ m^2 dose to be estimated on the basis of mass. A dose determination study combining medetomidine (1.0 mg/m^2) with increasing concentrations of vatinoxan (15, 30 or 50 mg/m^2) showed that vatinoxan dose-and time-dependently antagonised the physiological changes induced by medetomidine in the dog. Subsequent Pharmacokinetic (Pk)-Pharmacodynamic (Pd) modelling of this data and data from the literature confirmed that a ratio of 1:20 (medetomidine:vatinoxan) was the most effective for this combination. A Pk study showed that the onset and offset of sedation with medetomidine were slightly delayed and accelerated, respectively, by vatinoxan, although peak sedation scores were similar. Importantly, the peripheral 'adverse effects' were largely reduced.

iv. Another dose determination and confirmation study was provided that modelled (Pk-Pd): Pk interaction and effect of dose ratio. Pilot and published data was used to undertake Pk-Pd modelling. The study confirmed that vatinoxan at a ratio of 1:20 (medetomidine:vatinoxan) increases the clearance of dexmedetomidine (the active enantiomer of medetomidine) in a concentration dependent fashion.

v. A multi-centre field trial used 233 mixed breed dogs and compared *Zenalpha* combination of actives with dexmedetomidine, the active enantiomer of medetomidine, when undertaking minor procedures. This study reported that the onset of sedation was quicker for the test combination, but also was shorter in duration, while analgesia was similar.

vi. The information presented in the application supported efficacy and safety of *Zenalpha* in the dog. The addition of vatinoxan to medetomidine improves the safety of the latter, while there was good support in the literature and the clinical trials presented for efficacy.

vii. The APVMA has determined that *Zenalpha* in the dog is efficacious, when used in accordance with the label directions and administered 1 mg of medetomidine hydrochloride and 20 mg of vatinoxan hydrochloride (equivalent to 2 mL of solution) per square meter of body surface area, given intramuscularly (IM).

3) The APVMA has considered the application, 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:

viii. The intended use is in companion animals only (dogs); therefore, no assessment of residues or trade is required. The APVMA is satisfied that the proposed use of *Zenalpha Injection for Dogs* would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing 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 vatinoxan hydrochloride 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 *Zenalpha Injection for Dogs* 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.

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 10:

Table 10: 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
47106/0698 47106/0804 47106/121138	Bushman Plus Personal Insect Repellent / Bushman Repellent Plus Personal Insect Repellent	Label approval	Juno Limited	Not applicable	28 January 2025
53080/0600 53080/0909 53080/59860 53080/124068	Accensi Abamectin Insecticide	Label approval	Australian Agribusiness (Holdings) Pty Ltd	May not meet the labelling criteria	28 January 2025
54914/1201	4Farmers Abamectin 18 EC Miticide - Insecticide	Label approval	4Farmers Australia Pty Ltd	May not meet the labelling criteria	28 January 2025
55561/1112 55561/61120	Conquest Diuron 900 WG Herbicide	Label approval	Conquest Crop Protection Pty Ltd	Not applicable	28 January 2025
59000/0606 59000/0305	Kill-A-Mite	Label approval	Wholesale Horticultural Group Pty Ltd	May not meet the labelling criteria	28 January 2025
65190/50369 65190/100912 65190/127156	Cyhella Insecticide	Label approval	Arch Wood Protection (Aust) Pty Limited	Not applicable	28 January 2025
65750/51790 65750/124749	Rainbow Abamectin Insecticide / Miticide	Label approval	Shandong Rainbow International Co Ltd	May not meet the labelling criteria	28 January 2025
66545/53848	Abamix 18 EC Insecticide/Miticide	Label approval	Hextar Chemicals Pty Ltd	May not meet the labelling criteria	28 January 2025
66904/54662	AC Whistler Miticide / Insecticide	Label approval	Axichem Pty Ltd	May not meet the labelling criteria	28 January 2025
69463/60859	Bushman Repellent Plus Personal Insect Repellent Pump Spray	Label approval	Juno Limited	Not applicable	28 January 2025
69669/115238 69669/61397	Agrocn Abamectin 18 EC Insecticide/Miticide	Label approval	Shanghai Archana Chemical Co Ltd	May not meet the labelling criteria	28 January 2025
82872	Apparent Lawn Buff Weeder	Product Registration	Titan Ag Pty Ltd	May not met the safety criteria	28 January 2025
93923/140912	Naadco Abamectin 18 EC Insecticide / Miticide	Label approval	New Australia Agricultural Development Company Pty Ltd	May not meet the labelling criteria	28 January 2025

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 10.

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 10 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 10 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 10 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 10, 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 10 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.

Agvet chemical voluntary recall: DEMAND® 100CS Insecticide

Product name: DEMAND® 100CS Insecticide

APVMA registration number: 87293

APVMA approved label number: 118050

Batch number: EUA2K2770

Sold by: Pest control retailers nationally between 1 October 2024 to 29 January 2025.

On 29 January 2025, Syngenta Australia Pty Ltd (ACN 002 933 717) 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 presence of crystals has been discovered in 1 L packs of DEMAND® 100CS Insecticide (batch number EUA2K2770) which may cause blockages in application equipment. No other batches are affected.

Hazard

The sediment formed by the crystals may affect the expected performance of DEMAND® 100CS Insecticide (batch number EUA2K2770) and may lead to blockages in application equipment reducing the effectiveness of the product.

What to do if in possession of this chemical product

DO NOT use DEMAND® 100CS Insecticide from batch number EUA2K2770. Return unopened or partially used containers of DEMAND® 100CS Insecticide from the recalled batch to the retail outlet, from where the product was purchased, for a full refund.

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:

Syngenta Customer Service
Phone: 1800 022 035

Agvet chemical voluntary recall: ilium syntocin injection of synthetic oxytocin

Product name: ilium syntocin injection of synthetic oxytocin

APVMA registration number: 50435

APVMA approved label number: 128307

Batch number: 231028A

Sold by: Troy Laboratories Pty Ltd in all states and territories between 14 November 2023 to 31 January 2025.

On 31 January 2025, Troy Laboratories Pty Ltd (ABN: 000 283 769) 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

Over the shelf life of the product, the active ingredient was found to be below specification for batch 231028A.

Hazard

The defect may result in reduced efficacy.

What to do if in possession of this chemical product

Do not use the product from batch 231028A. Contact your supplier to arrange return and credit for the product from the affected batch.

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:

Troy Laboratories Customer Service
Phone: 02 8808 3611