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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.	147971
Product name	STYLUS Insecticide
Active constituent	500 g/kg pymetrozine
Applicant name	Centris Solutions Pty Ltd
Applicant ACN	682 650 577
Date of registration	29 July 2025
Product registration no.	96028
Label approval no.	96028/147971
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/kg pymetrozine water dispersible granule (WG) product for control of aphids in cotton, brassica vegetables, potatoes and stone fruit

Application no.	137982
Product name	Farmalinx Volt 120 SC Insecticide
Active constituent	120 g/L spinosad
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	31 July 2025
Product registration no.	93107
Label approval no.	93107/137982
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 120 g/L spinosad suspension concentrate (SC) product for treatment of argentine stem weevil (Listronotus bonariensis) in bentgrass

Application no.	143884
Product name	Primo HG Turf Growth Regulator
Active constituent	120 g/L trinexapac-ethyl
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of registration	1 August 2025
Product registration no.	94862
Label approval no.	94862/143884
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 120 g/L trinexapac-ethyl, micro-emulsion (ME) product for regulation of leaf and stem growth of grass lawns and as an aid in turf management

Application no.	148157
Product name	Swan Acidifier Pro 700 Spray Adjuvant
Active constituents	350 g/L soyal phospholipids, 350 g/L propionic acid
Applicant name	Swan Chemical Holdings Pty Ltd
Applicant ACN	669 863 067
Date of registration	5 August 2025
Product registration no.	96096
Label approval no.	96096/148157
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 350 g/L soyal phospholipids and 350 g/L propionic acid product, formulated as a dispersible concentrate (DC) for use as an acidifying and penetrating surfactant, which reduces alkaline hydrolysis of dimethoate, assists with uptake of foliar fertilisers and assists in management of spray droplet spectra

Application no.	143465
Product name	Agro-Essence Proteb 420 SC Fungicide
Active constituents	210 g/L prothioconazole, 210 g/L tebuconazole
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	5 August 2025
Product registration no.	94729
Label approval no.	94729/143465
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 210 g/L prothioconazole and 210 g/L tebuconazole suspension concentrate (SC) product for the control of various diseases in wheat, barley, oats, triticale, canola and pyrethrum

Application no.	148190
Product name	Thug Thug Wingman Rapid Death Flying Insect Killer Spray'n'Slay Fast and Deadly
Active constituents	1.0 g/kg esbiothrin, 0.5 g/kg permethrin, 0.2 g/kg imiprothrin
Applicant name	Aaron Laboratories Proprietary Limited
Applicant ACN	004 856 848
Date of registration	7 August 2025
Product registration no.	96105
Label approval no.	96105/148190
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 1.0 g/kg esbiothrin, 0.5 g/kg permethrin, and 0.2 g/kg imiprothrin aerosol product for the control of flying and crawling insects

Table 2: Variations of registration – agricultural chemical products

Application no.	149168
Product name	BinKill
Active constituent	7.8 g/kg transfluthrin
Applicant name	Lifeguard Sciences (Pty) Ltd
Applicant ACN	N/A
Date of variation	14 July 2025
Product registration no.	89119
Label approval no.	89119/149168
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 to 'BinKill' and the name that appears on the label from 'BinGuard' to 'BinKill Indoor'

Application no.	149213
Product name	Peanut Seed Protectant Fungicide
Active constituents	400 g/kg quintozene, 400 g/kg captan
Applicant name	Agnova Technologies Pty Ltd
Applicant ACN	097 705 158
Date of variation	21 July 2025
Product registration no.	50788
Label approval no.	50788/149213
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 'Uniroyal Chemical Peanut Seed Protectant Fungicide' to 'Peanut Seed Protectant Fungicide'

Application no.	149259
Product name	Hy-Clor Spa Bromine Tablets
Active constituents	650 g/kg bromine (Br) present as bromochlorodimethylhydantoin, 280 g/kg chlorine (Cl) present as bromochlorodimethylhydantoin
Applicant name	Hy-Clor (Australia) Pty Ltd
Applicant ACN	000 655 381
Date of variation	23 July 2025
Product registration no.	56160
Label approval no.	56160/149259
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 ‘Hy-Clor Spa Sanitiser Spa Tablets’ to ‘Hy-Clor Spa Bromine Tablets’

Application no.	149258
Product name	Plafin Mosquito Coil
Active constituent	2 g/kg D-allethrin
Applicant name	Vinico Sdn Bhd
Applicant ACN	N/A
Date of variation	23 July 2025
Product registration no.	68861
Label approval no.	68861/149258
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 name that appears on the label from ‘Atlas Mosquito Coils Repels for Up To 8 Hours 30 Coil Value Pack’ to ‘Atlas Repels for Up To 8 Hours Mosquito Coils’

Application no.	148051
Product name	Titan S-metolachlor 960 Herbicide
Active constituent	960 g/L S-metolachlor
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	29 July 2025
Product registration no.	69410
Label approval no.	69410/148051
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label approval to add uses

Application no.	148011
Product name	Enviroside International Moth Kill Hangers
Active constituent	4.5 g/kg transfluthrin
Applicant name	Yanco Limited
Applicant ACN	N/A
Date of variation	29 July 2025
Product registration no.	88148
Label approval no.	88148/148011
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label to change the packaging format and modify the directions for use

Application no.	N/A – variation under section 29A of the Agvet Code
Product name	SCA Ammonium Sulphate Herbicide Adjuvant
Active constituent	980 g/kg ammonium sulphate
Applicant name	Specialised Chemicals (Aust) Pty Ltd
Applicant ACN	657 238 849
Date of variation	29 July 2025
Product registration no.	95088
Label approval no.	95088/144635v
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to change the distinguishing product name and the name that appears on the label from ‘SC Ammonium Sulphate’ to ‘SCA Ammonium Sulphate’

Application no.	145584
Product name	Imtrade Motto RMR Miticide
Active constituents	110 g/L etoxazole, 110 g/L piperonyl butoxide
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of variation	30 July 2025
Product registration no.	92373
Label approval no.	92373/145584
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of label and label approval to extend uses in pome fruit, stone fruit (except cherries), citrus and capsicum

Application no.	147848
Product name	Seasol Earthcare Ready to Use Glyphosate Free Organic* Weedkiller
Active constituent	36.8 g/L nonanoic acid
Applicant name	Duluxgroup (Australia) Pty Ltd
Applicant ACN	000 049 427
Date of variation	30 July 2025
Product registration no.	90632
Label approval no.	90632/147848
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to change the product name and vary the pack size range to 750 mL–5 L

Application no.	144408
Product name	Boxer Gold Herbicide
Active constituents	800 g/L prosulfocarb, 120 g/L S-metolachlor
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	5 August 2025
Product registration no.	61234
Label approval no.	61234/144408
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 extend the use in oats and triticale to include a split application (IBS followed by PSPE), early post emergent (EPE) application and control of toad rush

Application no.	148158
Product name	Jasper 520 EC Herbicide
Active constituent	520 g/L haloxyfop present as the haloxyfop-r methyl ester
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	5 August 2025
Product registration no.	69584
Label approval no.	69584/148158
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration particulars and label approval to update the solvent in the constituent statement and the first aid instructions

Application no.	148179
Product name	Method 240 SL Herbicide
Active constituent	240 g/L aminocyclopyrachlor present as the potassium salt
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	6 August 2025
Product registration no.	90496
Label approval no.	90496/148179
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of label to make minor variations to the product label

Application no.	146595
Product name	Protim Optimum PTB Concentrate
Active constituents	180 g/L propiconazole, 180 g/L tebuconazole, 34 g/L bifenthrin
Applicant name	Koppers Performance Chemicals Australia Pty Ltd
Applicant ACN	088 260 575
Date of variation	6 August 2025
Product registration no.	88698
Label approval no.	88698/146595
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars

Application no.	148189
Product name	Pacific Abamectin 18 EC Insecticide / Miticide
Active constituent	18 g/L abamectin
Applicant name	Pacific Agriscience Pty Ltd
Applicant ACN	096 082 316
Date of variation	6 August 2025
Product registration no.	66330
Label approval no.	66330/148189
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to correct the erroneous rate on citrus for control of mites, amend the constituent statements to include diethylene glycol monobutyl ether, and update the first aid instructions and safety directions

Application no.	145581
Product name	Mortein Powergard Easy Reach Crawling Insect Surface Spray
Active constituents	2.0 g/kg cypermethrin, 0.7 g/kg imiprothrin
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of variation	6 August 2025
Product registration no.	70109
Label approval no.	70109/145581
Description of the application and its purpose, including the intended use of the chemical product	Variation to label approval to extend the claim for control to 12 months

Application no.	146557
Product name	Kingfisher Systemic Fungicide
Active constituent	250 g/L difenoconazole
Applicant name	Grochem Australia Pty Ltd
Applicant ACN	169 400 033
Date of variation	7 August 2025
Product registration no.	84390
Label approval no.	84390/146557
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and the label approval to add uses to control of powdery mildew in grapes, and pack size variation to 5 L–1000 L

Application no.	145705
Product name	Titan Glufosinate 200 Herbicide
Active constituent	200 g/L glufosinate-ammonium
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	7 August 2025
Product registration no.	66364
Label approval no.	66364/145705
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add over the top use in XtendFlex cotton for control of a variety of annual broadleaf and grass weeds

Application no.	145064
Product name	Clama 50SC Insecticide
Active constituent	50 g/L emamectin present as emamectin benzoate
Applicant name	ADAMA New Zealand Ltd
Applicant ACN	N/A
Date of variation	7 August 2025
Product registration no.	89922
Label approval no.	89922/145064
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 add uses for Heliothis (Helicoverpa spp.), cluster caterpillar (Spodoptera litura), loopers (Chrysodeixis spp.), cabbage centre grub (Hellula hydralis) in brassica vegetables, cluster caterpillar (Spodoptera litura) in lettuce, add new use patterns in root and tuber vegetables (except potatoes), leafy vegetables and brassica leafy vegetables (except lettuce), cucurbits, legume vegetables, and strawberries and extend crops groups

Application no.	148177
Product name	Ensystex Requiem Termite Bait
Active constituent	1 g/kg chlorfluazuron
Applicant name	Ensystex Australasia Pty Ltd
Applicant ACN	102 221 965
Date of variation	7 August 2025
Product registration no.	56580
Label approval no.	56580/148177
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add new pack sizes and update 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.	146506
Product name	Farmers' Own Dicyclanil 12.5 g/L Spray-on Blowfly Treatment for Sheep
Active constituent	12.5 g/L dicyclanil
Applicant name	Arrovet Pty Ltd
Applicant ACN	674 072 532
Date of registration	4 August 2025
Product registration no.	95609
Label approval no.	95609/146506
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 12.5 g/L dicyclanil blowfly treatment product for the protection of sheep against fly strike for up to 11 weeks and for the protection of marking wounds on lambs against fly strike for up to 11 weeks

Application no.	147867
Product name	Cyrex PS Liquid Sheep Blowfly and Lice Treatment
Active constituents	12.5 g/L spinosad, 500 g/L cyromazine
Applicant name	Pharm Smart Australia Pty Ltd
Applicant ACN	635 495 135
Date of registration	7 August 2025
Product registration no.	96002
Label approval no.	96002/147867
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 12.5 g/L spinosad, 500 g/L cyromazine liquid suspension concentrate product for the control of Spinosad-susceptible strains of lice (Bovicola ovis) for 8–11 weeks on sheep with long wool, protection of long wool sheep for up to 14 weeks from strike by cyromazine-susceptible strain of blowfly (Lucilia cuprina), including organophosphate resistant strains, when applied by jetting, treatment of blowfly strike in sheep

Application no.	147672
Product name	Zengard Oral Paste for Horses
Active constituent	370 mg/g omeprazole
Applicant name	Zen Pharma Pty Ltd
Applicant ACN	680 162 421
Date of registration	8 August 2025
Product registration no.	95948
Label approval no.	95948/147672
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 370 mg/g omeprazole oral paste product for the treatment and prevention of gastric ulcers in horses and foals

Table 4: Variations of registration – veterinary chemical products

Application no.	149215
Product name	AVET Meloxicam Dog Oral Suspension
Active constituent	1.5 mg/mL meloxicam
Applicant name	Chanelle Pharmaceuticals Manufacturing Limited
Applicant ACN	N/A
Date of variation	21 July 2025
Product registration no.	63653
Label approval no.	63653/149215
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 '[Wagg & Purr] Meloxicam Dog Oral Suspension' to 'AVET Meloxicam Dog Oral Suspension'

Application no.	149230
Product name	Recocam 20 mg/mL Solution for Injection for Cattle, Sheep, Pigs and Horses
Active constituent	20 mg/mL meloxicam
Applicant name	Bimeda (Australia) Pty Limited
Applicant ACN	058 196 508
Date of variation	22 July 2025
Product registration no.	70328
Label approval no.	70328/149230
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 'Recocam 20 mg/mL Solution for Injection for Cattle, Pigs and Horses' to 'Recocam 20 mg/mL Solution for Injection for Cattle, Sheep, Pigs and Horses'

Application no.	149241
Product name	Avet Meloxicam 1 mg Tablets
Active constituent	Each tablet contains 1 mg meloxicam
Applicant name	Chanelle Pharmaceuticals Manufacturing Limited
Applicant ACN	N/A
Date of variation	23 July 2025
Product registration no.	92224
Label approval no.	92224/149241
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 '[Wagg & Purr] Meloxicam 1 mg Tablets' to 'Avet Meloxicam 1 mg Tablets'

Application no.	149242
Product name	Avet Meloxicam 2.5 mg Tablets
Active constituent	Each tablet contains 2.5 mg meloxicam
Applicant name	Chanelle Pharmaceuticals Manufacturing Limited
Applicant ACN	N/A
Date of variation	23 July 2025
Product registration no.	92225
Label approval no.	92225/149242
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 '[Wagg & Purr] Meloxicam 2.5 mg Tablets' to 'Avet Meloxicam 2.5 mg Tablets'

Application no.	149262
Product name	Paw Pure Animal Wellbeing Mediderm Gentle Medicated Shampoo
Active constituent	7.21 g/L piroctone olamine
Applicant name	Blackmores Limited
Applicant ACN	009 713 437
Date of variation	24 July 2025
Product registration no.	63479
Label approval no.	63479/149262
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 'Paw Pure Animal Wellbeing by Blackmores Mediderm Gentle Medicated Shampoo' to 'Paw Pure Animal Wellbeing Mediderm Gentle Medicated Shampoo'

Application no.	149263
Product name	Paw Pure Animal Wellbeing Nutriderm Replenishing Conditioner
Active constituent	21 g/L colloidal oatmeal
Applicant name	Blackmores Limited
Applicant ACN	009 713 437
Date of variation	24 July 2025
Product registration no.	91972
Label approval no.	91972/149263
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 'Paw Pure Animal Wellbeing by Blackmores Nutriderm Replenishing Conditioner' to 'Paw Pure Animal Wellbeing Nutriderm Replenishing Conditioner'

Application no.	149264
Product name	Paw Pure Animal Wellbeing Osteosupport Joint Relief for Dogs
Active constituent	Each capsule contains 500 mg green lipped mussel powder (Perna canaliculus)
Applicant name	Blackmores Limited
Applicant ACN	009 713 437
Date of variation	24 July 2025
Product registration no.	61081
Label approval no.	61081/149264
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 'Paw Pure Animal Wellbeing by Blackmores Osteosupport Joint Relief for Dogs' to 'Paw Pure Animal Wellbeing Osteosupport Joint Relief for Dogs'

Application no.	149265
Product name	Paw Pure Animal Wellbeing Osteosupport Joint Relief for Cats
Active constituent	Each capsule contains 500 mg green lipped mussel powder (Pema canaliculus)
Applicant name	Blackmores Limited
Applicant ACN	009 713 437
Date of variation	24 July 2025
Product registration no.	65473
Label approval no.	65473/149265
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 'Paw Pure Animal Wellbeing by Blackmores Osteosupport Joint Relief for Cats' to 'Paw Pure Animal Wellbeing Osteosupport Joint Relief for Cats'

Application no.	149266
Product name	Paw Pure Animal Wellbeing Nutriderm Replenishing Shampoo
Active constituent	20 g/L colloidal oatmeal
Applicant name	Blackmores Limited
Applicant ACN	009 713 437
Date of variation	24 July 2025
Product registration no.	65958
Label approval no.	65958/149266
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 'Paw Pure Animal Wellbeing by Blackmores Nutriderm Replenishing Shampoo' to 'Paw Pure Animal Wellbeing Nutriderm Replenishing Shampoo'

Application no.	147573
Product name	Equipalazone Granules
Active constituent	Each sachet contains: 1 g phenylbutazone
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	28 July 2025
Product registration no.	35620
Label approval no.	35620/147573
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 updating the contraindication, precaution, side effect, dosage and administration and general direction statements and aligning the label with the current Veterinary Labelling Code (VLC), together with an addition of a new pack size

Application no.	149323
Product name	Exilice Gold Dual Active Pour on Lice Control for Sheep
Active constituents	35 mg/mL imidacloprid, 4 mg/mL abamectin
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	31 July 2025
Product registration no.	92535
Label approval no.	92535/149323
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 'Exishield Gold Dual Active Pour on Lice Control' to 'Exilice Gold Dual Active Pour on Lice Control for Sheep'

Application no.	145417
Product name	Simparica Trio Chews for Dogs 1.25 - 2.5 kg
Active constituents	Each chew contains: 12.5 mg pyrantel (as embonate), 3 mg sarolaner, 0.06 mg moxidectin
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	6 August 2025
Product registration no.	88220
Label approval no.	88220/145417
Description of the application and its purpose, including the intended use of the chemical product	Variation of particulars of product registration and label approval to add new claims

Application no.	147203
Product name	Beransa 20 mg Solution for Injection for Dogs
Active constituents	Each 1 mL vial contains 20 mg bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	7 August 2025
Product registration no.	89655
Label approval no.	89655/147203
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and disposal statements

Application no.	147205
Product name	Beransa 30 mg Solution for Injection for Dogs
Active constituents	Each 1 mL vial contains 30 mg bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	7 August 2025
Product registration no.	89695
Label approval no.	89695/147205
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and disposal statements

Application no.	147208
Product name	Beransa 15 mg Solution for Injection for Dogs
Active constituent	Each 1 mL vial contains 15 mg bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	14 August 2025
Product registration no.	89656
Label approval no.	89656/147208
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and disposal statements

Application no.	147469
Product name	Beransa 5 mg Solution for Injection for Dogs
Active constituent	Each 1 mL vial contains 5 mg bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	7 August 2025
Product registration no.	89658
Label approval no.	89658/147469
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and disposal statements

Application no.	147470
Product name	Beransa 10 mg Solution for Injection for Dogs
Active constituent	Each 1 mL vial contains 10 mg bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	7 August 2025
Product registration no.	89657
Label approval no.	89657/147470
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and disposal statements

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.	148425
Active constituent	Triclabendazole
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	1 August 2025
Approval no.	96170
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent triclabendazole for use in veterinary chemical products

Application no.	144685
Active constituent	Bixafen
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	1 August 2025
Approval no.	95105
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.	148124
Active constituent	Meloxicam
Applicant name	Bimeda (Australia) Pty Limited
Applicant ACN	058 196 508
Date of approval	5 August 2025
Approval no.	96081
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent meloxicam for use in veterinary chemical products

Application no.	145252
Active constituent	Topramezone
Applicant name	Hebei Lansheng Biotech Co Ltd
Applicant ACN	N/A
Date of approval	6 August 2025
Approval no.	95312
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

Table 6: Variations of active constituent

Application no.	148288
Active constituent	Milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	28 July 2025
Approval no.	95244
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

Application no.	148473
Active constituent	Oxytetracycline dihydrate
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	4 August 2025
Approval no.	83442
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

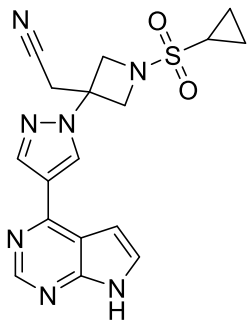
New veterinary chemical products containing a new veterinary active constituent

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, **ilunocitinib**, in conjunction with applications for the registration of a suite of new products, **Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs,** for the reduction of pruritus associated with allergic dermatitis and reduction of clinical signs of atopic dermatitis in dogs.

Ilunocitinib

As part of the applications to register Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs containing ilunocitinib, the APVMA has evaluated the safety of the new active constituent, ilunocitinib.

Table 7: Particulars of the active constituent Ilunocitinib

Common name	Ilunocitinib
IUPAC name	2-[1-cyclopropylsulfonyl-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)pyrazol-1-yl]azetidin-3-yl]acetonitrile
CAS name	3-Azetidineacetonitrile, 1-(cyclopropylsulfonyl)-3-[4-(7H-pyrrolo(2,3-d)pyrimidin-4-yl)-1H-pyrazol-1-yl]-
CAS registry number	1187594-14-4
Manufacturer's codes	3411067, LY3411067, LSN3411067, E4003631, C16042526-H, LEMA-04, SF7, Swift, Zenrelia
Minimum purity	98-102% (as is)
Molecular formula	$C_{17}H_{17}N_7O_2S$
Molecular weight	383.43 g/mol
Structure	
Chemical family	Janus kinase (JAK) inhibitor
Mode of action	Ilunocitinib primarily functions as a janus kinases inhibitor (JAKi). JAKi are a class of medications that target Janus kinases (JAKs), a family of enzymes involved in immune and inflammatory signalling pathways. Ilunocitinib is a non-selective JAKi that inhibits the function of a variety of pruritogenic, pro-inflammatory, and allergy-related cytokines that are dependent upon JAK enzymes. Ilunocitinib has a high potency for JAK1, JAK2, and tyrosine kinase 2 (TYK2) inhibition.

Summary of the APVMA's evaluation of ilunocitinib active constituent

A summary of the APVMA's evaluation of ilunocitinib 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:

    a. The APVMA is satisfied that the chemistry aspects of ilunocitinib active constituent (physico-chemical properties, identification, stability, manufacturing process, quality control procedures, batch analysis results, and analytical methods) are acceptable.

    b. The APVMA is satisfied that the toxicological and human health aspects of ilunocitinib active constituent are acceptable.

        i. Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) have been established, as no uses in food producing species are currently proposed.

        ii. Noting that the proposed products are to be supplied by veterinarians under prescription, the Scheduling Delegate has included ilunocitinib in **Schedule 4** of the Poisons Standard, with no exceptions or cut-offs.

        iii. Impurities are not expected to be present in ilunocitinib at toxicologically significant levels.

        iv. The health and toxicology assessment has indicated that there are no objections on toxicological grounds to the approval of the active constituent ilunocitinib.

    c. The APVMA is satisfied that the proposed importation and use of ilunocitinib would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

Zenrelia Tablets for Dogs containing ilunocitinib

In addition to the application to approve the new active constituent ilunocitinib, the APVMA has under consideration applications to register a suite of four new products containing ilunocitinib, Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs.

Table 8: Particulars of the product/s

<table>
<tr><td rowspan="4">Proposed product name/s</td><td>Zenrelia 15 mg Tablets for Dogs</td></tr>
<tr><td>Zenrelia 8.5 mg Tablets for Dogs</td></tr>
<tr><td>Zenrelia 6.4 mg Tablets for Dogs</td></tr>
<tr><td>Zenrelia 4.8 mg Tablets for Dogs</td></tr>
<tr><td>Applicant company</td><td>ELANCO AUSTRALASIA PTY LTD</td></tr>
<tr><td>Name of active constituent</td><td>ilunocitinib</td></tr>
<tr><td>Signal heading</td><td>Schedule 4</td></tr>
<tr><td>Summary of proposed use</td><td>Zenerelia Tablets for Dogs contains Ilunocitinib, a synthetic Janus Kinase (JAK) inhibitor. Ilunocitinib is a member of the pyrimidines class of JAK inhibitors and is an immunomodulator.
Zenerelia Tablets for Dogs is for the reduction of pruritus associated with allergic dermatitis and reduction of clinical signs of atopic dermatitis in dogs.</td></tr>
<tr><td>Dose rate</td><td>0.6 to 0.8 mg ilunocitinib/kg body weight administered orally, once daily.
The dosing table below shows the number of tablets required. For dogs weighing between 3 and 75 kg, an appropriate combination of complete or halved tablets may also be used, provided the dose rate of 0.6 to 0.8 mg ilunocitinib/kg body weight is maintained. The tablets may be halved along the score line.
<table>
<tr><th rowspan="2">Weight Range (in kg)</th><th colspan="4">Number of Tablets to be Administered</th></tr>
<tr><th>4.8 mg</th><th>6.4 mg</th><th>8.5 mg</th><th>15 mg</th></tr>
<tr><td>3.0 – 4.0</td><td>0.5</td><td></td><td></td><td></td></tr>
<tr><td>4.1 – 5.3</td><td></td><td>0.5</td><td></td><td></td></tr>
<tr><td>5.4 – 6.5</td><td></td><td></td><td>0.5</td><td></td></tr>
<tr><td>6.6 – 8.0</td><td>1</td><td></td><td></td><td></td></tr>
<tr><td>8.1 – 10.6</td><td></td><td>1</td><td></td><td></td></tr>
<tr><td>10.7 – 14.1</td><td></td><td></td><td>1</td><td></td></tr>
<tr><td>14.2 – 16.0</td><td></td><td>1.5</td><td></td><td></td></tr>
<tr><td>16.1 – 19.5</td><td></td><td></td><td>1.5</td><td></td></tr>
<tr><td>19.6 – 24.9</td><td></td><td></td><td></td><td>1</td></tr>
<tr><td>25.0 – 28.3</td><td></td><td></td><td>2</td><td></td></tr>
<tr><td>28.4 – 37.4</td><td></td><td></td><td></td><td>1.5</td></tr>
<tr><td>37.5 – 49.9</td><td></td><td></td><td></td><td>2</td></tr>
<tr><td>50.0 – 62.4</td><td></td><td></td><td></td><td>2.5</td></tr>
<tr><td>62.5 – 74.9</td><td></td><td></td><td></td><td>3</td></tr>
<tr><td>≥ 75</td><td colspan="4">Administer the appropriate combination of tablet strengths</td></tr>
</table></td></tr>
<tr><td>Pack sizes</td><td>10 count tablets
30 count tablets
90 count tablets</td></tr>
<tr><td>Withholding period</td><td>N/A</td></tr>
</table>

A summary of the APVMA's evaluation of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs in accordance with the requirements of section 14(1)(c) 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 that proposed use of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs would not be an undue hazard to the safety of people exposed to it during its **handling and use.**

   a. A quantitative user safety risk assessment was provided addressing the risk to adults (including persons of childbearing potential) administering the product to dogs. This was evaluated for the purpose of the APVMA's user risk assessment. The APVMA deemed there was sufficient information to inform a user risk assessment for a tablet formulation administered orally to dogs by owners for the medium- to long-term, under the direction of a veterinarian. There was a large margin of exposure without PPE. Management of health risks is achieved primarily via label directions, established from a consideration of the acute hazards of the product in conjunction with possible adverse health effects from repeated exposure to both workers and the general public. The risk management outcomes are as follows:

      i. Ilunocitinib is currently included in Schedule 4 of the Poisons Standard (Health, 2025). 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 Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). As Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs contain a Schedule 4 substance, it will require the signal heading 'PRESCRIPTION ANIMAL REMEDY'.

      ii. The product (film-coated tablet) is intended for use by or under the direction of veterinarian. The level of permitted dispensing and relevant disclaimer statement is to appear on the label as the first statement above the claim statement.

      iii. The individual administering the product (vet or pet owner) may need to split tablets to achieve the appropriate dosing. The use pattern is likely to be long-term and exposure will be mainly via the dermal route. The occupational exposure and risks for veterinarians are not expected to be any greater than the risk for pet owners. Exposure via inhalation may occur when scoring/breaking tablets but is expected to be minimal. Based on the ingredients in the formulation, the product is estimated to have low acute oral, dermal and inhalation toxicity. It is not a skin or eye irritant and is estimated to not be a skin sensitiser. PPE is not required to mitigate acute hazards. The repeat exposure risk assessment demonstrated acceptable margin of exposure from repeat dermal exposure without PPE.

      iv. Accidental ingestion by toddlers/children could occur, with possible pharmacological effects. These risks can be mitigated with child-resistant packaging and label directions i.e. Schedule 4 signal heading 'Keep out of reach of children'. The tablets are packaged in child-resistant blister packaging, which limits availability. The storage statement also includes the instruction 'Halved tablets should be placed back in the original opened blister and used within 20 days'.

   b. To mitigate potential risks, the following signal headings, statement of claims (class or level of permitted prescribing), first aid instructions, and safety directions statements are to appear on the product labels:

      Signal Heading

      PRESCRIPTION ANIMAL REMEDY

      KEEP OUT OF REACH OF CHILDREN

      FOR ANIMAL TREATMENT ONLY

      READ SAFETY DIRECTIONS

Claims

For use by, or under direction of, a veterinarian.

Dosage and administration

Halved tablets should be placed back in the original opened blister and used within 20 days.

First aid instructions

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

Safety directions

Wash hands after use.

c. After consideration of the toxicological profile and likely human exposure associated with the use of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs, 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) and adhering to the recommended safety directions.

ii. The APVMA is satisfied that the proposed use of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs 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 (dogs) only. Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs are therefore, unlikely to enter the food chain.

iii. The APVMA is satisfied that the proposed use of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs is not likely to have an unintended effect that is harmful to the **environment** if used according to the product label directions.

a. Environmental risks of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs (containing ilunocitinib [15 mg, 8.5 mg, 6.4 mg or 4.8mg per tablet) were assessed according to the VICH Phase I decision tree. The assessment determined that the amount of ilunocitinib introduced to the environment is expected to be negligible based on its uses in non-food animals (dogs). 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 general labelling requirements:

Disposal

Dispose of container by wrapping with paper and putting in garbage. Alternatively, empty blister packs can be recycled through an appropriate blister recycling program

iv. The APVMA is satisfied that the proposed use of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs containing the active constituent ilunocitinib would not be likely to have an unintended effect that is harmful to **animals (dogs)** if used according to the product label directions.

a. Three efficacy & target animal (TAS) field studies were conducted in privately-owned dogs in which the proposed product was administered at the proposed dose 0.6 to 0.8 mg ilunocitinib/kg body weight once per day. In addition, TAS was investigated in two pivotal Margin of safety studies, one using the Zenrelia tablet product (Investigational Veterinary Product (IVP)) and second study using 2.4, 3.6, 5.4, and 16 mg ilunocitinib tablet strengths (dose rate up to 4.0 mg/kg per os (PO) and/or duration of treatment up to 6 months).

b. Based on the Margin of Safety Studies (at 0, 1X, 2X, 3X and 5X the maximum recommended dose of 0.8 mg/kg) (8 per group) for 6 months showed dose-dependent changes as follows:

- Increase in the frequency and severity of interdigital furunculosis (cysts), with or without discharge on one or more paws;
- Increased paw skin thickening and/or discolouration with swelling and/or scabbing; and
- Minimal to moderate decrease in haematocrit (HCT), haemoglobin (HGB), and red blood cell (RBC) count without a corresponding increase in absolute reticulocyte count.

Other findings at overdose levels included:

- A minimal to mild decrease in mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentrations (MCHC), and eosinophil counts;
- Macro- and microscopic pathology changes of decreased prostate gland weights (in the 5x group males);
- Interdigital papillomas and/or dermatitis/furunculosis, predominantly in the 5X group;
- Minimally lower myeloid:erythroid ratios consistent with a physiological bone marrow response to the lower red blood cell mass despite no apparent effect on absolute reticulocytes (5X group);
- Abnormal clinical pathology observations (considered secondary to the interdigital furunculosis), which included minimal to moderate increases in fibrinogen concentrations, total protein, C-reactive protein, and globulin, and decreases in albumin, albumin/globulin ratio and calcium levels; and
- Reactive lymph nodes associated with interdigital furunculosis (5X group).
- There were no Zenrelia-related effects on lymphocytes, monocytes, and basophils.

c. The typical clinical signs observed in the field studies were different from overdose studies, which was due to the study design using privately-owned dogs with investigator and owner-based observations.

   i. Field study evaluating Zenrelia for allergic dermatitis:

      1. Serious adverse events (SAEs, as classified by Investigators) were rare, involving one placebo dog (ruptured splenic hemangiosarcoma) and three Zenrelia-treated (IVP) dogs (hypoxic event due to a tight collar, acute renal dysfunction due to toxin or bacterial exposure, and pre-existing renal issues that worsened on Day 4). These appear to not be related to the product treatment. The frequency of reported adverse events in Zenrelia and placebo treated dogs was comparable and included systemic disorders, digestive upsets, skin and appendage disorders. A small number of Zenrelia-treated dogs had reduced white blood cell counts and elevated nucleated red blood cells at various timepoints during the study; however, group means for all haematology parameters remained within normal ranges at all time points. Of the serum chemistry parameters, mean values for triglycerides and cholesterol were slightly elevated in the Zenrelia-treated group compared to placebo.

   ii. Field study evaluating Zenrelia for atopic dermatitis:

      1. The first field study comparing Zenrelia (IVP) against placebo reported five SAEs; however, none appear to be treatment-related (two involved placebo dogs (lymphocytosis in one, haemorrhagic gastroenteritis and dehydration in the other) and three involved IVP dogs (ruptured hepatic hemangiosarcoma, trauma-related tendon injury and puncture wound, and neutropenia). As per the previous clinical trial, the frequency of non-serious adverse events in Zenrelia and placebo treated dogs were comparable and consisted of systemic disorders, digestive upsets, skin and appendage

disorders. The treatment group means for total white blood cell counts and some of the differential (eosinophils, monocytes, neutrophils) decreased by Day 28 and remained lower through the study, although generally the shift was not clinically relevant, and means were within normal ranges.

2. The second field study compared Zenrelia (IVP) to positive control (Oclacitinib). The frequency of adverse events was comparable between groups throughout the study and primarily consisted of systemic disorders, digestive upsets, skin and appendage disorders. Of the four SAEs, three were in the control group (traffic accident, mass spread to the mammary gland, and increased liver parameters) and one in the treatment group (enlarged testis). None of the SAEs were treatment related. No notable abnormalities were seen in the serum chemistry results. Decreases in band neutrophils (% and absolute), basophils (absolute), monocytes (absolute), eosinophils (% and absolute) and leucocytes were seen in both treatment groups over the study period; however, most of these remained within normal laboratory reference ranges.

iii. Based on the results of the three field studies and assessment of causality, the relevant adverse events related to Zenrelia treatment are as follows:

1. Digestive tract disorders included vomiting/nausea and diarrhoea (>1 animal/10 animals treated).

2. Lethargy, anorexia, coughing or wheezing, urinary tract infection, dermal growths (including papilloma and histiocytoma), lipoma, sneezing, ocular discharge, elevated liver enzymes, increased serum lipids and weight gain (1 to 10 animals/100 animals treated).

3. Ataxia, polyuria, pyoderma, leukopenia, leucocytosis, and increased appetite (1 to 10 animals/1000 animals treated).

d. The safety of ilunocitinib has not been studied in breeding, pregnant, or lactating dogs nor in dogs younger than 12 months of age or weighing less than 3 kg. Its use in combination with glucocorticoids, cyclosporin, or other systemic immunosuppressive agents has also not been evaluated.

e. The APVMA has concluded that the administration of Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs is generally well tolerated. The following statements must be included on the label to mitigate the risks identified:

Contraindications

- Not to be used in dogs with serious infections.
- Not to be used in dogs with evidence of immunosuppression. The active substance has not been evaluated in dogs with evidence of immunosuppression, e.g. hyperadrenocorticism, or with proven progressive malignant neoplasia.
- Not to be used in dogs with known hypersensitivity to ilunocitinib.

Precautions

- The use of Zenrelia should be based on a risk-benefit assessment for each individual as conducted by the responsible veterinarian.
- The safety of Zenrelia has not been investigated in dogs younger than 12 months of age or weighing less than 3 kg.
- Use with caution in breeding, pregnant, or lactating dogs as the use of Zenrelia has not been evaluated in these classes of animals.

- Use with caution in combination with glucocorticoids, cyclosporin, or other systemic immunosuppressive agents, as the use of Zenrelia in combination with these types of products has not been evaluated.
- Zenrelia modulates the immune system and may increase susceptibility to opportunistic infections. Dogs receiving Zenrelia should therefore be monitored for the development of infections.

Side effects

- Side effects recorded during the three field studies assessing effectiveness and safety of Zenrelia in dogs were as follows:
    - The most commonly reported (>1 animal/10 animals treated) side effects were digestive tract disorders including vomiting/nausea and diarrhoea.
    - Commonly occurring (1 to 10 animals/100 animals treated) side effects included: lethargy, anorexia, coughing or wheezing, urinary tract infection, dermal growths (including papilloma and histiocytoma), lipoma, sneezing, ocular discharge, elevated liver enzymes, increased serum lipids and weight gain.
    - Uncommonly occurring (1 to 10 animals/1000 animals treated) side effects included: ataxia, polyuria, pyoderma, leukopenia, leucocytosis, and increased appetite.

Overdose

- Ilunocitinib tablets were administered orally to healthy 11–12-month-old Beagle dogs once daily for 6 months at 0.8 mg/kg, 1.6 mg/kg, 2.4 mg/kg and 4.0 mg/kg body weight. Clinical signs that were likely to be related to ilunocitinib treatment were classified as a form of interdigital pyoderma (including interdigital cysts with or without discharge, swollen and/or scabs on the paws, and paw thickening and/or discolouration).
- There was a mild but significant decrease in mean haemoglobin in pooled sexes at 2X and higher the recommended dose, with haematocrit and red blood cell count decreased at doses 3X and higher. This corresponded to a significant decrease in mean corpuscular haemoglobin and mean corpuscular haemoglobin concentration over time.
- There is no specific antidote and in case of signs of overdose the dog should be treated symptomatically.

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:

v. 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.

a. Pharmacokinetics:

i. Nine *in vivo* studies investigated the pharmacokinetics of ilunocitinib (phosphate salt or base) in dogs after intravenous (IV) or oral administration (fed or fasted state, solution or tablets) at various doses. Some studies used the final tablet formulation.

ii. After oral administration of the tablet at 0.8 mg/kg ilunocitinib in fed dogs, the absolute bioavailability was 80% with a Cmax of 268 ng/mL. The elimination half-life was 5.0 hours. In fasted dogs, oral bioavailability was 58%, with a Cmax of 122 ng/mL and a similar elimination half-life as observed in fed dogs (5.4 hours). Time to peak plasma concentrations (Tmax) was between 1 to 4 hours. After repeated oral administration there was no significant accumulation.

iii. After IV administration of 0.8 mg/kg, ilunocitinib had a low plasma clearance of 437 mL/h/kg. The volume of distribution was 1.58 L/kg and terminal half-life was 4.4 hours.

b. Dose 0.6 to 0.8 mg ilunocitinib/kg body weight was chosen based on a dose confirmation study that investigated doses of ilunocitinib of 0.1, 0.4, and 0.8 mg ilunocitinib/kg body weight.

c. Three confirmatory/pivotal field studies were conducted in privately-owned dogs. The proposed product was administered at the recommended dose 0.6 to 0.8 mg ilunocitinib/kg body weight once per day. Tablets may be administered in the fed or fasted state. The pivotal study program was as follows:

i. For allergic dermatitis (pruritus), which is considers a shorter-term indication based on the causative allergen, the therapeutic success requirement was a 50% reduction in Owner Pruritus Visual Analog Scale (PVAS) on at least 5 of the first 7 days.

Secondary endpoints: reduction from baseline in investigator‐assessed dermatitis Visual Analog Scale (DVAS) and PVAS, the proportion of dogs with at least a 50% reduction from baseline in PVAS and the proportion of dogs with ≥2-unit reduction from baseline in owner PVAS.

ii. For atopic dermatitis, the therapeutic success requirement was a 50% reduction from baseline at Day 28 for PVAS and/or Canine Atopic Dermatitis Extent and Severity Index-4 (CADESI-4), compared to placebo.

Secondary endpoints: included proportion of dogs at selected time-points with ≥50% reduction from baseline in PVAS and CADESI4 and the proportion of dogs with ≥2-unit reduction from baseline in PVAS and CADESI4.

d. Field study evaluating Zenrelia for allergic dermatitis:

i. A double-blind, randomised, placebo-controlled field study was conducted in the US, enrolling 306 client-owned dogs diagnosed with various types of allergic dermatitis. Dogs were randomised to once daily treatment with Zenrelia at 0.6 – 0.8 mg/kg or placebo, at a ratio of 2:1 respectively. The proportion of Zenrelia treated dogs that were therapeutic successes (25.4%) was statistically significantly different (p=0.006) to the placebo group (7.7%).

ii. For DVAS scores: At the Day 28 visit 74.7% of Zenrelia (IVP) treated dogs were in the normal category versus 35.6% in the placebo (p<0.001). At D56, the differences between groups appeared minimal (89.2%IVP, 78.9%Placebo). By Day 84, the placebo group exhibited higher cases with normal DVAS scores than the treated group (87.9%IVP; 100% Placebo). Due to the attrition in control dogs, interpretation of results after Day 28 is unclear.

iii. For PVAS scores: At Day 28, 51.4% of Zenrelia (IVP) treated dogs were in the normal category versus 15.3% in the placebo (p<0.001). Thereafter the proportion of IVP cases with normal scores were 58.0%, 69.3% and 79.2% on days 56, 84 and 112 respectively, while the proportion of placebo-treated dogs with normal scores on the same days were 36.8%, 43.8%, 53.3%. Due to the attrition in control dogs, interpretation of results after Day 28 is unclear.

e. Field studies evaluating Zenrelia for atopic dermatitis:

i. A double-blind, randomised, placebo-controlled field study was conducted in the US and Canada, enrolling 268 client-owned dogs diagnosed with atopic dermatitis. Dogs were

randomised to once daily treatment with Zenrelia at 0.6–0.8 mg/kg or placebo, at a ratio of 2:1 respectively. The proportion of dogs in the Zenrelia-treated group that were therapeutic successes (82.9%) was significantly different (p <0.001) to the placebo group (30.9%) on day 28.

vi. For PVAS scores: PVAS scores shifted from moderate/severe (at least 6) at baseline toward the mild (4) to normal (<2) categories over time in both groups. The percentages of Zenrelia (IVP) treated dogs with scores of normal were 32.7%, 43.5% and 47.1% at days 14, 28 and 56 respectively, vs 9.6%, 7.4% and 10.8 % respectively in the placebo group. While the percentages of Zenrelia (IVP) treated dogs with scores of very mild to normal were 60.2%, 66.7%, 77.1% at days 14, 28 and 56 respectively, vs 16.4%, 24.1% and 35.1 % respectively in the placebo group. By Day 84, over 85% of the dogs treated with Zenrelia and 57% of the placebo animals were assessed by their owners as normal or having very mild pruritus. Statistically, overall, the differences in PAS scores between Zenrelia (IVP) and placebo treated dogs were significant (p = 0.006 overall).

For CADESI4 scores: By Day 28, scores were in the normal range for 32.7% of IVP dogs versus 0% for placebo dogs (p<0.001). At Day 56 and 84, scores were in the normal range for 50.3% and 54.8% of Zenrelia (IVP) treated dogs versus 13.5% and 21.4 % placebo treated dogs, respectively (p<0.001). While 63.2% of IVP dogs in were in the normal range on Day 112, 28.6% of placebo dogs were also in the normal range (p<0.001).

i. Another double-blind, randomised, positive-controlled, multi-site field study was conducted in the EU. A total of 338 dogs diagnosed with atopic dermatitis were enrolled and randomised in a 1:1 ratio to the Zenrelia group and the positive control group (administered oclacitinib as an alternative JAK inhibitor). Dogs were dosed orally daily for up to 112 days. The evaluable population (334 dogs: 168 Zenrelia and 166 control) was assessed for the percentage reduction from baseline in the owner-assessed pruritus and investigator-assessed lesion score, at day 28. Non-inferiority to the positive control was demonstrated at day 28 (primary endpoint). The Zenrelia group achieved a mean of 67.8% reduction from baseline in pruritus, compared to 59.6% reduction in the oclacitinib group. The difference was statistically significant (p=0.005). The mean percentage reduction from baseline for skin lesions was 73.3% for the Zenrelia group and 68.8% for the oclacitinib group. The difference was statistically significant (p=0.042).

For PVAS: By Day 28, 41.8% in the CP (Oclacitinib) group and 48.1% in the Zenerlia (IVP) treated group were classified as normal. On Day 56 of the study, 62.0% of the dogs in the Zenrelia (IVP) treated group were categorised as normal versus 45.0% in the Oclacitinib group. By Day 84, 68.9% of the Zenrelia (IVP) treated dogs in the continuation phase were in the normal category, versus 57.3% in the CP treated group. Similarly at Day 112, 77.1% of the Zenrelia (IVP) treated were in the normal category, versus 60.6% in the CP treated group.

For CADESI4 Scores: By Day 28, 37.3% and 49.7% of dogs were assessed as “normal” or “mild” in the CP (Oclacitinib) group and 37.8% and 57.7% in the Zenrelia (IVP) treated group, respectively. The maximum improvement was observed on Day 112 for both treatment groups (CP: 66.7% “normal” and 31.8% “mild”; Zenrelia (IVP): 65.2% “normal” and 30.4% “mild”).

vii. Zenrelia tablets are designed for direct oral administration to dogs and are not expected to be consumed by voluntary ingestion or as part of a food additive. Therefore, no separate palatability studies were conducted.

viii. Compatibility of Zenrelia with several dog vaccines was investigated:

a. Vaccine-naïve dogs receiving Zenrelia at 3X label dose were vaccinated with standard modified live virus (MLV) antigens (canine parvovirus (CPV), canine distemper virus (CDV), canine adenovirus-2 (CAV-2), and canine parainfluenza virus (CPiV)) to evaluate response to primary vaccination. At 28 days after first vaccination, treated and control dogs showed acceptable immune responses to CPV, CDV, and CAV-2. CPiV response at this timepoint was below the acceptable threshold in 4/6 ZENRELIA-treated dogs and 8/8 control dogs. At 28 days after second vaccination, 2/6 Zenrelia-treated dogs and 2/8 control dogs remained below the acceptable threshold for CPiV. One Zenrelia-treated dog showed a reduced CDV response at 28 days after second vaccination. This study also examined response to inactivated rabies vaccination, which was delayed in Zenrelia-treated dogs: 4/6 treated dogs did not achieve acceptable immune response, whereas all control dogs achieved acceptable response by 28 days after vaccination. By 56 days after vaccination, 5/6 Zenrelia-treated dogs achieved acceptable immune response to rabies vaccination. An outbreak of coccidiosis and CAV-1 occurred during this study and the impact of these infections on the immune response to vaccination are unclear.

b. In a separate study, response to booster vaccinations for CPV, CDV, CAV-2 and rabies were evaluated in dogs receiving 1X and 3X the labelled dose of Zenrelia. Responses in treated animals were not statistically significantly different from control animals. All Zenrelia-treated and control animals responded with adequate immune responses 15- and 28-days post-booster vaccination for CPV, CAV-2 and rabies. For CDV, the control and 3X groups each had 1 dog not meeting study criteria for acceptable immune response at 15 days post-booster. The 1X group had 100% of dogs achieving an acceptable immune response at 15 days post-booster. Titre levels for CDV in all groups dropped between 15- and 28-days post-booster. This corresponded to 91, 88, and 76% of dogs showing acceptable immune response in the control, 1X and 3X groups respectively, similar to pre-booster results of 91, 75, and 71% of dogs.

ix. The APVMA has therefore, concluded that Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dog, would be effective for the reduction of reduction of pruritus associated with allergic dermatitis and clinical signs of atopic dermatitis in dogs. Relevant statements to mitigate the risks identified will be included on the product label:

Claims

- For use by or under direction of a veterinarian.
- For the reduction of pruritus associated with allergic dermatitis and reduction of clinical signs of atopic dermatitis in dogs.

Dosage and administration

- Halved tablets should be placed back in the original opened blister and used within 20 days. Discard unused tablet portions.
- Regular clinical evaluation and blood tests are recommended to monitor the health and response of the patient. The requirement for long-term maintenance therapy should be based on an individual risk-benefit assessment.
- For oral use only.
- 0.6 to 0.8 mg ilunocitinib/kg body weight administered orally, once daily.
- Tablets may be administered in the fed or fasted state.
- Be certain that the entire dose is consumed; watch your dog for several minutes after dosing to ensure that this is the case.
- The dosing table (see above Table 2) shows the number of tablets required. For dogs weighing between 3 and 75 kg, an appropriate combination of complete or halved tablets may also be used, provided the dose

rate of 0.6 to 0.8 mg ilunocitinib/kg body weight is maintained. The tablets may be halved along the score line.

General directions

- When treating pruritus associated with allergic dermatitis with ilunocitinib, investigate and treat any underlying causes (e.g. flea allergy dermatitis, contact dermatitis, food hypersensitivity). Furthermore, in cases of allergic dermatitis and atopic dermatitis, it is recommended to investigate and treat complicating factors, such as bacterial, fungal or parasitic infections/infestations (e.g. flea and mange).
- Veterinarians should assess the risks and benefits of vaccinating dogs which are receiving an immunomodulator.

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 Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets for Dogs, would not adversely affect trade between Australia and places outside Australia. The product is for use in dogs, which are not food producing animals, and which do not produce any major Australian export commodities.

ii. Therefore, there are no concerns from a trade perspective relating to the registration of this product.

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 ilunocitinib 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 Zenrelia [4.8 mg, 6.4 mg, 8.5 mg, 15 mg] Tablets 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 considered 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, Australia

Privacy

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

Agvet chemical voluntary recall: Randlab Gentamicin Injection

Product name: Randlab Gentamicin Injection

APVMA registration number: 90730

APVMA approved label number: 143727

Batch numbers: 24073F, 24074F and 24083F

Sold by: Randlab Pty Ltd (on behalf of Randlab Australia Pty Ltd) and veterinary wholesalers nationally between 1 July 2024 to 11 August 2025

On 11 August 2025, Randlab Australia Pty Ltd (ACN 114 948 837) 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

Small number of adverse effects in horses involving mild signs such as pawing, sweating and agitation, lasting for 10 to15 minutes and self-resolving.

Hazard

Potential adverse effects such as pawing, sweating and agitation, lasting for 10 to 15 minutes and self-resolving.

What to do if in possession of this chemical product

Cease use of Randlab Gentamicin Injection from above-mentioned batches immediately. Wholesalers should immediately quarantine any stock on hand of the recalled product and contact Randlab Pty Ltd to arrange return. End users are advised to contact Randlab Pty Ltd to organise return.

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

Please direct all calls and any queries concerning this voluntary recall to Randlab Pty Ltd on (02) 9728 3505 or to info@randlab.com.au.

Notice under section 34AC of decision on reconsideration of the Agricultural and Veterinary Chemicals Code: fenitrothion reconsideration

1) I, Sheila Logan, Executive Director, Risk Assessment Capability, publish this notice of my decision on the fenitrothion reconsideration pursuant to section 34AC(1)(b) of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).

2) Pursuant to section 34A(1) of the Agvet Code, I have varied the relevant particulars and or conditions of the approvals and registrations listed in Table 1 in such a way to allow the approvals and registrations to be affirmed.

3) Pursuant to section 34(1) of the Agvet Code, I have affirmed the fenitrothion active constituent approval, product registrations and label approvals listed in Table 1 of this notice as varied.

Table 1: Fenitrothion active constituent approvals, product registrations and label approvals that have been varied and then affirmed pursuant to sections 34(A)1 and 34(1) of the Agvet Code

Type of approval or registration	Approval or registration number	Name	Holder	Affirmed label approval number associated with the product
Active constituent	44499	Fenitrothion	Sumitomo Chemical Australia Pty Ltd	n/a
Product	46127	Methograin Fenitrothion 1000 Insecticide	Babolna Bioenvironmental Centre Private Limited Company	46127/RV25
Product	50775	Sumithion 1000EC Insecticide	Sumitomo Chemical Australia Pty Ltd	50775/RV25
Product	56170	Kendon Fenitrothion 1000EC Insecticide	Kendon Plant Care Pty Ltd	56170/RV25
Product	66520	Grain-Guard Duo Insecticide	Sumitomo Chemical Australia Pty Ltd	66520/RV25
Product	67186	Freezone Fenitrothion Insecticide	Freezone Public Health Pty Ltd	67186/RV25
Product	67567	Freezone Smart Grain Dual Insecticide	Freezone Public Health Pty Ltd	67567/RV25
Product	91551	Titan Dual Grain Treatment	Freezone Public Health Pty Ltd	91551/RV25

Brief reasons for decisions

4) The APVMA published notice of the proposed regulatory decision for the reconsideration of fenitrothion active constituent approvals, chemical product registrations, and label approvals under Part 2, Division 4 of the Agvet Code on in the APVMA Gazette on 9 April 2024. The proposed regulatory decision was subject to a 3-month public consultation. I have had regard to all submissions received in response to the public consultation before making this decision.

5) The APVMA received 9 written submissions on the fenitrothion proposed regulatory decisions, 3 of which the APVMA received permission to publish. The APVMA's subject-matter-expert staff have considered all written submissions received and updated, where appropriate, the technical and scientific assessments of the hazards and risks associated with fenitrothion approvals and registrations in the Fenitrothion Final Review Technical Report. I have reviewed that Report in detail, considered its methodology and the evidence on which it is based, and agree with its conclusions. I have had regard to all submissions received in response to the public consultation on the fenitrothion proposed regulatory decisions, and the updated technical and scientific assessment in the Fenitrothion Final Review Technical Report, before making this decision. This final regulatory decision reflects both the revised material findings of facts from those previously made in the published proposed decision, and the revised reasons for this final regulatory decision.

Active constituents

6) In accordance with section 34A(1) of the Agvet Code, I have decided to vary the condition of approval referred to as the 'Agricultural Active Constituents Quality Assurance Requirements' to remove an obsolete definition and to remove duplicate conditions imposed by the Agvet Regulations or the requirements of the *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022* (Active Constituent Standards 2022).

7) I have also amended the maximum impurities listed in the APVMA record for the approval of the active constituent to align with the updated Declaration of Composition provided to the APVMA in response to a notice issued under section 33 of the Agvet Code.

8) I am satisfied that the active constituent approval listed in Table 1, as varied, meets the safety criteria and complies with any requirements prescribed by the regulations. Therefore, pursuant to section 34(1) of the Agvet Code, I have affirmed the active constituent approval listed in Table 1 of this notice.

Chemical products

9) In my proposed regulatory decision, the use of fenitrothion to control insect pests was not supported in any currently approved situation except for treatment of stored grain, because exposure to non-target species or workers exceeded acceptable levels, or because of risks to trade or lack of efficacy. Additional data supplied during the consultation period allowed revision of the environment assessment, which determined that some of the risks to non-target species posed by fenitrothion use could be mitigated by removal of instructions for use in specific crops, additional instructions and restraints.

10) Additional information provided and assessed in relation to worker exposure demonstrated that additional restraints and variations to the instructions for use, resulted in acceptable exposure for worker health and safety from use of fenitrothion in field uses that meet the safety criteria with respect to non-target species, specifically: cereals (excluding corn, maize and rice) and grazing sorghum, between growth stages BBCH 40 until flowering is complete (BBCH 69).

11) Information provided in relation to the potential for undue risks to trade resulting from use of fenitrothion on stored grain in bulk handling facilities demonstrated that that industry has adequate process in place to manage the risks appropriately.

12) The risk assessment outcomes for all other situations indicated in the instructions for use remain the same as the recommendations in my proposed decision.

13) Accordingly, I have varied the instructions for use entered in the Register for the fenitrothion products listed in Table 1 as I previously proposed to do, except that I have:

    a) Varied the instructions for use of fenitrothion in cereal crops and grazing sorghum (products 50775, 56170 and 67186) to limit the rate to between 270 and 330 g ac/ha for Australian Plague Locust, Spur-throated Locust and Migratory Locust.

    b) Varied the instructions for use for products that include field uses (50775, 56170 and 67186), to remove current instructions that direct users to apply the product more than once per year and include restraints to protect worker health and safety, non-target species and sensitive areas.

    c) For protection of non-target species, the following restraints have been added to products including field uses (50775, 56170 and 67186), in addition to those listed in my proposed decision:

        - '*DO NOT apply more than once per year*,'
        - *'Toxic to birds and wild mammals. To protect wildlife, DO NOT apply before booting (BBCH <40) or after flowering is complete (BBCH >69).'*

- *'Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers. To avoid runoff, DO NOT apply if heavy rains or storms are forecast within 3 days. DO NOT irrigate to the point of field runoff for at least 3 days after application.'*
- *'Toxic to bees. DO NOT apply to bee-attractive crops from the onset of flowering (BBCH >60). DO NOT allow spray drift to flowering weeds or flowering crops in the vicinity of the treatment area. Before spraying, notify beekeepers to move hives to a safe location with an untreated source of nectar and pollen, if there is potential for managed hives to be affected by the spray or spray drift.'*
- *'Toxic to beneficial arthropods. Not compatible with integrated pest management (IPM) programs utilising beneficial arthropods. Minimise spray drift to reduce harmful effects on beneficial arthropods in non-crop areas.'*

d) For the protection of worker health and safety the following restraints have been added to products including field uses (50775, 56170 and 67186), in addition to those listed in my proposed decision:

- *'A single operator MUST NOT mix and apply more than 110 L of neat product per day (equivalent to spraying an area of no more than 320 ha per day at the maximum rate of 330 mL/ha or no more than 400 ha per day at the minimum rate of 270 mL/ha.'*
- *'DO NOT use open mixing/loading equipment. Closed mixing and loading must be used,'* and removing instructions that recommend but do not mandate closed mixing and loading.'
- *'DO NOT apply using open cab equipment. Enclosed cab application MUST be used.'*
- *'DO NOT enter treated cereal and grazing sorghum crops for 11 days after treatment for scouting and 16 days after treatment for irrigation (handset). When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves. Clothing must be laundered after each day's use.'*

e) For the protection of areas sensitive to spray drift the following restraints have been added to products including field uses (50775, 56170 and 67186):

'DO NOT allow bystanders to come into contact with the spray cloud.'

'DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas'

'DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.'

'DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.'

'DO NOT apply by a boom sprayer unless the following requirements are met:

- *spray droplets not smaller than a COARSE spray droplet size category*
- *minimum distances between the application site and downwind sensitive areas (see 'Mandatory downwind buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.'*

Application rate	Boom height above the target canopy	Mandatory downwind buffer zones (metres)				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 330 mL/ha	0.5 m or lower	0	400	0	0	0
270 mL/ha or lower	0.5 m or lower	0	350	0	0	0

f) The condition referred as the 'Agricultural Products Active Constituent Quality Assurance Requirements' has been varied to remove an obsolete definition and unnecessary duplication already imposed by the Agvet Code and Agvet Regulations, as I proposed.

14) Having made the variations that I listed in my proposed decision and also those that I have listed above, I am satisfied that the chemical product registrations listed in Table 1, as varied, meet the safety, efficacy and trade criteria and comply with any requirements prescribed by the regulations. Therefore, pursuant to section 34(1) of the Agvet Code, I have affirmed the chemical product registrations listed in Table 1 of this notice.

Labels for chemical products

15) In accordance with section 34A(1) of the Agvet Code, the particulars of the label approvals have been varied to include the instructions noted above and as in my proposed decision.

16) I am satisfied that the labels for fenitrothion products listed in Table 1, as varied, meet the labelling criteria and comply with any requirements prescribed by the regulations. Therefore, pursuant to section 34(1) of the Agvet Code, I have affirmed the label approvals for fenitrothion products listed in Table 1 of this notice.

17) Furthermore, I have determined, pursuant to section 81(3)(c) of the Agvet Code, that subsection 81(3) applies in respect of the supply of the products listed in Table 2, bearing labels that were previously approved but have now been varied, if the supply takes place not later than 1 year from the date of affirmation. Products bearing the previously approved labels listed in Table 2 must not be supplied after 15 August 2026. I note that this determination does not authorise manufacture of new products bearing previously approved labels after the date of the decision.

Table 2: Fenitrothion products bearing previously approved labels subject to the determination made under section 81(3) of the Agvet Code

Type of approval or registration	Approval or registration number	Name	Holder	Previously approved label number(s) associated with the registered product
Product	46127	Methograin Fenitrothion 1000 Insecticide	Babolna Bioenvironmental Centre Private Limited Company	46127/129275
Product	50775	Sumithion 1000EC Insecticide	Sumitomo Chemical Australia Pty Ltd	50775/128296
Product	56170	Kendon Fenitrothion 1000EC Insecticide	Kendon Plant Care Pty Ltd	56170/136950, 56170/0702

Type of approval or registration	Approval or registration number	Name	Holder	Previously approved label number(s) associated with the registered product
Product	66520	Grain-Guard Duo Insecticide	Sumitomo Chemical Australia Pty Ltd	66520/53810
Product	67186	Freezone Fenitrothion Insecticide	Freezone Public Health Pty Ltd	67186/55411
Product	67567	Freezone Smart Grain Dual Insecticide	Freezone Public Health Pty Ltd	67567/56362
Product	91551	Titan Dual Grain Treatment	Freezone Public Health Pty Ltd	91551/132629

Sheila Logan
Executive Director, Risk Assessment Capability

With the delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*

Contact information

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 Australia

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

Notice of merits review rights

An application may be made to the Administrative Review Tribunal by or on behalf of a person whose interests are affected by a decision under subsections 34A(1) and section 34AA of the Agvet Code.

Subject to the Administrative Review Tribunal Act 2024, a person whose interests are affected by this decision may also make an application to the ART for a review of this decision. A person whose interest are affected by this decision may also, in accordance with the Administrative Review Tribunal Act 2024, make an application to receive a statement of reasons for this decision.

Notice of cancellation under section 45A of the Agricultural and Veterinary Chemicals Code: fenitrothion reconsideration

1) I, Sheila Logan, Executive Director, Risk Assessment Capability, pursuant to section 45A of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code), hereby publish notice that I have cancelled the fenitrothion product registration and label approval listed in Table 3 of this notice.

2) The approval and registration listed in Table 3 have been cancelled pursuant to section 34AA(1) of the Agvet Code because I am not satisfied that the chemical product meets the safety criteria, and I am not satisfied that the label meets the labelling criteria. Further, I am not satisfied that the particulars or conditions of these approval and registration could be varied in such a way that would allow the approval and registration to be affirmed.

Table 3: Fenitrothion product registrations and label approvals cancelled pursuant to section 34AA(1) of the Agvet Code

Type of approval or registration	Approval or registration number	Name	Holder	Label approval number associated with the registered product	Date of cancellation
Product	50774	Sumitomo Sumithion ULV Premium Grade Insecticide	Sumitomo Chemical Australia Pty Ltd	50774/0500	15 August 2025

Brief reasons for decisions

3) The APVMA gave notice of the proposed regulatory decision for the reconsideration of fenitrothion active constituent approvals, chemical product registrations, and label approvals to all holders of active constituent approvals, product registrations and label approvals relating to fenitrothion, under Part 2, Division 4 of the Agvet Code on 9 April 2024. The proposed regulatory decision was subject to a 3-month public consultation.

4) The APVMA received 9 written submissions on the fenitrothion proposed regulatory decisions, 3 of which the APVMA received permission to publish. The APVMA's expert staff have considered all written submissions received and updated, where appropriate, the technical and scientific assessments of the hazards and risks associated with fenitrothion approvals and registrations in the Fenitrothion Final Review Technical Report.

5) I have reviewed that Report in detail, considered its methodology and the evidence on which it is based, and agree with its conclusions. I have had regard to all submissions received in response to the public consultation on the fenitrothion proposed regulatory decisions, and the updated technical and scientific assessment in the Fenitrothion Final Review Technical Report, before making this decision. This final regulatory decision reflects both the revised material findings of facts from those previously made in the published proposed decision, and the revised reasons for this final regulatory decision.

6) In the proposed regulatory decision, the use of fenitrothion to control locust and grasshopper pests on field crops was not supported due to risks to non-target species that could not be mitigated. Additional data supplied during the consultation period allowed revision of the environment assessment, which determined that some of the risks to non-target species posed by fenitrothion use could be mitigated by removal of instructions for use in specific crops.

7) I have regard to the results of the spray drift risk assessment and considered whether the risk posed to sensitive areas by downwind spray drift could be mitigated by additional instructions and restraints. I concluded that the instructions for use for ultra-low (UL) volume fenitrothion products could not be varied as buffer zones for sensitive aquatic areas were either impractically large for ground application, or could not be established for aerial application, as they exceeded the limits of the model (greater than 2999m).

8) I consider that the risks to sensitive aquatic areas associated with the use of UL fenitrothion cannot be mitigated as the instructions for use concerning spray drift could not be varied in such a way to meet the safety criteria. As application to cereal crops and grazing sorghum was the only remaining use pattern supported by all other risks areas for the sole fenitrothion product formulated as UL (50774), I do not consider that the instructions for use of the product can be varied in such a way to meet the safety criteria and therefore the registration of the product cannot be affirmed.

9) Therefore:

   a) I am **not satisfied** that the fenitrothion chemical product registration listed in Table 3 meets the safety criteria and is not satisfied that the particulars or conditions of this registration could be varied in such a way to allow the registration to be affirmed.

   b) I am **not satisfied** that the associated label approval meets the labelling criteria and is not satisfied that the particulars or conditions of the approval could be varied in such a way to allow the approvals to be affirmed.

   c) Pursuant to section 34AA(1) of the Agvet Code, I have cancelled the product registration and associated label approval listed in Table 3 of this notice.

Deemed permit and instructions

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

A person who possesses, has custody of or uses the cancelled product or product bearing a cancelled label referred to in Table 3 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 product or product bearing a cancelled label, in accordance with those instructions.

If the APVMA revokes the cancellation or declares that the deemed permit ceases to apply with respect to the cancelled active constituent under section 45B(2) of the Agvet Code, written notice will be provided to the holder and published in the APVMA Gazette.

Possession or custody

A person may possess the cancelled product or product bearing a cancelled label referred to in Table 3 in accordance with its label instructions for 1 year from the date of cancellation.

Use, supply or otherwise deal with

A person may use the cancelled product or products bearing a cancelled label referred to in Table 3 according to its label instructions, including any conditions relating to shelf life or expiry date, for 1 year after the date of cancellation.

A person may supply or cause to be supplied at wholesale or retail level the cancelled product, or product bearing a cancelled label referred to in Table 3, for 1 year after the date of cancellation.

Contraventions

After the day that is 1 year from the date of cancellation it will be an offence against the Agvet Code to have possession or custody of the cancelled products or products bearing a cancelled label with the intention to supply, or to supply the cancelled product or product bearing a cancelled label.

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled products or products bearing the cancelled label listed in Table 3 in a manner that contravenes the above instructions.

Sheila Logan
Executive Director, Risk Assessment Capability

With the delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*

Contact information

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 Australia

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

Notice of merits review rights

An application may be made to the Administrative Review Tribunal by or on behalf of a person whose interests are affected by a decision under subsections 34A(1) and section 34AA of the Agvet Code.

Subject to the Administrative Review Tribunal Act 2024, a person whose interests are affected by this decision may also make an application to the ART for a review of this decision. A person whose interest are affected by this decision may also, in accordance with the Administrative Review Tribunal Act 2024, make an application to receive a statement of reasons for this decision.