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# Gazette

## Agricultural and veterinary chemicals

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**Australian Pesticides and  
Veterinary Medicines Authority**

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

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Assistant Director, Communications  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

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

Website: [apvma.gov.au](http://apvma.gov.au)

## **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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## **APVMA contacts**

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

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## Agricultural chemical products and approved labels

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

**Table 1: Agricultural products based on existing active constituents**

<b>Application no:</b>	130983
<b>Product name:</b>	Sino Great Tribenuron 750 Herbicide
<b>Active constituent/s:</b>	750 g/kg tribenuron-methyl
<b>Applicant name:</b>	Shanghai SinoGreatland Industrial Co., Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For the control of certain broadleaf weeds in fallows and pre-crop situations
<b>Date of registration:</b>	14 September 2021
<b>Product registration no.:</b>	91119
<b>Label approval no.:</b>	91119/130983

<b>Application no:</b>	131423
<b>Product name:</b>	Pacific Chlorothalonil 720 SC Fungicide
<b>Active constituent/s:</b>	720 g/L chlorothalonil
<b>Applicant name:</b>	Pacific Agriscience Pty Ltd
<b>Applicant ACN:</b>	096 082 316
<b>Summary of use:</b>	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, grapes, onions, peaches, peanuts, pulses, plums, potatoes, tomatoes and vegetables
<b>Date of registration:</b>	15 September 2021
<b>Product registration no.:</b>	91219
<b>Label approval no.:</b>	91219/131423

<b>Application no:</b>	132081
<b>Product name:</b>	TRS Personal Insect Repellent Tropical Strength
<b>Active constituent/s:</b>	191 g/kg diethyltoluamide, 40 g/kg N-octyl bicycloheptene dicarboximide
<b>Applicant name:</b>	Pascoe's Pty Ltd
<b>Applicant ACN:</b>	055 220 463
<b>Summary of use:</b>	For protection against mosquitoes and to repel flies, sandflies, fleas, leeches, ticks and other annoying and biting insects
<b>Date of registration:</b>	15 September 2021
<b>Product registration no.:</b>	91388
<b>Label approval no.:</b>	91388/132081

<b>Application no:</b>	131158
<b>Product name:</b>	CropSure Abacus 36EC Insecticide
<b>Active constituent/s:</b>	36 g/L abamectin
<b>Applicant name:</b>	CropSure Pty Ltd
<b>Applicant ACN:</b>	643 829 190
<b>Summary of use:</b>	For the control of a range of mite and insect pests in beans, peas, berry crops, sweet corn, almond, avocado, cut flowers, duboisia, fruiting vegetables, nursery stock, oil tea tree, ornamentals and other fruits and vegetables
<b>Date of registration:</b>	15 September 2021
<b>Product registration no.:</b>	91188
<b>Label approval no.:</b>	91188/131158

<b>Application no:</b>	130606
<b>Product name:</b>	Mortein Mosquito Pro-Shield
<b>Active constituent/s:</b>	100 g/kg metofluthrin
<b>Applicant name:</b>	RB (Hygiene Home) Australia Pty Ltd
<b>Applicant ACN:</b>	629 549 506
<b>Summary of use:</b>	For the control of mosquitoes in domestic situations
<b>Date of registration:</b>	15 September 2021
<b>Product registration no.:</b>	90965
<b>Label approval no.:</b>	90965/130606

<b>Application no:</b>	131430
<b>Product name:</b>	IA Outperform 630 EC Insecticide/Miticide
<b>Active constituent/s:</b>	600 g/L chlorpyrifos, 30 g/L bifenthrin
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of use:</b>	For the control of certain insect pests of broad-acre crops, cotton, sugarcane and tomatoes
<b>Date of registration:</b>	17 September 2021
<b>Product registration no.:</b>	91222
<b>Label approval no.:</b>	91222/131430

<b>Application no:</b>	132629
<b>Product name:</b>	Titan Dual Grain Treatment
<b>Active constituent/s:</b>	600 g/L fenitrothion, 60 g/L (S)-methoprene
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use:</b>	For the control of insect pests in stored cereal grains, including malting barley
<b>Date of registration:</b>	21 September 2021
<b>Product registration no.:</b>	91551
<b>Label approval no.:</b>	91551/132629

<b>Application no:</b>	132630
<b>Product name:</b>	Titan Onza Blue Rodenticide Grain Bait
<b>Active constituent/s:</b>	0.05 g/kg difenacoum
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use:</b>	For the control of brown or Norway rats ( <i>Rattus norvegicus</i> ) and mice, including those resistant to other anticoagulants
<b>Date of registration:</b>	21 September 2021
<b>Product registration no.:</b>	91552
<b>Label approval no.:</b>	91552/132630

<b>Application no:</b>	132645
<b>Product name:</b>	Titan Onza Blue Rodenticide Paste
<b>Active constituent/s:</b>	0.05 g/kg difenacoum
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use:</b>	For the control of brown or Norway rats ( <i>Rattus norvegicus</i> ) and mice, including those resistant to other anticoagulants
<b>Date of registration:</b>	22 September 2021
<b>Product registration no.:</b>	91555
<b>Label approval no.:</b>	91555/132645

<b>Application no:</b>	132635
<b>Product name:</b>	Titan Onza Red Rodenticide Paste
<b>Active constituent/s:</b>	0.05 g/kg brodifacoum
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use:</b>	For the control of brown or Norway rats ( <i>Rattus norvegicus</i> ) and mice, including those resistant to other anticoagulants
<b>Date of registration:</b>	22 September 2021
<b>Product registration no.:</b>	91553
<b>Label approval no.:</b>	91553/132635

<b>Application no:</b>	132644
<b>Product name:</b>	Titan Onza Red Rodenticide Blocks
<b>Active constituent/s:</b>	0.05 g/kg brodifacoum
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use:</b>	For use in damp or dry situations in and around industrial, commercial, agricultural and domestic buildings to control rats and mice
<b>Date of registration:</b>	22 September 2021
<b>Product registration no.:</b>	91554
<b>Label approval no.:</b>	91554/132644

<b>Application no:</b>	132647
<b>Product name:</b>	Titan Onza Blue Rodenticide Blocks
<b>Active constituent/s:</b>	0.05 g/kg difenacoum
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use:</b>	For the control of brown or Norway rats ( <i>Rattus norvegicus</i> ) and mice, including those resistant to other anticoagulants
<b>Date of registration:</b>	22 September 2021
<b>Product registration no.:</b>	91556
<b>Label approval no.:</b>	91556/132647

<b>Application no:</b>	132628
<b>Product name:</b>	Titan IGR Grain Treatment
<b>Active constituent/s:</b>	300 g/L (S)-methoprene
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use:</b>	For protection against immature stages of lesser grain borer, rust-red flour beetle and sawtoothed grain beetle, including organophosphate resistant strains as per the directions for use table
<b>Date of registration:</b>	22 September 2021
<b>Product registration no.:</b>	91550
<b>Label approval no.:</b>	91550/132628

<b>Application no:</b>	127920
<b>Product name:</b>	Kelpie Cleth-D 360 Herbicide
<b>Active constituent/s:</b>	360 g/L clethodim
<b>Applicant name:</b>	Sinochem International Australia Pty Ltd
<b>Applicant ACN:</b>	160 164 616
<b>Summary of use:</b>	For the control of certain grass weeds in beetroot, cabbage, canola, cotton, lettuce, non-bearing fruit trees, peanuts, pulses (including adzuki beans, broad beans, chickpeas, faba beans, field peas, lentils, lupins and mung beans), soybeans and pasture legume (lucerne, clover and medic), seed crops and pastures
<b>Date of registration:</b>	22 September 2021
<b>Product registration no.:</b>	90181
<b>Label approval no.:</b>	90181/127920

<b>Application no:</b>	129144
<b>Product name:</b>	Protect-Us Aquacell Ready-To-Use Insect Killer
<b>Active constituent/s:</b>	4.3 g/L hydroxypropyl methylcellulose
<b>Applicant name:</b>	Ensystem Australasia Pty Ltd
<b>Applicant ACN:</b>	102 221 965
<b>Summary of use:</b>	For the control of crawling and flying insects in household situations
<b>Date of registration:</b>	23 September 2021
<b>Product registration no.:</b>	90503
<b>Label approval no.:</b>	90503/129144

<b>Application no:</b>	131536
<b>Product name:</b>	F.S.A. Bifenthrin 100 EC Insecticide
<b>Active constituent/s:</b>	100 g/L bifenthrin
<b>Applicant name:</b>	Four Seasons Agribusiness Pty Ltd
<b>Applicant ACN:</b>	115 133 189
<b>Summary of use:</b>	For the control of <i>Helicoverpa spp.</i> , certain species of mites, wireworms, weevils and other insect pests in cotton, bananas, grapes, citrus, sugarcane, tomatoes, lucerne seed crops, wheat, barley and other various crops
<b>Date of registration:</b>	23 September 2021
<b>Product registration no.:</b>	91259
<b>Label approval no.:</b>	91259/131536

Table 2: Variations of registration

<b>Application no.</b>	132661
<b>Product name</b>	Oxafert Herbicide and Fertiliser
<b>Active constituent/s</b>	10 g/kg oxadiazon
<b>Applicant name</b>	Farmalinx Pty Ltd
<b>Applicant ACN</b>	134 353 245
<b>Summary of variation</b>	To vary the distinguishing name that appears on the label from 'Oxafert PK Herbicide and Fertiliser' to 'ProForce Echelon G Herbicide and Fertiliser'
<b>Date of variation</b>	2 September 2021
<b>Product registration no.</b>	70376
<b>Label approval no.</b>	70376/132661

<b>Application no.</b>	132714
<b>Product name</b>	Naturalure Fruit Fly Bait Concentrate Qalcova Active Insecticide
<b>Active constituent/s</b>	0.24 g/L spinosad
<b>Applicant name</b>	Corteva Agriscience Australia Pty Ltd
<b>Applicant ACN</b>	003 771 659
<b>Summary of variation</b>	To vary the distinguishing product name and the name that appears on the label from 'Naturalure Fruit Fly Bait Concentrate' to 'Naturalure Fruit Fly Bait Concentrate Qalcova Active Insecticide'
<b>Date of variation</b>	6 September 2021
<b>Product registration no.</b>	58234
<b>Label approval no.</b>	58234/132714



<b>Application no.</b>	132725
<b>Product name</b>	Nufarm Saracen Herbicide
<b>Active constituent/s</b>	50 g/L florasulam
<b>Applicant name</b>	Nufarm Australia Limited
<b>Applicant ACN</b>	004 377 780
<b>Summary of variation</b>	To vary the distinguishing product name and the name that appears on the label from 'Saracen Herbicide' to 'Nufarm Saracen Herbicide'
<b>Date of variation</b>	7 September 2021
<b>Product registration no.</b>	89267
<b>Label approval no.</b>	89267/132725

<b>Application no.</b>	132786
<b>Product name</b>	Nufarm Sentry Herbicide
<b>Active constituent/s</b>	525 g/kg imazapic, 175 g/kg imazapyr
<b>Applicant name</b>	Nufarm Australia Limited
<b>Applicant ACN</b>	004 377 780
<b>Summary of variation</b>	To vary the distinguishing product name and the name that appears on the label from 'Sentry Herbicide' to 'Nufarm Sentry Herbicide'
<b>Date of variation</b>	9 September 2021
<b>Product registration no.</b>	67951
<b>Label approval no.</b>	67951/132786

<b>Application no.</b>	132799
<b>Product name</b>	Atlas Kill & Protect High Performance Crawling Flying All In One Indoor & Outdoor Multi Insect Spray
<b>Active constituent/s</b>	1.26 g/kg esbiothrin, 0.5 g/kg permethrin
<b>Applicant name</b>	Pascoe's Pty Ltd
<b>Applicant ACN</b>	055 220 463
<b>Summary of variation</b>	To vary the distinguishing product name and the name that appears on the label from 'Atlas Kill & Protect High Performance Multi All In One Insect Spray' to 'Atlas Kill & Protect High Performance Crawling Flying All In One Indoor & Outdoor Multi Insect Spray'
<b>Date of variation</b>	10 September 2021
<b>Product registration no.</b>	91251
<b>Label approval no.</b>	91251/132799

<b>Application no.</b>	132828
<b>Product name</b>	Conquest Indoxacarb 150 EC Insecticide
<b>Active constituent/s</b>	150 g/L S-indoxacarb
<b>Applicant name</b>	Conquest Crop Protection Pty Ltd
<b>Applicant ACN</b>	098 814 932
<b>Summary of variation</b>	To vary the distinguishing product name and the name that appears on the label from 'Conquest Stalwart 150 EC Insecticide' to 'Conquest Indoxacarb 150 EC Insecticide'
<b>Date of variation</b>	13 September 2021
<b>Product registration no.</b>	87447
<b>Label approval no.</b>	87447/132828

<b>Application no.:</b>	126172
<b>Product name:</b>	Zampro Fungicide
<b>Active constituent/s:</b>	300 g/L ametoctradin, 225 g/L dimethomorph
<b>Applicant name:</b>	BASF Australia Ltd.
<b>Applicant ACN:</b>	008 437 867
<b>Summary of variation:</b>	To add control of downy mildew in bulb vegetables, leafy vegetables, including brassica leafy vegetables, cucurbits, beetroots and poppies
<b>Date of variation:</b>	14 September 2021
<b>Product registration no.:</b>	63651
<b>Label approval no.:</b>	63651/126172

<b>Application no.</b>	132867
<b>Product name</b>	Kordon Termite System
<b>Active constituent/s</b>	4 g/kg deltamethrin
<b>Applicant name</b>	Bayer Cropscience Pty Ltd
<b>Applicant ACN</b>	000 226 022
<b>Summary of variation</b>	To vary the distinguishing product name and the name that appears on the label from 'Kordon Termite Barrier' to 'Kordon Termite System'
<b>Date of variation</b>	15 September 2021
<b>Product registration no.</b>	60759
<b>Label approval no.</b>	60759/132867

<b>Application no.:</b>	129989
<b>Product name:</b>	TH5 Broad Spectrum Disinfectant Against Bacteria, Fungi And Viruses
<b>Active constituent/s:</b>	327.5 g/L benzalkonium chloride, 100 g/L glutaraldehyde
<b>Applicant name:</b>	Mediralis Pty Ltd
<b>Applicant ACN:</b>	605 830 626
<b>Summary of variation:</b>	To include use as a virucidal agent
<b>Date of variation:</b>	20 September 2021
<b>Product registration no.:</b>	88612
<b>Label approval no.:</b>	88612/129989

<b>Application no.:</b>	127349
<b>Product name:</b>	Seguris Flexi Fungicide
<b>Active constituent/s:</b>	125 g/L isopyrazam
<b>Applicant name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of variation:</b>	To add the control of diseases in almonds
<b>Date of variation:</b>	23 September 2021
<b>Product registration no.:</b>	80618
<b>Label approval no.:</b>	80618/127349

<b>Application no.:</b>	131472
<b>Product name:</b>	Smart Glyphosate 450 Herbicide
<b>Active constituent/s:</b>	450 g/L glyphosate (present as the isopropylamine salt)
<b>Applicant name:</b>	Crop Smart Pty Ltd
<b>Applicant ACN:</b>	093 927 961
<b>Summary of variation:</b>	To amend the constituent statement, storage and disposal, first aid instructions and safety directions
<b>Date of variation:</b>	23 September 2021
<b>Product registration no.:</b>	60952
<b>Label approval no.:</b>	60952/131472

<b>Application no.:</b>	131487
<b>Product name:</b>	Tordon 75-D Herbicide
<b>Active constituents:</b>	300 g/L 2,4-d present as the triisopropanolamine salt, 75 g/l picloram present as the triisopropanolamine salt
<b>Applicant name:</b>	Corteva Agriscience Australia Pty Ltd
<b>Applicant ACN:</b>	003 771 659
<b>Summary of variation:</b>	To amend the product label in line with the 2,4-D reconsideration final regulatory decision and add the use of agricultural non-crop areas, commercial and industrial areas, pastures, rights of way under the permit to label project
<b>Date of variation:</b>	23 September 2021
<b>Product registration no.:</b>	40487
<b>Label approval no.:</b>	40487/131487

## 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**

<b>Application no:</b>	131005
<b>Product name:</b>	Moximax Long Acting Injection for Cattle
<b>Active constituent/s:</b>	100 mg/mL moxidectin
<b>Applicant name:</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For the treatment and control of moxidectin sensitive internal and external parasites in cattle
<b>Date of registration:</b>	15 September 2021
<b>Product registration no.:</b>	91130
<b>Label approval no.:</b>	91130/131005

<b>Application no.:</b>	130614
<b>Product name:</b>	Ferrari Cyclosporin Oral Solution for Cats
<b>Active constituent/s:</b>	100 mg/mL cyclosporin
<b>Applicant name:</b>	Ferrari Animal Health Pty Ltd
<b>Applicant ACN:</b>	162 206 671
<b>Summary of use:</b>	For the treatment of allergic dermatitis in cats
<b>Date of registration:</b>	20 September 2021
<b>Product registration no.:</b>	90969
<b>Label approval no.:</b>	90969/130614

<b>Application no:</b>	130917
<b>Product name:</b>	Jurox GnRH Injection
<b>Active constituent/s:</b>	47.6 µg/mL gonadorelin equivalent to 50 µg/mL gonadorelin acetate
<b>Applicant name:</b>	Jurox Pty Ltd
<b>Applicant ACN:</b>	000 932 230
<b>Summary of use:</b>	For use in oestrus synchronisation programs in combination with PGF2a; for the treatment of cystic ovaries, prevention of delayed ovulation and improvement of postpartum fertility in cattle
<b>Date of registration:</b>	21 September 2021
<b>Product registration no.:</b>	91092
<b>Label approval no.:</b>	91092/130917

<b>Application no:</b>	126258
<b>Product name:</b>	Increxxa Injectable Solution
<b>Active constituent/s:</b>	100 mg/mL tulathromycin
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of use:</b>	For the treatment of tulathromycin sensitive bacterial respiratory infections in pigs and in cattle, including dairy heifers up to the point of first mating
<b>Date of registration:</b>	23 September 2021
<b>Product registration no.:</b>	89866
<b>Label approval no.:</b>	89866/126258

<b>Application no:</b>	126327
<b>Product name:</b>	DeLaval Prima
<b>Active constituent/s:</b>	102.9 g/L glycerine, 5.1 g/L hydrogen peroxide
<b>Applicant name:</b>	Delaval Pty Ltd
<b>Applicant ACN:</b>	004 210 459
<b>Summary of use:</b>	For use as an aid in reducing the spread of mastitis-causing organisms in dairy cattle
<b>Date of registration:</b>	27 September 2021
<b>Product registration no.:</b>	89910
<b>Label approval no.:</b>	89910/126327

<b>Application no:</b>	131602
<b>Product name:</b>	Mectoguard Fly & Lice Jetting Fluid
<b>Active constituent/s:</b>	16 g/L ivermectin
<b>Applicant name:</b>	Four Seasons Agribusiness Pty Ltd
<b>Applicant ACN:</b>	115 133 189
<b>Summary of use:</b>	For the treatment of, and protection against, blowfly strike on sheep for up to 12 weeks under low to moderate fly pressure and treatment of biting lice by jetting in long woolled sheep
<b>Date of registration:</b>	27 September 2021
<b>Product registration no.:</b>	91287
<b>Label approval no.:</b>	91287/131602

Table 4: Variations of registration

<b>Application no.</b>	132723
<b>Product name</b>	YP Amoxicillin soluble powder
<b>Active constituent/s</b>	870 mg/g amoxicillin as amoxicillin trihydrate
<b>Applicant name</b>	South Yarra Pharma Pty Ltd
<b>Applicant ACN</b>	629 173 351
<b>Summary of variation</b>	To vary the distinguishing product name and the name that appears on the label from 'Solu-cillin Soluble' to 'YP Amoxicillin soluble powder'
<b>Date of variation</b>	7 September 2021
<b>Product registration no.</b>	88291
<b>Label approval no.</b>	88291/132723

<b>Application no.:</b>	127002
<b>Product name:</b>	Tri-Solfen P
<b>Active constituent/s:</b>	40.6 g/L lignocaine as hydrochloride, 24.8 mg/L adrenaline as acid tartrate, 5.0 g/L cetrimide, 4.2 g/L bupivacaine as hydrochloride
<b>Applicant name:</b>	Dechra Veterinary Products (Australia) Pty. Ltd.
<b>Applicant ACN:</b>	614 716 700
<b>Summary of variation:</b>	To extend the claims to pigs and horses, add the pack sizes of 250 mL and 500 mL, add the WHP of 90 days for pigs and add a restraint statement for horses
<b>Date of variation:</b>	15 September 2021
<b>Product registration no.:</b>	88635
<b>Label approval no.:</b>	88635/127002

<b>Application no.:</b>	131429
<b>Product name:</b>	Ultravac BEF Vaccine
<b>Active constituent/s:</b>	Bovine Ephemeral Fever Standard Strain (BB2271-919) at $\geq 10^{4.3}$ TCID <sub>50</sub> /2 mL dose
<b>Applicant name:</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN:</b>	156 476 425
<b>Summary of variation:</b>	To update the signal heading and to add an additional pack size
<b>Date of variation:</b>	15 September 2021
<b>Product registration no.:</b>	41461
<b>Label approval no.:</b>	41461/131429

Application no.:	130697
Product name:	Rhinogard Bovine Herpesvirus 1 Live Intranasal Vaccine For Cattle
Active constituent/s:	Contains $\geq 10^4$ CCID <sub>50</sub> /dose (2 mL) BHV1
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To vary the relevant particulars and label approval to change the product name and amend the trade advice
Date of variation:	23 September 2021
Product registration no.:	49679
Label approval no.:	49679/130697

Table 5: Variation of label approval

Application no.:	130868
Product name:	Medetate Injection
Active constituent/s:	1 mg/mL medetomidine hydrochloride
Applicant name:	Jurox Pty Ltd
Applicant ACN:	000 932 230
Summary of variation:	To add additional pharmacology statements
Date of variation:	16 September 2021
Product registration no.:	65829
Label approval no.:	65829/130868

Application no.:	128307
Product name:	Ilium Syntocin Injection of Synthetic Oxytocin
Active constituent/s:	10 IU/ mL oxytocin
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	To vary the in-use-shelf-life on the approved label
Date of variation:	16 September 2021
Product registration no.:	50435
Label approval no.:	50435/128307

Application no.:	131558
Product name:	Vanguard B-Oral Live Vaccine For Dogs
Active constituent/s:	Live attenuated <i>Bordetella bronchiseptica</i> $\geq 1.4 \times 10^8$ CFU/dose
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To vary the label to update the dosage and administration instructions
Date of variation:	23 September 2021
Product registration no.:	88237
Label approval no.:	88237/131558

## Approved active constituents

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

**Table 6: Active constituent**

<b>Application no.:</b>	127481
<b>Active constituent/s:</b>	tulathromycin
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	23 September 2021
<b>Approval no.:</b>	90106

**Table 7: Variations of active constituent**

<b>Application no.:</b>	127945
<b>Active constituent/s:</b>	<i>Bacillus amyloliquefaciens</i> MBI 600
<b>Applicant name:</b>	BASF Australia Ltd.
<b>Applicant ACN:</b>	008 437 867
<b>Summary of variation:</b>	Variation of relevant particulars or conditions of an approved active constituent
<b>Date of variation:</b>	17 September 2021
<b>Approval no.:</b>	83292

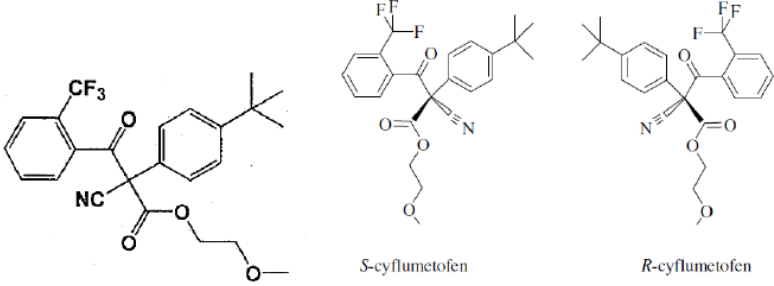
<b>Application no.:</b>	131497
<b>Active constituent/s:</b>	trilostane
<b>Applicant name:</b>	Dechra Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	Variation of relevant particulars or conditions of an approved active constituent
<b>Date of variation:</b>	23 September 2021
<b>Approval no.:</b>	86002



## New active constituent: cyflumetofen

The APVMA has before it an application for the approval of a new active constituent, cyflumetofen.

**Table 8: Particulars of the active constituent – cyflumetofen**

<b>Common name</b>	Cyflumetofen
<b>IUPAC name</b>	2-methoxyethyl (2 <i>RS</i> )-2-(4- <i>tert</i> -butylphenyl)-2-cyano-3-oxo-3-[2-(trifluoromethyl)phenyl]propanoate
<b>CAS name</b>	2-methoxyethyl $\alpha$ -cyano- $\alpha$ -[4-(1,1-dimethylethyl)phenyl]- $\beta$ -oxo-2-(trifluoromethyl)benzenepropanoate
<b>CAS registry number</b>	400882-07-7
<b>Manufacturer's codes</b>	OK-5101
<b>Minimum purity</b>	975 g/kg
<b>Molecular formula</b>	C <sub>24</sub> H <sub>24</sub> F <sub>3</sub> NO <sub>4</sub>
<b>Molecular weight</b>	447.45 g/mol
<b>Structure</b>	
<b>Chemical family</b>	Beta-ketonitrile derivatives
<b>Mode of action</b>	The mode of action of cyflumetofen involves the inhibition of mitochondrial electron transport, which facilitates the rapid knockdown of spider mites and phytophagous mites.

## Summary of the APVMA's evaluation of cyflumetofen active constituent

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

The APVMA has completed a toxicological evaluation of cyflumetofen. The acceptable daily intake (ADI) for cyflumetofen proposed by APVMA is 0.2 mg/kg bw/d, based on a NOAEL of 16.5 mg/kg bw/d from both the 90-day and the 2-year rat studies. The NOAEL was established based on observed increases in vacuolation of adrenal cortical cells. An uncertainty factor of 100 is applied to account for inter-species extrapolation and intra-species variability in response.

An acute reference dose (ARfD) is not considered necessary for cyflumetofen.

The Scheduling Delegate of the Department of Health has made a final decision to include cyflumetofen in Schedule 5 of the Poisons Standard, with an implementation date of 1 October 2021.

The APVMA considers that there are no objections on toxicological grounds to the approval of the active constituent cyflumetofen.

Based on the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for cyflumetofen technical active constituent:

Constituent	Specification
Cyflumetofen	975 g/kg minimum

Other compounds of toxicological significance are not expected to occur in cyflumetofen technical active constituent.

The APVMA is satisfied that the proposed importation and use of cyflumetofen would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

## 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 cyflumetofen 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.

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.

**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:

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

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

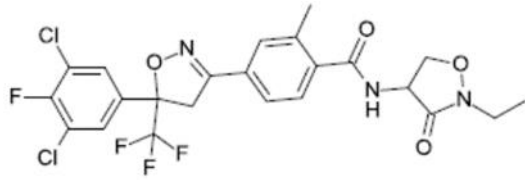
## Privacy

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

## New active constituent: isocycloseram

The APVMA has before it an application for the approval of a new active constituent, isocycloseram.

**Table 9: Particulars of the active constituent – isocycloseram**

<b>Common name</b>	Isocycloseram
<b>IUPAC name</b>	A mixture comprised of 80-100% 4-[(5 <i>S</i> )-5-(3,5-dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]- <i>N</i> -((4 <i>R</i> )-2-ethyl-3-oxo-1,2-oxazolidin-4-yl)-2-methylbenzamide and 20-0% of the (5 <i>R</i> ,4 <i>R</i> ), (5 <i>R</i> ,4 <i>S</i> ) and (5 <i>S</i> ,4 <i>S</i> ) isomers
<b>CAS name</b>	Benzamide, 4-[5-(3,5-dichloro-4-fluorophenyl)-4,5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]- <i>N</i> -(2-ethyl-3-oxo-4-isoxazolidinyl)-2-methyl-
<b>CAS registry number</b>	2061933-85-3
<b>Manufacturer's codes</b>	SYN547407
<b>Minimum purity</b>	960 g/kg
<b>Molecular formula</b>	C <sub>23</sub> H <sub>19</sub> Cl <sub>2</sub> F <sub>4</sub> N <sub>3</sub> O <sub>4</sub>
<b>Molecular weight</b>	548.3 g/mol
<b>Structure</b>	
<b>Chemical family</b>	Isioxazoline
<b>Mode of action</b>	Insecticide with a novel GABA-gate chloride antagonist mode of action

### Summary of the APVMA's evaluation of isocycloseram active constituent

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

The APVMA has completed a toxicological evaluation of isocycloseram. The acceptable daily intake (ADI) for isocycloseram proposed by APVMA is 0.02 mg/kg bw/d, based on a NOAEL of 1.7 mg/kg bw/d from in male and 1.8 mg/kg bw/d in females in an 80-week dietary study in mice. The NOAEL was based on lymphatic and non-lymphatic plasmacytosis in males and females at the next higher dose. An uncertainty factor of 100 is applied to account for inter-species extrapolation and intra-species variability in response.

An acute reference dose (ARfD) has been established for isocycloseram at 0.08 mg/kg bw/d for women of child-bearing age based on a NOAEL of 7.5 mg/kg bw/d identified on the basis of an increased incidence of bifid sternum in rats which might be attributable to a single exposure to isocycloseram at 15 mg/kg bw/d in a rat developmental toxicity study. In the absence of any chemical specific data to adjust the uncertainty factor for extrapolation from laboratory animals to humans or take account of differences in human responses a default 100-fold uncertainty factor is applied to the NOAEL.

The Scheduling Delegate of the Department of Health has made a final decision to include isocycloseram in Schedule 6 of the Poisons Standard, with no concentration cut-off. The implementation date is 1 October 2021.

The APVMA considers that there are no objections on toxicological grounds to the approval of the active constituent isocycloseram.

Based on the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for isocycloseram technical active constituent:

Constituent	Specification	Level
Isocycloseram	Isocycloseram [sum of 4 stereoisomers, (5S, 4R), (5S, 4S), (5R, 4R) and (5R, 4S)]	960 g/kg minimum
	(5S, 4R) isomer	875 g/kg minimum
	(5S, 4S) isomer	30 g/kg maximum
	(5R, 4R) isomer	55 g/kg maximum
	(5R, 4S) isomer	1 g/kg maximum

Other compounds of toxicological significance are not expected to occur in isocycloseram technical active constituent.

The APVMA is satisfied that the proposed importation and use of isocycloseram would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

## 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 isocycloseram 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.

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.

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:

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

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

## Privacy

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

## Prescribed date for payment of levy

Pursuant to section 6(1)(c) of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* notice is hereby given that for the 2020–21 financial year the prescribed date for payment of any levy that is payable is 15 January 2022.

Pursuant to section 6(1)(d) of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* notice is hereby given, that the levy amount payable is the levy amount generated from the 2020–21 sales declaration.

Further, it is directed under section 6(1)(d) that interested persons have the option to make payment of the entire levy payable in full by 15 January 2022, or nominate to pay the levy amount in two instalments of 50% of the total levy, with the first instalment amount payable by 15 January 2022 and the second instalment amount payable by 15 June 2022. If payment of the levy is made by instalments by the specified dates then the levy will be taken to have been paid by the prescribed date for payment for the 2020–21 financial year.

## APVMA contact

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

Finance  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

Phone: +61 2 6770 2300

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