

Commonwealth of Australia

Gazette

Agricultural and veterinary chemicals

No. APVMA 24, 30 November 2021

Published by the Australian Pesticides and Veterinary Medicines Authority



Australian Government

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.

© Commonwealth of Australia 2021

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority (APVMA). Requests and inquiries concerning reproduction and rights should be addressed to:

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

Email: communications@apvma.gov.au

Website: 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

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

If you would like to subscribe to receive email notification when a new edition is published, please complete a subscription form.

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.

Privacy

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

Contents

Agricultural chemical products and approved labels	1
Veterinary chemical products and approved labels	17
Approved active constituents	24
Licensing of veterinary chemical manufacturers	27
Amendments to the APVMA MRL Standard	29
Proposal to amend Schedule 20 in the Australian New Zealand Food Standards Code	30
Notice of cancellation at the request of the holder	36
Mateno Complete Herbicide containing aclonifen, diflufenican, pyroxasulfone	38
New veterinary chemical product containing a new veterinary active constituent: SOLENSIA Solution for Injection Cats containing frunevetmab	
List of tables	
Table 1: Agricultural products based on existing active constituents	1
Table 2: Variations of registration	5
Table 3: Label approval	14
Table 4: Variation of label approval	15
Table 5: Veterinary products based on existing active constituents	17
Table 6: Variations of registration	21
Table 7: Variation of label approval	23
Table 8: Active constituent	24
Table 9: New licenses issued by the APVMA under subsection 123(1) of the Agvet Code	27
Table 10: Licenses cancelled by the APVMA under subsection 127(1) of the Agvet Code	27
Table 11: Active constituent approval/product registration/label approval cancelled at the request of the holder	36
Table 12: Particulars of the application	38
Table 13: Particulars of the active constituent	40
Table 14: Particulars of the product	41
Table 15: Dosage and administration	44

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.	130972
Product name	Atlas Kill & Protect High Performance 2 In 1 Indoor & Outdoor Automatic Insect Control System
Active constituent/s	10.0 g/kg permethrin, 5.0 g/kg transfluthrin
Applicant name	Pascoe's Pty Ltd
Applicant ACN	055 220 463
Date of registration	8 November 2021
Product registration no.	91114
Label approval no.	91114/130972
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 g/kg permethrin and 5 g/kg transfluthrin aerosol product for the control of flies and insects indoors and outdoors

Application no.	130603
Product name	Kenso Agcare Pincer Selective Herbicide
Active constituent/s	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
Applicant name	Kenso Corporation (M) Sdn. Bhd.
Applicant ACN	N/A
Date of registration	9 November 2021
Product registration no.	90962
Label approval no.	90962/130603
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L pinoxaden and 25 g/L cloquintocet-mexyl emulsifiable concentrate product for the control of key grass weeds and selective spray topping of wild oats in wheat and barley

Application no.	132189
Product name	CropSure Atrazine 900WG Herbicide
Active constituent/s	900 g/kg atrazine
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of registration	9 November 2021
Product registration no.	91426
Label approval no.	91426/132189
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 900 g/kg atrazine water dispersible granule product for the control of weeds and grasses in sorghum, maize, sugar cane, TT-canola, lucerne and for fallow area maintenance and other situations

Application no.	132621
Product name	Buctril 200 EC Herbicide
Active constituent/s	200 g/L bromoxynil present as the N-octanoyl ester
Applicant name	Bayer Cropscience Pty Ltd
Applicant ACN	000 226 022
Date of registration	9 November 2021
Product registration no.	91548
Label approval no.	91548/132621
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L bromoxynil emulsifiable concentrate for the control of weeds in wheat, oats, barley, cereal rye and triticale, linseed, clover and lucerne pastures, turf, fallow, non-crop, roadsides, and rights-of-ways as specified in the directions for use table

Application no.	132328
Product name	Titan Vegetable Oil Ester Adjuvant
Active constituent/s	700 g/L fatty acid methyl esters
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	10 November 2021
Product registration no.	91472
Label approval no.	91472/132328
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 700 g/L fatty acid methyl ester emulsifiable concentrate product to assist the effectiveness of agricultural chemicals

Application no.	132460
Product name	CropSure Esstane LV 680 Herbicide
Active constituent/s	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of registration	10 November 2021
Product registration no.	91506
Label approval no.	91506/132460
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 680 g/L 2,4-D present as the 2-ethylhexyl ester emulsifiable concentrate product for selective control of various weeds in crops, pastures, and non-agricultural areas as per the directions for use table

Application no.	132494
Product name	Titan Rot-nil Fungicide
Active constituent/s	375 g/kg cyprodinil, 250 g/kg fludioxonil
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	12 November 2021
Product registration no.	91516
Label approval no.	91516/132494
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 375 g/kg cyprodinil and 250 g/kg fludioxonil water dispersible granule product for the control of various fungal diseases in capsicum, cut flowers, grapes, leafy vegetables, lettuce, nursery stock, onions, pyrethrum, and strawberries

Application no.	130642
Product name	Mortein Naturgard Crawling Insect Control Bomb Eucalyptus Scent
Active constituent/s	8.3 g/kg pyrethrins, 5.4 g/kg permethrin
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of registration	17 November 2021
Product registration no.	90976
Label approval no.	90976/130642
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 8.3 g/kg pyrethrins and 5.4 g/kg permethrin total release fogger for the control of crawling insects in domestic applications

Application no.	129062
Product name	Macphersons Japonica 850 WG Herbicide
Active constituent/s	850 g/kg pyroxasulfone
Applicant name	TGAC Australia Pty Ltd
Applicant CAN	134 570 700
Date of registration	18 November 2021
Product registration no.	90472
Label approval no.	90472/129062
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg pyroxasulfone water dispersible granule for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat) and triticale

Application no.	132369
Product name	Garden Basics Organic Weed Kill Concentrate
Active constituent/s	525 g/L nonanoic acid
Applicant name	Pinegro Products Pty Ltd
Applicant ACN	005 531 546
Date of registration	19 November 2021
Product registration no.	91484
Label approval no.	91484/132369
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 525 g/L nonanonic acid emulsifiable concentrate for non-selective control of seedling and young broadleaf and grass weeds, for suppression of established weeds and perennial species and for the control of moss and algae

Application no.	132439
Product name	CropSure MCPA 750 Herbicide
Active constituent/s	750 g/L MCPA present as the dimethylamine salt
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of registration	19 November 2021
Product registration no.	91502
Label approval no.	91502/132439
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 750 g/L MCPA present as the dimethylamine salt soluble concentrate for the selective control of broadleaf weeds in cereals, linseed, oilseed poppies, pastures, rice, sugar cane and turf as per directions for use table

Table 2: Variations of registration

Application no.	133344
Product name	SilaGROW Max Gibberellic Acid Growth Regulant
Active constituent/s	100 g/L gibberellic acid
Applicant name	Australian Adjuvants Pty Ltd
Applicant ACN	614 361 705
Date of variation	25 October 2021
Product registration no.	46740
Label approval no.	46740/133344
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 'Silawrap Max Gibberellic Acid Growth Regulant' to 'SilaGROW Max Gibberellic Acid Growth Regulant'

Application no.	133373
Product name	Roundup Ready Herbicide with Plantshield
Active constituent/s	690 g/kg glyphosate present as the mono-ammonium salt
Applicant name	Monsanto Australia Pty Ltd
Applicant ACN	006 725 560
Date of variation	26 October 2021
Product registration no.	63268
Label approval no.	63268/133373
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 update the safety directions appearing on the label to reflect the current FAISD Handbook

Application no.	133425
Product name	Nufarm Triflurx Herbicide
Active constituent/s	480 g/L trifluralin
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	1 November 2021
Product registration no.	56421
Label approval no.	56421/133425
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 'Nufarm Triflurx Selective Herbicide' to 'Nufarm Triflurx Herbicide'

Application no.	133428
Product name	Conserve Qalcova active Grain Protector
Active constituent/s	120 g/L spinosad
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	1 November 2021
Product registration no.	59914
Label approval no.	59914/133428
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 'Conserve Grain Protector' to 'Conserve Qalcova active Grain Protector'

Application no.	133429
Product name	Delegate Jemvelva active Insecticide
Active constituent/s	250 g/kg spinetoram
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	1 November 2021
Product registration no.	61717
Label approval no.	61717/133429
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 'Delegate Insecticide' to 'Delegate Jemvelva active Insecticide'

Application no.	133430
Product name	Conserve Plus Qalcova active Grain Protector
Active constituent/s	100 g/L spinosad, 100 g/L s-methoprene
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	1 November 2021
Product registration no.	81465
Label approval no.	81465/133430
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 'Conserve Plus Grain Protector' to 'Conserve Plus Qalcova active Grain Protector'

Application no.	133448
Product name	Kelpie Tric-P 600 Herbicide
Active constituent/s	600 g/L triclopyr present as the butoxyethyl ester
Applicant name	Sinochem International Australia Pty Ltd
Applicant ACN	160 164 616
Date of variation	3 November 2021
Product registration no.	67235
Label approval no.	67235/133448
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 'Accensi Triclopyr 600 Herbicide' to 'Kelpie Tric-P 600 Herbicide'

Application no.	133463
Product name	IA Nosclex 800 WG Fungicide
Active constituent/s	800 g/kg procymidone
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of variation	4 November 2021
Product registration no.	87227
Label approval no.	87227/133463
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 'Kelpie Procym 800 WG Fungicide' to 'IA Nosclex 800 WG Fungicide'

Application no.	132102
Product name	Venturi Insecticide
Active constituent/s	240 g/L methoxyfenozide
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	8 November 2021
Product registration no.	86724
Label approval no.	86724/132102
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 use in almonds, update the signal heading, restraints, WHP, safety directions and first aid instructions

Application no.	131197
Product name	Nufarm Tri-Base Blue Flowable Copper Fungicide
Active constituent/s	190 g/L copper (Cu) present as tribasic copper sulphate
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	9 November 2021
Product registration no.	53568
Label approval no.	53568/131197
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 consolidate current label uses into crop groups, add additional diseases in tree nuts and use in olives

Application no.	132330
Product name	Genfarm Captan 900 WG Fungicide
Active constituent/s	900 g/kg captan
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	9 November 2021
Product registration no.	67547
Label approval no.	67547/132330
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 almonds, update the withholding period and first aid instructions

Application no.	132441
Product name	Sabakem Imidacloprid 350SC Soil Insecticide
Active constituent/s	350 g/L imidacloprid
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of variation	9 November 2021
Product registration no.	69122
Label approval no.	69122/132441
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 the use into sugarcane (plant cane), peanuts, apples, citrus, brassicas, and potatoes

Application no.	132493
Product name	Nemasol
Active constituent/s	423 g/L metham present as sodium salt
Applicant name	Eastman Chemical Australia Pty Ltd
Applicant ACN	077 977 649
Date of variation	9 November 2021
Product registration no.	67922
Label approval no.	67922/132493
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 use in blueberries and <i>Rubus spp</i> . berries to product containing 423 g/L metham under the permit to label project

Application no.	131025
Product name	Rapidol Turf Fungicide
Active constituent/s	250 g/L mandestrobin
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of variation	11 November 2021
Product registration no.	89251
Label approval no.	89251/131025
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 claim from suppression to control of brown patch

Application no.	132370
Product name	Accensi 2,4-D / Picloram Herbicide
Active constituent/s	300 g/L 2,4-D as the triisopropanolamine salt, 75 g/L picloram as the triisopropanolamine salt
Applicant name	Accensi Pty Ltd
Applicant ACN	079 875 184
Date of variation	11 November 2021
Product registration no.	67490
Label approval no.	67490/132370
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 amend the product label in line with the 2,4-D reconsideration final regulatory decision and add uses for the control of <i>Pimelea sp</i> under the permit to label project

Application no.	132346
Product name	Maestro 200SC Insecticide
Active constituent/s	200 g/L fipronil
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	11 November 2021
Product registration no.	70280
Label approval no.	70280/132346
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 in pasture and mushrooms

Application no.	133533
Product name	Nufarm Kamba 750 Herbicide
Active constituent/s	750 g/L dicamba as the dimethylamine and monomethylamine salts
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	11 November 2021
Product registration no.	69302
Label approval no.	69302/133533
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 'Nufarm Kamba 750 Selective Herbicide' to 'Nufarm Kamba 750 Herbicide'

Application no.	132264
Product name	Accensi MCPA Di-Clo Turf Selective Herbicide
Active constituent/s	300 g/L MCPA present as the potassium salt, 20 g/L clopyralid present as the potassium salt, 15 g/L diffufenican
Applicant name	Accensi Pty Ltd
Applicant ACN	079 875 184
Date of variation	12 November 2021
Product registration no.	63728
Label approval no.	63728/132264
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 a pack size range with a smaller minimum pack size

Application no.	131112
Product name	Vaporfaze Emate Insecticide
Active constituent/s	901 g/L ethyl formate
Applicant name	Robert F. Ryan
Applicant ACN	56 202 487 758
Date of variation	12 November 2021
Product registration no.	64944
Label approval no.	64944/131112
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 the fumigation of insect pests in fresh fruit and vegetables

Application no.	132410
Product name	Mortein Kills Rats & Mice Rodent Throwpacks
Active constituent/s	0.05 g/kg brodifacoum
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of variation	12 November 2021
Product registration no.	54661
Label approval no.	54661/132410
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 vary the distinguishing product name and the name that appears on the label from 'Mortein Rat Kill Professional' to 'Mortein Kills Rats & Mice Rodent Throwpacks'

Application no.	132666
Product name	Farmalinx 2,4-D LV Ester 450 Herbicide
Active constituent/s	450 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	12 November 2021
Product registration no.	68007
Label approval no.	68007/132666
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 approve variations to the existing product registration and in line with the 2,4-D reconsideration final regulatory decision

Application no.	130930
Product name	Vectorforce ULV & Thermal Fogging RTU Insecticide
Active constituent/s	0.5 g/L cypermethrin
Applicant name	Sherwood Chemicals Australasia Pty Ltd
Applicant ACN	136 993 630
Date of variation	12 November 2021
Product registration no.	88242
Label approval no.	88242/130930
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 spiders to the label

Application no.	133612
Product name	Nufarm Weedmaster DST Herbicide
Active constituent/s	470 g/L glyphosate present as the potassium & mono-ammonium salt
Applicant name	Nufarm Australia Limited
Applicant CAN	004 377 780
Date of variation	16 November 2021
Product registration no.	62723
Label approval no.	62723/133612
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 'Nufarm Weedmaster DST Dual Salt Technology Herbicide' to 'Nufarm Weedmaster DST Herbicide'

Application no.	133613
Product name	Nufarm Crucial Herbicide
Active constituent/s	600 g/L glyphosate as potassium, monomethylamine & ammonium salt
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	16 November 2021
Product registration no.	86761
Label approval no.	86761/133613
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 'Nufarm CRUCIAL Advanced Technology Herbicide' to 'Nufarm CRUCIAL Herbicide'

Application no.	129336
Product name	Permatek BT 100 Timber Insecticide
Active constituent/s	100 g/L bifenthrin
Applicant name	Arch Wood Protection (Aust) Pty Ltd
Applicant ACN	003 780 872
Date of variation	17 November 2021
Product registration no.	56896
Label approval no.	56896/129336
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 vary the distinguishing product name and the name that appears on the label from 'Permatek 100 Timber Insecticide' to 'Permatek BT 100 Timber Insecticide'

Application no.	132656
Product name	Sanonda Herbicide 2,4-D ester 680EC
Active constituent	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name	Sanonda (Australia) Pty Ltd
Applicant ACN	059 813 973
Date of variation	17 November 2021
Product registration no.	87991
Label approval no.	87991/132656
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 amend the product label in line with the 2,4-D reconsideration final regulatory decision

Application no.	132892
Product name	GF-2576 Herbicide
Active constituents	300 g/L 2,4-D present as the triisopropanolamine salt, 75 g/L picloram present as the triisopropanolamine salt, 7.5 g/L aminopyralid present as the triisopropanolamine salt
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	17 November 2021
Product registration no.	65701
Label approval no.	65701/132892
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 amend the product label in line with the 2,4-D reconsideration final regulatory decision

Application no.	130568
Product name	Healthguard Miticide
Active constituent/s	56 g/L benzalkonium chloride, 40 g/L permethrin (40:60:cis:trans)
Applicant name	Global Speciality Chemicals Pty Ltd
Applicant ACN	050 237 977
Date of variation	19 November 2021
Product registration no.	53819
Label approval no.	53819/130568
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 include a use for repellence of mosquitoes on the product label. In addition to update the protections, storage and disposal statements, safety directions and first aid instructions in line with Agricultural Labelling Code and FAISD Handbook guidelines

Application no.	129119
Product name	Belanty Fungicide
Active constituent/s	75 g/L mefentrifluconazole
Applicant name	BASF Australia Ltd.
Applicant ACN	008 437 867
Date of variation	19 November 2021
Product registration no.	84344
Label approval no.	84344/129119
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 the control of blossom blight/brown rot in almond and husk spot in macadamia and suppression of alternaria in apples and shot hole, hull rot and leaf rust in almond

Table 3: Label approval

Application no.	133099
Product name	Blue Planet Pond Algae Control Blocks
Active constituent/s	13.75 g/kg diuron
Applicant name	QPharma Pty Ltd
Applicant ACN	145 418 882
Date of variation	17 November 2021
Product registration no.	62162
Label approval no.	62162/133099
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for the product 'Blue Planet Pond Algae Control Blocks' with the label name 'Pondmax For Gardens That Go The Extra Yard Algae Block'

Application no.	132977
Product name	Zoono Z-71 "Ready To Use" Poultry Guard Sanitiser And Protectant
Active constituent/s	0.67 g/L quaternary ammonium compound
Applicant name	Zoono Group Limited
Applicant ACN	006 645 754
Date of variation	19 November 2021
Product registration no.	89529
Label approval no.	89529/132977
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for the product 'Zoono Z-71 "Ready To Use" Poultry Guard Sanitiser and Protectant' with the label name 'YP VET 71 Surface Sanitiser and Protectant'

Application no.	133086
Product name	Farmalinx Techdeck Penetrant
Active constituent	1020 g/L polyether modified polysiloxane
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	19 November 2021
Product registration no.	67751
Label approval no.	67751/133086
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for the product 'Farmalinx Techdeck Penetrant' with the label name 'ProForce Scrubwet Penetrant Surfactant'

Table 4: Variation of label approval

Application no.	132266
Product name	Fyfanon 440 EW Insecticide
Active constituent/s	440 g/L malathion
Applicant name	FMC Australasia Pty Ltd
Applicant ACN	095 326 891
Date of variation	12 November 2021
Product registration no.	51150
Label approval no.	51150/132266
Description of the application and its purpose, including the intended use of the chemical product	Variation to the conditions of label approval to correct the application rates for stored cereal grain use pattern

Application no.	132248
Product name	Off! Botanicals Insect Repellent Spray
Active constituent/s	270 g/L oil of lemon eucalytpus (hydrated, cyclized)
Applicant name	S.C. Johnson & Son Pty Ltd
Applicant ACN	000 021 009
Date of variation	15 November 2021
Product registration no.	90891
Label approval no.	90891/ 132248
Description of the application and its purpose, including the intended use of the chemical product	Variation to the label approval to add a new label name and amended statement of claims

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 5: Veterinary products based on existing active constituents

Application no.	129786
Product name	Eprisure Pour-On for Cattle
Active constituent/s	5 mg/mL eprinomectin
Applicant name	Alleva Animal Health Limited
Applicant ACN	N/A
Date of registration	8 November 2021
Product registration no.	90690
Label approval no.	90690/129786
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 5 mg/mL eprinomectin pour-on product for the treatment and control of internal and external parasites of beef and dairy cattle and internal parasites of deer

Application no.	131892
Product name	StressEase Calming Diffuser for Cats
Active constituent/s	16.5 mg/mL synthetic analogue of F3 fraction of feline facial pheromone
Applicant name	Ceva Animal Health Pty Ltd
Applicant ACN	002 692 426
Date of registration	8 November 2021
Product registration no.	91341
Label approval no.	91341/131892
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 16.5 mg/mL synthetic analogue of F3 fraction of feline facial pheromone, liquid diffuser, to aid in alleviating signs associated with fear and stress in kittens and cats

Application no.	131904
Product name	StressEase Calming Collar for Dogs
Active constituent/s	50 g/kg synthetic analogue of the canine appeasing pheromone
Applicant name	Ceva Animal Health Pty Ltd
Applicant ACN	002 692 426
Date of registration	8 November 2021
Product registration no.	91342
Label approval no.	91342/131904
Description of the application and its purpose, including the intended use of the chemical product	Registration of a dog collar with 50 g/kg synthetic analogue of the canine appeasing pheromone, for aiding in alleviating or preventing fear related signs in dogs

Application no.	131905
Product name	StressEase Calming Collar for Puppies
Active constituent/s	50 g/kg synthetic analogue of the canine appeasing pheromone
Applicant name	Ceva Animal Health Pty Ltd
Applicant ACN	002 692 426
Date of registration	8 November 2021
Product registration no.	91343
Label approval no.	91343/131905
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 50 g/kg synthetic analogue of the canine appeasing pheromone collar for aiding in alleviating or preventing fear related signs in puppies

Application no.	131906
Product name	StressEase Calming Diffuser for Dogs
Active constituent/s	16.5 mg/mL synthetic analogue of the canine appeasing pheromone
Applicant name	Ceva Animal Health Pty Ltd
Applicant ACN	002 692 426
Date of registration	8 November 2021
Product registration no.	91344
Label approval no.	91344/131906
Description of the application and its purpose, including the intended use of the chemical product	Registration of a liquid diffuser product containing 16.5 mg/mL synthetic analogue of the canine appeasing pheromone for aiding in alleviation of signs associated with fear and stress in dogs and puppies

Application no.	131907
Product name	StressEase Calming Spray for Dogs
Active constituent/s	15.72 mg/mL synthetic analogue of the canine appeasing pheromone
Applicant name	Ceva Animal Health Pty Ltd
Applicant ACN	002 692 426
Date of registration	8 November 2021
Product registration no.	91345
Label approval no.	91345/131907
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 15.72 mg/mL liquid spray product for aiding in treatment and prevention of fear and stress related signs in puppies and adult dogs

Application no.	129369
Product name	Flyscreen Pour-On Insecticide for Horses
Active constituent/s	87 g/L permethrin (25:75 cis:trans)
Applicant name	Bocko P/L & Flexsky P/L in Partnership
Applicant ACN	147 389 678
Date of registration	9 November 2021
Product registration no.	90589
Label approval no.	90589/129369
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 87 g/L permethrin 25:75 (cis:trans) pour-on product for horses, for the control of susceptible Buffalo Fly (<i>Haematobia irritans exigua</i>), Stable Fly (<i>Stomoxys calcitrans</i>) and sandflies (<i>Culicoides spp.</i>) and aids in the treatment of Queensland Itch

Application no.	132303
Product name	DYFLY LONG BLOW Spray-On Sheep Blowfly Treatment
Active constituent/s	65 g/L dicyclanil
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	9 November 2021
Product registration no.	91462
Label approval no.	91462/132303
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 65 g/L topical solution of dicyclanil for the protection of sheep against fly strike caused by dicyclanil-susceptible strains of blowflies <i>Lucilia cuprina</i> , for up to 29 weeks. For the protection of mulesing and marking wounds on sheep against fly strike caused by dicyclanil-susceptible strains of blowflies <i>Lucilia cuprina</i> , during the wound healing process

Application no.	131115
Product name	Bainbridge Poultry Wormer
Active constituent/s	8.48 g/L levamisole present as levamisole hydrochloride
Applicant name	Bainbridge Pty Ltd
Applicant ACN	097 002 205
Date of registration	11 November 2021
Product registration no.	91175
Label approval no.	91175/131115
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 8.48 g/L levamisole (present as levamisole hydrochloride) oral solution product for the treatment of worms in food producing birds

Application no.	132375
Product name	TalentCare Moxidectin Pour-On for Cattle and Red Deer
Active constituent/s	5 g/L moxidectin
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	12 November 2021
Product registration no.	91485
Label approval no.	91485/132375
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 5 g/L moxidectin topical pour-on for the treatment and control of moxidectin sensitive internal and external parasites of cattle and for the treatment and control of lungworm and gastrointestinal roundworms of red deer

Application no.	130526
Product name	Reflex-F Pour-On for Cattle
Active constituent/s	300 mg/mL triclabendazole, 5 mg/mL abamectin
Applicant name	Alleva Animal Health Limited
Applicant ACN	N/A
Date of registration	17 November 2021
Product registration no.	90929
Label approval no.	90929/130526
Description of the application and its purpose, including the intended use of the chemical product	For the registration of a 300 mg/mL triclabendazole and 5 mg/mL abamectin pour-on solution product for the treatment and control of roundworms, liver fluke and external parasites of beef cattle

Application no.	132444
Product name	Overstrike Spray-On Sheep Blowfly Treatment
Active constituent/s	60 g/L cyromazine
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	18 November 2021
Product registration no.	91503
Label approval no.	91503/132444
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 60 g/L topical solution of cyromazine for the protection of long wool sheep against fly strike for 11 weeks when used as directed

Table 6: Variations of registration

Application no.	132368
Product name	Flukazole C Combination Fluke and Roundworm Drench for Cattle and Sheep
Active constituent/s	120 g/L triclabendazole, 45.3 g/L oxfendazole
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	10 November 2021
Product registration no.	52899
Label approval no.	52899/132368
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registered particulars of the chemical product and particulars of label approval, by adding the additional claim for the control of benzimidazole-sensitive mature and immature roundworms, lungworms, tapeworms, and early immature (including 2-week-old fluke), immature and mature liver fluke (<i>Fasciola hepatica</i>) in sheep

	·
Application no.	128476
Product name	Benzicare Mebendazole Lamb and Sheep Drench
Active constituent/s	50 g/L mebendazole
Applicant name	Parafarm Pty Ltd
Applicant ACN	161 661 696
Date of variation	10 November 2021
Product registration no.	38841
Label approval no.	38841/128476
Description of the application and its purpose, including the intended use of the chemical product	Variation of the particulars of the registered chemical product and label approval to add additional pack sizes

Application no.	132422
Product name	Meloxidolor 20 mg/mL Solution for Injection for Cattle, Pigs, Horses and Sheep
Active constituent/s	20 mg/mL meloxicam
Applicant name	Le Vet Beheer B. V.
Applicant ACN	N/A
Date of variation	10 November 2021
Product registration no.	88026
Label approval no.	88026/132422
Description of the application and its purpose, including the intended use of the chemical product	Variation of the registered particulars of the chemical product and particulars of label approval, by adding the additional claim in cattle for the reduction of pain and inflammation associated with surgery

Application no.	130030
Product name	Cetrigen Antibacterial Wound Aerosol
Active constituent/s	Each 100g contains: 4 g diethyltoluamide, 0.1 g cetrimide
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	12 November 2021
Product registration no.	38731
Label approval no.	38731/130030
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of a registered chemical product and label approval by removing active ingredient Di-n-propyl Isocinchomeronate and adding a new 250 g pack size

Application no.	130644
Product name	Cetrigen Antibacterial Wound Spray
Active constituent/s	40 mg/mL diethyltoluamide, 1 mg/mL cetrimide
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	12 November 2021
Product registration no.	45797
Label approval no.	45797/130644
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of a registered chemical product and label approval by removing active ingredient Di-n-propyl Isocinchomeronate

Application no.	133462
Product name	YP Amoxycillin feed grade
Active constituent/s	870 g/kg amoxycillin as the trihydrate
Applicant name	South Yarra Pharma Pty Ltd
Applicant ACN	629 173 351
Date of variation	4 November 2011
Product registration no.	88947
Label approval no.	88947/133462
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 'Solu-cillin FG' to 'YP Amoxycillin feed grade'

Application no.	132377
Product name	Cydectin Long Acting Injection for Sheep
Active constituent/s	20 g/L moxidectin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	17 November 2021
Product registration no.	58532
Label approval no.	58532/132377
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of both the product and label approval by adding a pack size of 550 mL, and updating the conditions of label approval to align with the current Veterinary Labelling Code

Table 7: Variation of label approval

Application no.	133548
Product name	Meloxidolor 20 mg/mL Solution for Injection for Cattle, Pigs, Horses and Sheep
Active constituent/s	20 mg/mL meloxicam
Applicant name	Le Vet Beheer B. V.
Applicant ACN	N/A
Date of variation	11 November 2021
Product registration no.	88026
Label approval no.	88026/133548
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of label approval to change the name that appears on the label from 'Meloxidolor 20 mg/mL Solution for Injection for Cattle, Pigs, Horses and Sheep' to 'Apex Meloxicam 20 mg/mL Solution for Injection for Cattle, Pigs, Horses and Sheep'

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 8: Active constituent

Application no.	130685
Active constituent/s	Eprinomectin
Applicant name	Alleva Animal Health Limited
Applicant ACN	N/A
Date of approval	8 November 2021
Approval no.	90997
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent eprinomectin for use in veterinary chemical products

Application no.:	132092
Active constituent/s:	Zinc phosphide
Applicant name:	Stotras Pty Ltd
Applicant ACN:	164 590 167
Date of approval:	9 November 2021
Approval no.:	91392
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent zinc phosphide for use in agricultural chemical products

Application no.:	129847
Active constituent/s:	Chlorantraniliprole
Applicant name:	UPL Australia Pty Ltd
Applicant ACN:	066 391 384
Date of approval:	9 November 2021
Approval no.:	90705
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlorantraniliprole for use in agricultural chemical products

Application no.:	130351
Active constituent/s:	MCPA
Applicant name:	Shanghai Hanfu Biotechnology Co Ltd
Applicant ACN:	N/A
Date of approval:	10 November 2021
Approval no.:	90893
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent MCPA for use in agricultural chemical products

Application no.:	131167
Active constituent/s:	Difenoconazole
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Date of approval:	10 November 2021
Approval no.:	91191
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent difenoconazole for use in agricultural chemical products

Application no.	132785
Active constituent/s	Triclabendazole
Applicant name	Alleva Animal Health Limited
Applicant ACN	N/A
Date of approval	17 November 2021
Approval no.	91598
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.	130050
Active constituent/s	Saflufenacil
Applicant name	ADAMA Australia Pty Limited
Applicant ACN	050 328 973
Date of approval	18 November 2021
Approval no.	90796
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent saflufenacil for use in agricultural chemical products

Application no.	124878
Active constituent/s	Isocycloseram
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	18 November 2021
Approval no.	89440
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent isocycloseram for use in agricultural chemical products

Application no.	132317
Active constituent/s	Benazepril hydrochloride
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	19 November 2021
Approval no.	91470
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent benazepril hydrochloride for use in veterinary chemical products

Licensing of veterinary chemical manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action with respect to the licensing of the following veterinary chemical manufacturers with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the APVMA website.

New licenses

The APVMA has issued the following licenses under subsection 123(1) of the Agvet Code:

Table 9: New licenses issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Dermcare- Vet Pty. Ltd	1109	010 280 010	7 Centenary Road Slacks Creek QLD 4127	Category 1: Sterile and immunobiological products Category 2: Creams/lotions and liquids Category 3: Creams/lotions and liquids	Quality assurance (QA) of raw materials, formulation including blending, filling, aseptic filling, packaging, repackaging, labelling, relabelling, analysis, and testing (physical, chemical and microbiological), storage and release for supply.	4 November 2021
Austasia Animal Products Pty Ltd	4090	083 458 566	29 Wongajong Road Forbes NSW 2871	Category 4: Premixes and supplements	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, pellet extrusion, storage, and release for supply.	4 November 2021

Licence cancellations

The APVMA has cancelled the following licenses under subsection 127(1) of the Agvet Code:

Table 10: Licenses cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Nutrien Ag Solutions Limited	6202	008 743 217	71 Colebard Street West Acacia Ridge QLD 4110	19 November 2021

^{*}Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: Single-step manufacturer

APVMA contact

Manufacturing Quality and Licensing Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2301 **Email:** <u>mls@apvma.gov.au</u>

^{*}Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: Single-step manufacturer

Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019. The MRL Standard lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The MRL Standard also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice, and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the MRL Standard and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 9) 2021.

The amendments will be incorporated into the compilation of the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019.

The MRL Standard is accessible via the Federal Register of Legislation website.

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

Proposal to amend Schedule 20 in the Australian New Zealand Food Standards Code

In the previous notice on page 32 of APVMA Gazette No. 24, the APVMA gazetted amendments which it has approved to vary maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out in the APVMA's MRL Standard.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (Agricultural and Veterinary Chemicals Code *(MRL Standard)* Amendment Instrument 2021 (No. 9)) to MRLs into Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The agreement between the Australian Government and the New Zealand Government concerning a Joint Food Standards System excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

A Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) will be made.

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.

Proposed variation to Schedule 20 in the Australia New Zealand Food Standards Code

30 November 2021

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunsetting.

To commence: on gazettal of variation

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] omitting the chemical residue definition for cyflumetofen and substituting the following

Agvet chemical: Cyflumetofen Permitted residue – commodities of plant origin: Cyflumetofen Permitted residue – commodities of animal origin: Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen

[1.2] inserting in alphabetical order

Agvet chemical: Florylpicoxamid

Permitted residue: commodities of plant origin: Sum of florylpicoxamid and (2S)-1,1-bis(4-fluorophenyl)propan-2-yl N-{[3-(hydroxy)-4-methoxypyridin-2-yl]carbonyl}-L-alaninate (X12485649), expressed as florylpicoxamid Permitted residue: commodities of animal origin: (2S)-1,1-bis(4-fluorophenyl)propan-2-yl N-{[3-(hydroxy)-4-methoxypyridin-2-yl]carbonyl}-L-alaninate (X12485649), expressed as florylpicoxamid

Edible offal (mammalian)	0.02	
Eggs	*0.01	
Meat (mammalian) (in the fat)	0.02	
Milks	*0.01	
Poultry meat (in the fat)	*0.01	
Poultry, edible offal of	*0.01	
Wheat	0.02	
Wheat bran, unprocessed	0.07	

[1.3] omitting from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Aclonifen			
Permitted residue: Aclonifen			
Meat (mammalian)	T*0.01		
Milks	T*0.01		
Poultry meat	T*0.01		

Agvet chemical:	Cyflumetofen
-----------------	--------------

Permitted residue – commodities of plant

origin: Cyflumetofen

Permitted residue - commodities of animal origin: Sum of cyflumetofen and 2trifluoromethylbenzoic acid, expressed as cyflumetofen

Grapes	0.6
Tomato	0.3

Agvet chemical: Dithiocarbamates

Permitted residue: Total dithiocarbamates, determined as carbon disulphide evolved during acid digestion and expressed as milligrams of carbon disulphide per kilogram of food

Fruiting vegetables, other than cucurbits [except roselle]

Agvet chemical: Propiconazole

Permitted residue: Propiconazole

T0.2 Soya bean (dry)

[1.4] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Aclonifen			
Permitted residue: Aclonifen			
Meat (mammalian) [in the fat]	*0.01		
Milks [in the fat]	*0.01		
Poultry meat [in the fat]	*0.01		

Agvet chemical: Cyflumetofen

Permitted residue - commodities of plant

origin: Cyflumetofen

Permitted residue - commodities of animal

origin: Sum of cyflumetofen and 2trifluoromethylbenzoic acid, expressed as cyflumetofen

Dried grapes (currants, raisins

and sultanas)

Edible offal (mammalian) *0.03 2

Fruiting vegetables, other than cucurbits

Grapes (except dried) 0.7 Meat (mammalian) *0.03

Milks *0.003

Agvet chemical: Cyprodinil		
Permitted residue: Cyprodinil		
Peppers, chili (except dried)	T0.7	

Agvet chemical: Dithiocarbamates

Permitted residue: Total dithiocarbamates, determined as carbon disulphide evolved during acid digestion and expressed as milligrams of carbon disulphide per kilogram of food

Fruiting vegetables, other than cucurbits [except roselle; tomato]

Tomato T5

Agvet chemical: Fludioxonil

Permitted residue – commodities of animal origin: Sum of fludioxonil and oxidisable metabolites, expressed as fludioxonil

Permitted residue – commodities of plant

origin: Fludioxonil

Peppers, chili (except dried) T2

Agvet chemical: Imazapic

Permitted residue: Sum of imazapic and its hydroxymethyl derivative

Oats *0.02

Agvet chemical: Imazapyr

Permitted residue: Imazapyr

Oats *0.01

Agvet chemical: Propiconazole

Permitted residue: Propiconazole

Pulses T0.3

Agvet chemical: Spirotetramat

Permitted residue: Sum of spirotetramat, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat

Peanut *0.02

[1.5] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Aclonifen		
Permitted residue: Aclonifen		
Barley	*A A1	

Agvet chemical: Aclonifen	
Edible offal (mammalian)	*0.01
Eggs	*0.01
Poultry, edible offal of	*0.01
Wheat	*0.01

Agvet chemical: Cyflumetofen

Permitted residue – commodities of plant origin: Cyflumetofen

Permitted residue – commodities of animal origin: Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen

Pome fruits	0.5
Strawberry	0.8

Agvet chemical: Glyphosate

Permitted residue: Sum of glyphosate, N-acetylglyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate

Invitation for submissions

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA.

Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, and surveys. Technical information should be in sufficient detail to allow independent scientific assessment.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

Deadline for public submissions

Submissions must be received by 28 December 2021. Submissions received after this deadline will only be considered by prior arrangement or if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the <u>public</u> consultation coversheet).

Please lodge your submission using the <u>public consultation coversheet</u>, 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.

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

Privacy

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

Notice of cancellation at the request of the holder

At the request of the holder, in accordance with section 42(1) of the *Agricultural and Veterinary Chemicals Code Act* 1994 (Agvet Code), the APVMA has cancelled the approvals and/or registrations set out in Table 11:

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

Approval or registration number	Name	Type of approval or registration	Holder	Reason for cancellation (if relevant pursuant to s 45A(3))	Date of cancellation
53738/54292 53738/0107 53738/0902	PY-BO Natural Pyrethrum Insecticidal Concentrate	Label approval	Pestech Australia Pty Ltd	At the request of the holder	15 October 2021
51150/101326 51150/59265 51150/0606 51150/0999	FYFANON 440 EW Insecticide	Label approval	FMC Australasia Pty Ltd	At the request of the holder	12 November 2021
44565	Benzofenap	Active constituent	OAT Agrio Co Ltd	At the request of the holder	16 November 2021
56139	Brodifacoum	Active constituent	Garrards Pty Ltd	At the request of the holder	22 November 2021

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

Instructions

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

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

Possession or custody

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 11 in accordance with its label instructions for 12 months from the date of cancellation.

Use, supply or otherwise deal with

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in Table 11 according to its label instructions, including any conditions relating to shelf life or expiry date, for 12 months after the date of cancellation.

A person may supply or cause to be supplied at wholesale or retail level the cancelled active constituent, cancelled product, or product bearing a cancelled label referred to in Table 11, for 12 months after the date of cancellation.

Contraventions

After the day that is 12 months from the date of cancellation it will be an offence against the Agvet Code to have possession or custody of the cancelled active constituents, cancelled products or products bearing a cancelled label with the intention to supply, or to supply the cancelled active constituent, cancelled product, or product bearing a cancelled label.

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

APVMA contact

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

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

Phone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au

More information

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

Mateno Complete Herbicide containing aclonifen, diflufenican, pyroxasulfone

The APVMA has before it an application for registration of a new product, Mateno Complete Herbicide containing a new active constituent, aclonifen and the existing approved actives diffusenican and pyroxasulfone.

Table 12: Particulars of the application

Proposed product name	Mateno Complete Herbicide
Applicant company	Bayer Cropscience Pty Ltd
Name of active constituent	aclonifen, diflufenican, pyroxasulfone
Signal heading	Poison
Summary of proposed use	Registration of a 400 g/L/aclonifen, 66 g/L/diflufenican and 100 g/L/pyroxasulfone suspension concentrate product for the pre-emergence or post-emergence control or suppression of various grass and broadleaf weeds in wheat (not durum wheat) and barley.
Pack sizes	1 L to 1000 L
Withholding period	Harvest: NOT REQUIRED WHEN USED AS DIRECTED Grazing: DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 6 WEEKS AFTER APPLICATION

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

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Mateno Complete Herbicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - ii. The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - iii. The APVMA is satisfied that the proposed use of Mateno Complete Herbicide will not be an undue hazard to the safety of people using anything containing its residues.
 - iv. The APVMA is satisfied that the proposed use of Mateno Complete Herbicide is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.
- 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 Mateno Complete Herbicide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the <u>APVMA website</u> or by contacting the APVMA as listed below.

Making a submission

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

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

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

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

Please lodge your submission with a <u>public submission coversheet</u>, 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: enquiries@apvma.gov.au

Post:

Executive Director Registration Management Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Privacy

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

New veterinary chemical product containing a new veterinary active constituent: SOLENSIA Solution for Injection for Cats containing frunevetmab

The APVMA has before it an application for the approval of a new active constituent frunevetmab, and application for registration of a new product containing the new active constituent. The product is SOLENSIA Solution for Injection for Cats for the alleviation of pain associated with osteoarthritis in cats.

Table 13: Particulars of the active constituent

Common name	Frunevetmab
CAS name	Immunoglobulin G1, anti-(Mus musculus nerve growth factor) (Felis catus – Rattus norvegicus monoclonal NV-02 heavy chain (HC), disulphide with Felis catus – Rattus novegicus monoclonal NV-02 light chain (LC), dimer
CAS registry number	1708936-80-4
Molecular formula	C6540H10114N1768O2060S48
Molecular weight	147,987.9 Da (without glycans and with all cysteines in disulphide bonds)
Structure	Heavy chain QVQLVESGAE LVQPGESLRL TCAASGFSLT NNNVNWVRQA PGKGLEWMGG 50 VWAGGATDYN SALKSRLTIT RDTSKNTVFL QMHSLQSEDT ATYYCARDGG 100 YSSSTLYAMD AWGQGTTVTV SAASTTAPSV FPLAPSCGTT SGATVALACL 150 VLGYFPEPVT VSWNSGALTS GVHTFPAVLQ ASGLYSLSSM VTVPSSRWLS 200 DTFTCNVAHP PSNTKVDKTV RKTDHPPGPK PCDCPKCPPP EMLGGPSIFI 250 FPPKPKDTLS ISRTPEVTCL VVDLGPDDSD VQITWFVDNT QVYTAKTSPR 300 EEQFNSTYRV VSVLPILHQD WLKGKEFKCK VNSKSLPSPI ERTISKAKGQ 350 PHEPQVYVLP PAQEELSRNK VSVTCLIKSF HPPDIAVEWE ITGQPEPENN 400 YRTTPPQLDS DGTYFVYSKL SVDRSHWQRG NTYTCSVSHE ALHSHHTQKS 450 LTQSPGK 457 Light chain DIEMTQSPLS LSVTPGESVS ISCRASEDIY NALAWYLQKP GRSPRLLIYN 50' TDTLHTGVPD RFSGSGSGTD FTLKISRVQT EDVGVYFCQH YFHYPRTFGQ 100' GTKLELKRSD AQPSVFLFQP SLDELHTGSA SIVCILNDFY PKEVNVKWKV 150' DGVVQNKGIQ ESTTEQNSKD STYSLSSTLT MSSTEYQSHE KFSCEVTHKS 200' LASTLVKSFN RSECQRE 217'
Chemical family	Monoclonal antibody
Mode of action	Frunevetmab is an IgG1 monoclonal antibody (mAb) directed at feline nerve growth factor (NGF). Binding of frunevetmab with the NGF prevents NGF binding to its cellular receptor and prevents the activation of nociceptive neurons to transmit pain signals from the peripheral to the central nervous system. This is associated with pain reduction in degenerative joint disease (osteoarthritis) in cats.

Summary of the APVMA's evaluation of frunevetmab active constituent

The APVMA has evaluated the new active constituent frunevetmab under sections 5A(1)(a),(b) and (c) of the Agvet Code and proposes to be satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry aspects of frunevetmab active constituent (identification and physico-chemical properties, starting materials, master seeds (source, identity, and purity), culture media, manufacturing process and quality control procedures, specifications, batch analysis and stability results and analytical methods) and found them to be acceptable.

The APVMA has considered the health aspect of the active. Based on the data supplied, in conjunction with an exposure assessment which indicated very low potential of human exposure. The main route of exposure is accidental self-injection/needle stick injury. Post-application exposure is limited to needle disposal. Exposure of the general public is not expected.

Frunevetmab is only for use in non-food producing animals (cats), hence establishment of health-based guidance values such as Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) are not required. The APVMA has considered the toxicological aspects of frunevetmab and concluded that there are no toxicological concerns to the approval of this active constituent.

Frunevetmab is a 'monoclonal antibody', which is included in a Schedule 4 generic entry for monoclonal antibodies of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The APVMA proposes to be satisfied that the proposed importation and use of frunevetmab in a veterinary chemical product 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.

Table 14: Particulars of the product

Proposed product name	SOLENSIA Solution For Injection For Cats
Applicant company	Zoetis Australia Pty Ltd
Name of active constituent	Frunevetmab
Scheduling	Schedule 4
Pharmaceutical form	Injectable solution
Summary of proposed use	For the alleviation of pain associated with osteoarthritis in cats.
Pack sizes	1 x 1 mL vial of 7 mg/mL
Withholding period	2 x 1 mL vials of 7 mg/mL

Summary of proposed product use:

SOLENSIA Solution for Injection for Cats is an immunological medicinal product for veterinary use which contains a felinised mAb as the active, targeting and inactivating the feline nerve growth factor (NGF) which mediates pain at sites of injury. The active frunevetmab inhibits NGF-mediated cell signalling activity (anti-NGF), which provides relief from pain associated to osteoarthritis in cats.

Dose and route of administration: Frunevetmab in SOLENSIA Solution for Injection for Cats is proposed to be administered subcutaneously to cats at a dose rate of 1 to 2.8 mg/kg. For ease of administration the applicant recommends 7 mg (1 mL) for cats between 2.5 and 7.0 kg and 14 mg (2 mL) for cats from more than 7.1 to 14.0 kgs. The product is administered in monthly intervals.

Side effects: Mild, focal skin reactions (dermatitis, alopecia and pruritis) were commonly observed.

Summary of the APVMA's evaluation of SOLENSIA Solution for injection for cats in accordance with the requirements of section 14(1)(c) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994:*

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:
 - i. The APVMA is satisfied that the proposed use of SOLENSIA Solution for Injection for Cats would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA conducted a risk assessment for the product and in conjunction with the estimated hazard profile, determined whether the proposed use of the product would be an undue health hazard to humans.

SOLENSIA Solution for Injection for Cats does not contain any adjuvants or novel excipients. The excipients in the proposed formulation are present in several products registered for use in Australia or overseas, and would be expected to be of low oral, dermal and inhalational toxicity. The APVMA has concluded that there are negligible risks to the health and safety of people from the proposed commercial release of frunevetmab, either in the short or long term.

SOLENSIA Solution for Injection for Cats is not intended for use by the general public. Given this product is injectable, human exposure to SOLENSIA Solution for Injection for Cats is expected to be minimal. The persons using SOLENSIA Solution for Injection for Cats would be veterinarians (or persons under their direction). These persons would be experienced/trained in the handling of animals and the administration of veterinary drugs, including injectable products and the use of aseptic technique and safety practices in withdrawing solution from a vial.

The volume of product to which a user might be exposed would be expected to be minimal, except possibly for accidental self-injection and breakage of the vial, where injection of the entire contents of the syringe or spillage of the entire contents of the vial onto the skin are worst-case scenarios.

The proposed product labelling includes appropriate first aid instructions, safety directions and the additional user safety statements. The product label will contain first aid statement: 'If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26'. Safety directions of 'Wash hands after use' and the additional user safety are included in the label to mitigate the risk.

Although the potential exposure risks by accidental self-injection is rare, the label contains following additional user safety statements:

Take care to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the Medical Practitioner.

Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection. These reactions are most likely to occur following the development of an immune response after repeated self-administration.

The importance of Nerve Growth Factor in ensuring normal foetal nervous system development is well-established and laboratory studies conducted on non-human primates with human anti-NGF antibodies have shown evidence of reproductive and developmental toxicity. Pregnant women, women trying to conceive, and breastfeeding women should take extreme care to avoid accidental self-injection or needle stick injuries.

ii. The APVMA is satisfied that the proposed use of SOLENSIA Solution for Injection for Cats will not be an undue hazard to the safety of people using anything containing their residues.

The product is for use in companion animals (cats) only. SOLENSIA Solution for Injection for Cats is unlikely to enter the food chain.

- iii. The APVMA is satisfied that the proposed use of SOLENSIA Solution for Injection for Cats containing the active constituent frunevermab is not likely to be harmful to human beings if used according to the product label directions.
- iv. Frunevetmab is a 'monoclonal antibody', which is included in a Schedule 4 generic entry for monoclonal antibodies of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The origin, preparation, passage history and testing of the master cell seed had been described adequately, and the results were acceptable. The working cell seed was also tested appropriately and the results were acceptable.

- v. The APVMA is satisfied that the proposed use of SOLENSIA Solution for Injection for Cats is not likely to have an unintended effect that is harmful to cats, plants or the environment if used according to the product label directions
- vi. For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.
- vii. This Veterinary Medicinal Product will only be used in non-food animals. Hence, it satisfies the requirements of VICH phase 1. The APVMA is therefore satisfied that the proposed product meets the environmental safety criteria.
- viii. Frunevetmab is an immunological product and disposal instructions consistent with the Veterinary Labelling Code will be included on the label.
- ix. The results of the target animal safety studies indicated that, at the proposed label dose rate of 1 2.8 mg/kg via a subcutaneous injection, SOLENSIA Solution for Injection for Cats is unlikely to cause serious adverse reactions in cats and appropriate, precautions, side effects and contraindication statements are included on the label.
- x. The safety studies were conducted up to 84 days with the proposed dose administered at monthly intervals. A sufficient argument was provided that the product will be safe for long term use. A precautionary statement to mitigate potential risks has been included on the label as: 'Duration of treatment should be based on the individual response of each animal. If a positive response is not observed, consider alternative treatments'.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy under section 5B(2)(a), 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 the proposed use.

The efficacy data submitted and assessed included clinical trials, scientific arguments and literature references on the use of the applicant's proposed product in cats. The efficacy data package comprised of published literature, dose determination studies, dose confirmation studies, laboratory efficacy studies and field/clinical efficacy studies. The APVMA has concluded that the data generated from the efficacy studies support the claim: 'For the alleviation of pain associated with osteoarthritis in cats' when the product is administered subcutaneously to cats at a dose rate of 1 to 2.8 mg/kg.

ii. The recommended minimum dose of SOLENSIA Solution for Injection for Cats is 1 mg/kg bodyweight, administered subcutaneously once a month. Cats will be treated according to the table below.

Table 15: Dosage and administration

Bodyweight(kg) of cat	SOLENSIA dosage
2.5 - 7.0	1 mL (1 vial)
7.1 - 14.0	2 mL (2 vials)

- 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, and proposes to determine that:
 - i. Review of the formulation indicates that the excipients are not novel, and the product is not for food producing animals (cats). 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 frunevetmab 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 SOLENSIA Solution For Injection For Cats should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

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

Please lodge your submission with a <u>public submission coversheet</u>, 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: enquiries@apvma.gov.au

Post:

Case Management and Administration Unit Veterinary Medicines Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Privacy

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