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Gazette

Agricultural and veterinary chemicals

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

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General information

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

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

Distribution and subscription

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

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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.	131777
Product name	Speramet Insecticide
Active constituent	240 g/L spirotetramat
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of registration	27 April 2022
Product registration no.	91307
Label approval no.	91307/131777
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L spirotetramat suspension concentrate product for the control of various pests in <i>Brassica</i> vegetables (broccoli, broccolini, Brussel sprouts, cabbage, cauliflower, kohlrabi), mangoes and cotton

Application no.	134427
Product name	ProForce Pistol 600 SC Fungicide
Active constituent	600 g/L thiram
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	28 April 2022
Product registration no.	92075
Label approval no.	92075/134427
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L thiram suspension concentrate product for use as a seed treatment for the control of various fungal diseases of seeds and as a drench to control fungal diseases of turf

Application no.	134675
Product name	Glyfo-TDI Herbicide
Active constituent	360 g/L glyphosate present as the isopropylamine salt
Applicant name	Globachem N.V.
Applicant ACN	N/A
Date of registration	28 April 2022
Product registration no.	92148
Label approval no.	92148/134675
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 360 g/L glyphosate present as the isopropyl amine salt product formulated as soluble liquid concentrate, a general-purpose total herbicide for the non-selective control of many annual and perennial weeds and grasses in certain situations

Application no.	131939
Product name	Altacor X-Force Insecticide
Active constituent	700 g/kg chlorantraniliprole
Applicant name	FMC Australasia Pty Ltd
Applicant ACN	095 326 891
Date of registration	29 April 2022
Product registration no.	91353
Label approval no.	91353/131939
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 700 g/kg chlorantraniliprole water dispersible granule product for the control of Lepidopteran species of insect pests in certain fruit and nut crops

Application no.	134889
Product name	Virkon Professional Tablets
Active constituents	494 g/kg potassium peroxomonosulfate triple salt, 15 g/kg sodium chloride
Applicant name	Alltech Lienert Australia Pty Ltd
Applicant ACN	008 293 007
Date of registration	29 April 2022
Product registration no.	92230
Label approval no.	92230/134889
Description of the application and its purpose, including the intended use of the chemical product	Registration of a broad-spectrum disinfectant containing 494 g/kg potassium peroxomonosulfate triple salt, 15 g/kg sodium chloride and 49 g/kg sulphamacacid for use in cleaning and disinfecting industrial, animal and agricultural equipment facilities

Application no.	130168
Product name	Imtrade Conjurer 750 WG Plant Growth Regulator
Active constituent	750 g/kg paclobutrazol
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	3 May 2022
Product registration no.	90833
Label approval no.	90833/130168
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 750 g/kg paclobutrazol water dispersible granule product to reduce vegetative growth in various fruiting tree crops

Application no.	129358
Product name	Farmalinx Slay'em Trio Fungicide
Active constituents	119 g/L thiophanate-methyl, 37.5 g/L fluazinam, 36 g/L tebuconazole
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	4 May 2022
Product registration no.	90578
Label approval no.	90578/129358
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 119 g/L thiophanate-methyl, 37.5 g/L fluazinam and 36 g/L tebuconazole suspension concentrate product for the control of various fungi species in turf

Application no.	134808
Product name	EuroChem Chlorpyrifos 750 WG Insecticide
Active constituent	750 g/kg chlorpyrifos (an anticholinesterase compound)
Applicant name	EuroChem Pty Ltd
Applicant ACN	622 603 507
Date of registration	6 May 2022
Product registration no.	92193
Label approval no.	92193/134808
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 750 g/kg water dispersible granule formulation of chlorpyrifos for the control of insect pests in fruit and other situations as specified in the directions for use

Application no.	134422
Product name	Gardenline Organic Weedkiller Ready to Use
Active constituent	36.8 g/L nonanoic acid
Applicant name	Denbies Pty Ltd
Applicant ACN	623 145 540
Date of registration	6 May 2022
Product registration no.	92073
Label approval no.	92073/134422
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 36.8 g/L nonanoic acid product for the control of weeds, moss and algae in gardens, paths and driveways

Application no.	134501
Product name	AgMerch Dicamba 500 Herbicide
Active constituent	500 g/L dicamba (present as the dimethylamine salt)
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Date of registration	6 May 2022
Product registration no.	92099
Label approval no.	92099/134501
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L dicamba (present as the dimethylamine salt) soluble concentrate product for the control of certain broadleaf weeds in winter cereals, pastures, conservation tillage, sugar cane, turf, rice and non-crop areas

Table 2: Variations of registration

Application no.	133265
Product name	Ultrathor Water-Based Termiticide and Insecticide
Active constituent	100 g/L fipronil
Applicant name	Ensystex Australasia Pty Ltd
Applicant ACN	102 221 965
Date of variation	26 April 2022
Product registration no.	64449
Label approval no.	64449/133265
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 list specific pest species under existing pest groups and to add new pests to existing situations

Application no.	133978
Product name	ProFume Gas Fumigant
Active constituent	998 g/kg sulfuryl fluoride
Applicant name	Douglas Products & Packaging Company
Applicant ACN	N/A
Date of variation	28 April 2022
Product registration no.	59952
Label approval no.	59952/133978
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label to include a new use for the pest rodents, as well as to update the product manual and various other label sections including the restraints, withholding periods, general instructions, protections, precautions and safety directions

Application no.	132663
Product name	UNYUNOX 250 EC Selective Herbicide
Active constituent	250 g/L ioxynil present as ioxynil octanoate
Applicant name	AgNova Technologies Pty Ltd
Applicant ACN	097 705 158
Date of variation	28 April 2022
Product registration no.	87974
Label approval no.	87974/132663
Description of the application and its purpose, including the intended use of the chemical product	Variation of the particulars of registration and label approval to include reduced label rates, earlier application timing (crop stage) and new re-entry periods

Application no.	134376
Product name	OzCrop Propaz Herbicide
Active constituent	500 g/L propyzamide
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of variation	28 April 2022
Product registration no.	66883
Label approval no.	66883/134376
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 canola and mustard

Application no.	132601
Product name	Avatar eVo Insecticide
Active constituent	303 g/kg indoxacarb
Applicant name	FMC Australasia Pty Ltd
Applicant ACN	095 326 891
Date of variation	4 May 2022
Product registration no.	86106
Label approval no.	86106/132601
Description of the application and its purpose, including the intended use of the chemical product	Variation of registered particulars and label approval to add use in macadamia nuts and amend the application rate for fruiting cucurbit vegetables

Application no.	134347
Product name	Imtrade Bromacil 800 WG Herbicide
Active constituent	800 g/kg bromacil
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of variation	6 May 2022
Product registration no.	87247
Label approval no.	87247/134347
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label particulars to add uses in citrus, pineapple and asparagus

Table 3: Label approval

Application no.	134795
Product name	Scotts Lawn Builder Weed, Feed & Green-up
Active constituents	15 g/L MCPA present as the dimethylamine salt, 2.3 g/L dicamba present as the dimethylamine salt
Applicant name	Evergreen Garden Care Australia Pty Ltd
Applicant ACN	003 123 162
Date of variation	27 April 2022
Product registration no.	47860
Label approval no.	47860/134795
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Scotts Lawn Builder Weed, Feed & Green-Up' with the label name 'Scotts Lawn Builder Weed, Feed & Green-Up 3 In 1 Weedkill & Fertiliser'

Application no.	134792
Product name	Scotts Lawn Builder, Bindii, Clover & Broadleaf, Kills and Prevents
Active constituents	8.7 g/L bromoxynil present as the potassium salt, 8.7 g/L MCPA present as the potassium salt
Applicant name	Evergreen Garden Care Australia Pty Ltd
Applicant ACN	003 123 162
Date of variation	27 April 2022
Product registration no.	84676
Label approval no.	84676/134792
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Scotts Lawn Builder, Bindii, Clover & Broadleaf, Kills and Prevents' with the label name 'Scotts Lawn Builder Bindii, Clover & Broadleaf, Weedkill & Prevent'

Application no.	134778
Product name	Scotts Lawn Builder Buffalo Weed, Feed & Green-up
Active constituents	8.7 g/L bromoxynil present as the potassium salt, 8.7 g/L MCPA present as the potassium salt
Applicant name	Evergreen Garden Care Australia Pty Ltd
Applicant ACN	003 123 162
Date of variation	6 May 2022
Product registration no.	82584
Label approval no.	82584/134778
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Scotts Lawn Builder Buffalo Weed, Feed & Green-Up' with the label name 'Scotts Lawn Builder Buffalo Weed, Feed & Green-Up 3 In 1 Weedkill & Fertiliser'

Table 4: Variation of label approval

Application no.	134278
Product name	PLEMAX Insecticide
Active constituents	(a) 320 g/L indoxacarb (75:25) (equivalent to 240 g/L active s-isomer), 80 g/L novaluron or (b) 267 g/L indoxacarb (90:10) (equivalent to 240 g/L active s-isomer), 80 g/L novaluron
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	28 April 2022
Product registration no.	88077
Label approval no.	88077/134278
Description of the application and its purpose, including the intended use of the chemical product	Variation to the conditions of label approval to amend the active constituent statement and update the spray drift instructions on the 'Quali-Pro Twister Insecticide' label

Veterinary chemical products and approved labels

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

Table 5: Variations of registration

Application no.	134224
Product name	Suprelorin 4.7 mg
Active constituent/s	4.7 mg/implant deslorelin as deslorelin acetate
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	28 April 2022
Product registration no.	56107
Label approval no.	56107/134224
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to change product name and minor label updates including alignment with the Veterinary Labelling Code

Application no.	134226
Product name	Suprelorin 9.4 mg
Active constituent/s	9.4 mg/implant deslorelin as deslorelin acetate
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	28 April 2022
Product registration no.	60359
Label approval no.	60359/134226
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to change product name and minor label updates including alignment with the Veterinary Labelling Code

Application no.	134273
Product name	Iverquantel Roundworm, Bot and Tapeworm Oral Paste for Horses
Active constituent/s	50 mg/mL praziquantel, 4 mg/mL ivermectin
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	28 April 2022
Product registration no.	59407
Label approval no.	59407/134273
Description of the application and its purpose, including the intended use of the chemical product	Variation of labelling particulars to update the environmental information

Application no.	133981
Product name	Milbemax Tablets for Small Cats
Active constituent/s	10 mg/tablet praziquantel, 4 mg/tablet milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	29 April 2022
Product registration no.	54264
Label approval no.	54264/133981
Description of the application and its purpose, including the intended use of the chemical product	Variation of the label approval to amend the dosing schedule table

Application no.	133982
Product name	Milbemax Tablets for Cats
Active constituent/s	40 mg/tablet praziquantel, 16 mg/tablet milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	2 May 2022
Product registration no.	54265
Label approval no.	54265/133982
Description of the application and its purpose, including the intended use of the chemical product	Variation of the label approval to amend dosing schedule table

Application no.	131942
Product name	
Product name	CLiK Extra Spray-On Sheep Blowfly Treatment
Active constituent/s	65 g/L dicyclanil
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	4 May 2022
Product registration no.	81863
Label approval no.	81863/131942
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered product and label approval, and variation to the conditions of registration by updating the dosing table

Table 6: Label approval

Application no.	134647
Product name	Equiwormer Plus Tape Oral Paste for Horses
Active constituent/s	46.2 mg/g praziquantel, 3.7 mg/g abamectin
Applicant name	RWR Veterinary Products Pty Ltd
Applicant ACN	088 423 018
Date of variation	4 May 2022
Product registration no.	58236
Label approval no.	58236/134647
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for the registered product 'Equiwormer Plus Tape Oral Paste for Horses' with the label name 'Curahorse Fusion Action Broadspectrum Oral Paste Wormer Plus Tape'

Application no.	134648
Product name	RWR Mor-N-Mectin Oral Horse Worming Paste
Active constituent/s	167 mg/g morantel tartrate, 4 mg/g abamectin
Applicant name	RWR Veterinary Products Pty Ltd
Applicant ACN	088 423 018
Date of variation	4 May 2022
Product registration no.	69678
Label approval no.	69678/134648
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for the registered product 'RWR Mor-N-Mectin Oral Horse Worming Paste' with the label name 'Curahorse Dual Action Broadspectrum Oral Paste Wormer Plus Boticide'

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 7: Active constituent

Application no.	130722
Active constituent	Imazapic
Applicant name	Wei Fang Cynda Group
Applicant ACN	N/A
Date of approval	27 April 2022
Approval no.	91007
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imazapic for use in agricultural chemical products

Application no.	133085
Active constituent	Pyroxasulfone
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of approval	28 April 2022
Approval no.	91671
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyroxasulfone for use in agricultural chemical products

Application no.	133553
Active constituent	Iron dextran complex
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	4 May 2022
Approval no.	91815
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent iron dextran complex for use in veterinary chemical products

Application no.	133133
Active constituent	Pyrasulfotole
Applicant name	Agroshine Australia Pty Ltd
Applicant ACN	105 873 023
Date of approval	5 May 2022
Approval no.	91686
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyrasulfotole for use in agricultural chemical products

Application no.	133270
Active constituent	Oclacitinib maleate
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of approval	5 May 2022
Approval no.	91726
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent oclacitinib maleate for use in veterinary chemical products

Application no.	133796
Active constituent	Barium selenate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	6 May 2022
Approval no.	91886
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent barium selenate for use in veterinary chemical products

New active constituent: Rescalure

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, rescalure. Rescalure is a synthetic copy of the naturally occurring mating attraction sex pheromone for Californian red scale (*Aonidiella aurantii*), which will be used for disrupting the mating activities of pest insects.

Table 8: Particulars of the active constituent

Common name:	Rescalure
IUPAC name:	(3S,6RS)-6-(Prop-1-en-2-yl)-3-methyldec-9-en-1-yl acetate
CAS name:	9-Decen-1-ol, 3-methyl-6-(1-methylethenyl)-,1-acetate
CAS registry numbers:	64309-03-1 (1:1 mixture of 3S,6R and 3S,6S isomers) 67601-06-3 for the (3S,6R) isomer 67601-10-9 for the (3S,6S) isomer
Manufacturer's codes:	California Red Scale Pheromone
Minimum purity:	806.8 g/kg The 3S,6R and 3S,6S isomer ratio should be 45:55 to 55:45
Molecular formula:	$C_{16}H_{28}O_2$
Molecular weight:	252.39 gmol ⁻¹
Structure:	(3S,6R)-6-(Prop-1-en-2-yl)-3-methyldec-9-en-1-yl acetate
Chemical family:	Alkenyl acetate
Mode of action:	Rescalure is a synthetic insect sex pheromone for Californian Red Scale (Aonidiella aurantii), which will be used for disrupting the mating activities of pest insects.

Summary of the APVMA's evaluation of rescalure active constituent

The APVMA has evaluated the chemistry aspects of rescalure active constituent (physico-chemical properties, identification, 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 rescalure.

An acceptable daily intake (ADI) and an acute reference dose (ARfD) were not established.

Three diastereomers of the Cluster 2 impurity have been identified as toxicologically significant impurities (as sensitisers) in technical rescalure.

Rescalure is included in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with an exemption from scheduling being appropriate for products such as that proposed for registration, CheckMate

CRS (Product No: 90682) that is an agricultural use when enclosed in a vapour releasing device which in normal use prevents access to its contents.

The APVMA Health Assessment Team has indicated that there are no objections on toxicological grounds to the approval of the active constituent rescalure.

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

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for rescalure:

Table 9: APVMA standard proposed for rescalure active constituent

Constituent	Specification	Level
Rescalure	Rescalure	806.8 g/kg minimum The 3S,6 <i>R</i> and 3S,6 <i>S</i> isomer ratio should be 45:55 to 55:45
Sum of Impurity <i>J</i> and its stereoisomers <i>J2</i> and <i>K</i>	Tetrahydro-2-[{3(RS)-methyl-6-[1(RS)-methylethenyl]-9-decen-1-yl}oxy]-2H-pyran	Total 10 g/kg maximum

Further information

A Public Release Summary (PRS) of the evaluations of the active and the associated product is available from the <u>APVMA website</u>.

Making a submission

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether rescalure 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.

When making a submission please include:

- contact name
- · company or group name (if relevant)
- · email or postal address
- the date you made the submission.

All personal and confidential commercial information (CCI) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

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

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

CheckMate CRS containing rescalure

The APVMA has before it an application for registration of a new product, CheckMate CRS containing a new active constituent, rescalure.

Table 10: Particulars of the application

Proposed product name	CheckMate CRS
Applicant company	Suterra LLC
Name of active constituent	(3S,6R)-(3S,6S)-6-isopropenyl-3-methyl-dec-9-en-1-yl acetate (rescalure)
Signal heading	Schedule 6
Summary of proposed use	Registration of a 70 mg/dispenser of (3S, 6R)-(3S, 6S)-3-methyl-6-isopropenyl-9-decen-1-yl acetate (Rescalure), a slow release generator Product (SR formulation), for the use in mating disruption of <i>Aonidiella aurantii Maskell</i> (California Red Scale) in citrus and any other crops where this species may be a pest.
Pack sizes	1000 dispensers (70 g)
Withholding period	Not required when used as directed

A summary of the APVMA's evaluation of CheckMate CRS 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 CheckMate CRS would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of CheckMate CRS will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of CheckMate CRS 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:
 - In relation to its assessment of efficacy, the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that when 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:
 - i. The APVMA is considering whether the proposed use of CheckMate CRS would not adversely affect trade between Australia and places outside Australia.

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 CheckMate CRS 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:

Post:

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

Email: casemanagement@apvma.gov.au

Privacy

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

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 licences

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

Table 11: New licences 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
DHL Supply Chain (Australia) Pty Ltd	6239	071 798 617	1 Botero Place Truganina VIC 3029	Category 6: (Single step manufacture) – all dosage forms	Storage (only)	25 March 2022
Linfox Australia Pty Ltd	6240	004 718 647	27-49 Lenore Drive Erskine Park NSW 2759	Category 6: (Single-step manufacture) – all dosage forms	Secondary packaging, secondary labelling, storage and release for supply	25 March 2022

Licence cancellations

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

Table 12: Licences 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	6201	008 743 217	Suite 3 Level 1, Building B 11 Talavera Road Macquarie Park NSW 2113	24 March 2022

APVMA contact

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

Phone: +61 2 6770 2301 **Email**: mls@apvma.gov.au

^{*}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

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. 3) 2022.

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 20 of APVMA Gazette No. 10, 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 2022 (No. 3)) 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

17 May 2022

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 from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Fluopyram	
Permitted residue – commodities of plant origin: Fluopyram	
Permitted residue – commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl benzamide, expressed as fluopyram)-
Almonds	0.05
Tree nuts	0.05
Agvet chemical: Fluroxypyr	
Permitted residue: Fluroxypyr	
Cereal grains	0.2

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

Agvet chemical: Bifenthrin	
Permitted residue: Bifenthrin	
Fig	T1
Agvet chemical: Diflufenican	
Permitted residue: Diflufenican	
Safflower seed	T*0.05
Agvet chemical: Fluopyram	
Permitted residue – commodities of plant origin: Fluopyram	
Permitted residue – commodities of animal origin: Sum of fluopyram and 2-(trifluoromethy benzamide, expressed as fluopyram	/l)-
Tree nuts [except walnuts]	0.05
Walnuts	T0.07
Agvet chemical: Fluroxypyr	
Permitted residue: Fluroxypyr	

Agvet chemical: Fluroxypyr	
Cereal grains [except rice bran, unprocessed]	0.2
Rice bran, unprocessed	T0.3

Agvet chemical: Prothioconazole

Permitted residue – commodities of plant origin: Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as Prothioconazole

Permitted residue – commodities of animal origin: Sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole

Sunflower seed	*0.02
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Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Sunflower seed	0.1
Agvet chemical: Tetraniliprole	
Permitted residue: Tetraniliprole	
Fig	T0.5
Agvet chemical: Trifludimoxazin	
Permitted residue: Trifludimoxazin	
Oats	*0.01
Triticale	*0.01

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

Agvet chemical: Indoxacarb	
Permitted residue: Sum of indoxacarb and its Risomer	-
Macadamia nuts	0.03

Agvet chemical: Thiabendazole

Permitted residue – commodities of plant

origin: Thiabendazole

Permitted residue - commodities of animal

origin: Sum of thiabendazole and 5-

hydroxylthiabendazole, expressed as thiabendazole

Taro

T50

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 14 June 2022. 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.

Variations to Schedule 20 of the Australian New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA MRL Standard and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Schedule 20 – Maximum residue limits of the Australia New Zealand Food Standards Code. This notice pertains to proposals (No. 1) gazetted on 08 February 2022 No. APVMA 3.

Submissions have been sought on these proposals and the APVMA has written separately to each person or organisation that made a submission. All matters raised in the submissions have been resolved.

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Schedule 20. A copy of the Amendment Instrument (No. APVMA 2, 2022) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the <u>Federal Register of Legislation</u>.

Based on dietary exposure assessments and current health standards, the APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied that these MRLs are not harmful to public health. 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 by minimising residues in foods consistent with the effective control of pests and diseases.

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 notification to the World Trade Organization (WTO) was also made in relation to the variations to MRLs in Schedule 20 and comment was received in response to that notice which has been addressed.

A copy of these variations have been given to FSANZ.

The variations take effect as from the date of this notice.

This notice is published in accordance with subsection 82(7) of the Food Standards Australia New Zealand Act 1991.

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

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Australian Government

Australian Pesticides and Veterinary Medicines Authority

Australia New Zealand Food Standards Code — Schedule 20 — Maximum residue limits Variation Instrument No. APVMA 2, 2022

I, Sheila Logan, delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals* (*Administration*) *Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Sheila Logan

Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this eleventh day of May 2022

Part 1 Preliminary

1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code* — *Schedule 20 – Maximum residue limits Variation Instrument No. APVMA 2, 2022* (Amendment Instrument).

2 Commencement

In accordance with subsection 82(8) of the *Food Standards Australia New Zealand Act* 1991, this instrument commences on the day it is published in the *Gazette*.

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia Agricultural and Veterinary Chemicals Gazette.

3 Object

The object of this instrument is for the APVMA to make variations to Schedule 20 – Maximum residue limits in the *Australia New Zealand Food Standards Code* to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

4 Interpretation

In this instrument: —

APVMA means the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and

Principal Instrument means Schedule 20–Maximum residue limits in the Australia New Zealand Food Standard Code as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the Code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that Code. Schedule 20 was published in the *Food Standards Gazette* FSC 96 on Thursday 10 April 2015 and was registered as a legislative instrument on 1 April 2015 (F2015L00468).

Part 2 Variations to Schedule 20– Maximum Residue Limits

5 Variations to Schedule 20

The Schedule to this instrument sets out the variations made to the Principal Instrument by this instrument.

Schedule

Variations to Schedule 20 - Maximum residue limits

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

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

Agvet chemical: Difenoconazole	
Permitted residue: Difenoconazole	
Beetroot	0.5
Carrot	0.2
Cereal grains	*0.01
Tomato	0.5
Agvet chemical: Pydiflumetofen	
Permitted residue: Pydiflumetofen	
Root and tuber vegetables	T0.05

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

Agvet chemical: Acequinocyl	
Permitted residue: Sum of acequinocyl and its metabolite 2-dodecyl-3-hydroxy-1,4-naphthoquexpressed as acequinocyl	inone,
All other foods except animal food commodities	0.02
Tomato	T0.3

Agvet chemical: Acetamiprid

Permitted residue – commodities of plant

origin: Acetamiprid

Permitted residue – commodities of animal origin: Sum of acetamiprid and N-demethyl acetamiprid ((E)-N¹-[(6-chloro-3-pyridyl)methyl]-N²-cyanoacetamidine), expressed as acetamiprid

Cane berries [except raspberries, 1 red, black]

Agvet chemical: Difenoconazole	
Permitted residue: Difenoconazole	
Cereal grains [except rice]	*0.01
Fruiting vegetables, cucurbits	0.3
Fruiting vegetables, other than cucurbits	1
Peanut	*0.01
Rice	T7

Agvet chemical: Difenoconazole	
Root and tuber vegetables [except celeriac; potato]	0.5
Agvet chemical: Mesotrione	
Permitted residue: Mesotrione	
Poppy seed	T*0.01
Agvet chemical: Methoxyfenozide	
Permitted residue: Methoxyfenozide	
Mango	T0.5
Agvet chemical: Pydiflumetofen	
Permitted residue: Pydiflumetofen	
Potato	T0.05
Root and tuber vegetables [except potato]	0.3
Agvet chemical: Pyriproxyfen	
Permitted residue: Pyriproxyfen	
Cane berries	1
Agvet chemical: Sulfoxaflor	
Permitted residue: Sulfoxaflor	
Blueberries	T2

Agvet chemical: Tulathromycin

Permitted residue: Sum of tulathromycin and its metabolites that are converted by acid hydrolysis to (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-ß-D-xylohexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one, expressed as tulathromycin equivalents

Sheep fat	*0.05
Sheep kidney	0.3
Sheep liver	1
Sheep muscle	0.15

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

Agvet chemical: Difenoconazole	
Permitted residue: Difenoconazole	
Celery	10

Agvet chemical: Pydiflumetofen	
Permitted residue: Pydiflumetofen	
Peanut	0.03

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 13:

Table 13: 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
53404/62929 53404/0401 53404/0101	Rid Australia Medicated Rid Insect Repellent Antiseptic + Chamomile + Vitamin E 4 Hours Mosquito Protection Neutral Scent Total Family Protection	Label	Cavalieri Investing Pty Ltd	Labelling criteria	26 April 2022
54760	Betamethasone	Active constituent	Jurox Pty Ltd	N/A	22 April 2022
62619	Brodifacoum	Active constituent	Agrimart Industries Pty Ltd	N/A	14 April 2022

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 13.

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 13 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 13 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 13 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 13, 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 13 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.