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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.	142095
Product name	F.S.A. Clopyralid 600 Advance Herbicide
Active constituent	600 g/L clopyralid present as the isopropylamine and monoethanolamine salts
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	16 February 2024
Product registration no.	94328
Label approval no.	94328/142095
Description of the application and its purpose, including the intended use of the chemical product	Registration of a soluble concentrate (SL) product containing 600 g/L clopyralid present as the isopropylamine and monoethanolamine salts for the control and suppression of broadleaf weeds in barley, canola, fallow land, forestry, industrial and commercial situations, oats, pastures, triticale, and wheat

Application no.	142027
Product name	OzCrop Fipronil 200 SC Insecticide
Active constituent	200 g/L fipronil
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of registration	20 February 2024
Product registration no.	94294
Label approval no.	94294/142027
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L fipronil suspension concentrate product for the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane, and swede

Application no.	141749
Product name	Genfarm Amitrole 250 SL Herbicide
Active constituents	250 g/L amitrole, 220 g/L ammonium thiocyanate
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	21 February 2024
Product registration no.	94171
Label approval no.	94171/141749
Description of the application and its purpose, including the intended use of the chemical product	Registration of a soluble concentrate herbicide formulation containing 250 g/L amitrole and 220 g/L ammonium thiocyanate for the control of weeds in orchards, vineyards, irrigation ditches and drains, eucalyptus and pine plantations, roadsides, pre-plant wheat and barley, and for general industrial situations

Application no.	142307
Product name	Sipcam Liquid AMS Herbicide Adjuvant
Active constituent	417 g/L ammonium sulfate
Applicant name	Sipcam Pacific Australia Pty.Ltd
Applicant ACN	073 176 888
Date of registration	22 February
Product registration no.	94392
Label approval no.	94392/142307
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 417 g/L ammonium sulphate soluble concentrate product for use with glyphosate based herbicides to minimise antagonism when tank mixing with flowable herbicides and improve performance under adverse environmental conditions

Application no.	142083
Product name	Swan Glyphosate 540 K Herbicide
Active constituent	540 g/L glyphosate present as the potassium salt
Applicant name	Swan Chemical Holdings Pty Ltd
Applicant ACN	669 863 067
Date of registration	22 February 2024
Product registration no.	94324
Label approval no.	94324/142083
Description of the application and its purpose, including the intended use of the chemical product	Registration of a non-selective and soluble concentrate (SL) herbicide product containing 540 g/L glyphosate present as the potassium salt for the control of many annual and perennial weeds

Application no.	135328
Product name	Imtrade Media RMR Miticide
Active constituents	250 g/L piperonyl butoxide, 100 g/L hexythiazox
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	23 February 2024
Product registration no.	92378
Label approval no.	92378/135328
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L hexythiazox and 250 g/L piperonyl butoxide emulsifiable concentrate product for the control of two-spotted mite (*Tetranychus urticae*) and European red mite (*Panonychus ulmi*) on apples, pears, stone fruit and ornamentals, and for control of two-spotted mite on strawberries

Table 2: Variations of registration – agricultural chemical products

Application no.	142682
Product name	Pomade Wetting Agent
Active constituent	1000 g/L polyoxyethylene sorbitan monolaurate
Applicant name	AgriNova New Zealand Limited
Applicant ACN	N/A
Date of variation	30 January 2024
Product registration no.	60828
Label approval no.	60828/142682
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 first aid instructions appearing on a label to reflect the current FAISD Handbook and the storage and disposal statements

Application no.	142775
Product name	CropSure Sparrowhawk 700WG Herbicide
Active constituent	700 g/kg imazamox
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of variation	7 February 2024
Product registration no.	93634
Label approval no.	93634/142775
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 ‘CropSure Raider 700WG Herbicide’ to ‘CropSure Sparrowhawk 700WG Herbicide’

Application no.	142064
Product name	OzCrop Diafenthiuron 500 SC Miticide/Insecticide
Active constituent	500 g/L diafenthiuron
Applicant name	OzCrop Pty Ltd
Applicant ACN	160 656 431
Date of variation	13 February 2024
Product registration no.	93925
Label approval no.	93925/142064
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 new uses, and add spray drift restraints

Application no.	141836
Product name	Promote Plus 900 Growth Regulator
Active constituent	900 g/L ethephon (an anticholinesterase compound)
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	13 February 2024
Product registration no.	69487
Label approval no.	69487/141836
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to add additional uses and update restraints

Application no.	140286
Product name	Bronco 400 Herbicide
Active constituent	400 g/L bromoxynil present as the N-octanoyl ester
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	20 February 2024
Product registration no.	80801
Label approval no.	80801/140286
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to update the label

Application no.	141589
Product name	N-Large Gibberellic Acid Growth Regulant
Active constituent	100 g/L gibberellic acid
Applicant name	Stoller Australia Pty.Ltd
Applicant ACN	065 320 747
Date of variation	20 February 2024
Product registration no.	58244
Label approval no.	58244/141589
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to update the product name and label name and to correct errors in the current label text

Application no.	141568
Product name	Titan Flumioxazin 500 WG Herbicide
Active constituent	500 g/kg flumioxazin
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	22 February 2024
Product registration no.	87182
Label approval no.	87182/141568
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add uses, add spray drift restraints, and amend the withholding period

Application no.	139445
Product name	Belanty Fungicide
Active constituent	75 g/L mefentrifluconazole
Applicant name	BASF Australia Ltd
Applicant ACN	008 437 867
Date of variation	22 February 2024
Product registration no.	84344
Label approval no.	84344/139445
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to change application timing for almonds, remove the currently registered use for suppression of hull rot in almonds, update the withholding periods, and make changes to the MRL standard

Application no.	142284
Product name	Genfarm Dimethoate 400 Insecticide
Active constituent	400 g/L dimethoate (an anticholinesterase compound)
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	22 February 2024
Product registration no.	80540
Label approval no.	80540/142284
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add use in sweetcorn and add spray drift restraints

Application no.	142008
Product name	Farmalinx Clop 300 Herbicide
Active constituent	300 g/L clopyralid present as the triisopropanolamine salt
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	22 February 2024
Product registration no.	64357
Label approval no.	64357/142008
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and label approval, to vary pack size from 5 L and 20 L to 5 L-1000 L, add uses in ACT, and amend label statements including spray drift restraints, harvest withholding period for cereals and canola and update safety directions

Application no.	141046
Product name	Valor EZE 480 SC Herbicide
Active constituent	480 g/L flumioxazin
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of variation	22 February 2024
Product registration no.	92955
Label approval no.	92955/141046
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to include a higher lay by application rate in cotton for residual control

Application no.	141406
Product name	Ultrathor X 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	22 February 2024
Product registration no.	64449
Label approval no.	64449/141406
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to modify the directions for use and general instructions

Application no.	139459
Product name	Vayego Forte Insecticide
Active constituent	480 g/L tetraniliprole
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of variation	23 February 2024
Product registration no.	87936
Label approval no.	87936/139459
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and label approval, to include uses in maize cereals, sweet corns, sorghum and millet against fall armyworm

Table 3: Label approval – agricultural chemical products

Application no.	142831
Product name	Farmalinx Winx Herbicide
Active constituent	100 g/kg iodosulfuron-methyl-sodium
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	9 February 2024
Product registration no.	88829
Label approval no.	88829/142831
Description of the application and its purpose, including the intended use of the chemical product	Variation to the name of a chemical product that is to appear on an approved label from ‘Novagreen Conquer Selective Herbicide’ to ‘Conquer Selective Herbicide’

Veterinary chemical products and approved labels

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

Table 4: Veterinary products based on existing active constituents

Application no.	138115
Product name	Multiboost
Active constituents	40 g/L zinc (as disodium zinc EDTA), 15 g/L copper (as disodium copper EDTA), 10 g/L manganese (as disodium manganese EDTA), 5 g/L selenium (as sodium selenite)
Applicant name	Biocell Corporation Limited
Applicant ACN	N/A
Date of registration	15 February 2024
Product registration no.	93152
Label approval no.	93152/138115
Description of the application and its purpose, including the intended use of the chemical product	Registration of an injectable solution product containing 40.0 g/L zinc (as disodium zinc EDTA), 15.0 g/L copper (as disodium copper EDTA), 10.0 g/L manganese (as disodium manganese EDTA) and 5.0 g/L selenium (as sodium selenite) indicated for administration to beef and dairy cattle deficient in and/or responsive to zinc, copper, manganese and/or selenium supplementation

Application no.	138116
Product name	Multiboost With B12
Active constituents	40 g/L zinc (as disodium zinc EDTA), 15 g/L copper (as disodium copper EDTA), 10 g/L manganese (as disodium manganese EDTA), 5 g/L selenium (as sodium selenite), 1.4 g/L cyanocobalamin
Applicant name	Biocell Corporation Limited
Applicant ACN	N/A
Date of registration	15 February 2024
Product registration no.	93153
Label approval no.	93153/138116
Description of the application and its purpose, including the intended use of the chemical product	Registration of an injectable solution product containing 40.0 g/L zinc (as disodium zinc EDTA), 15.0 g/L copper (as disodium copper EDTA), 10.0 g/L manganese (as disodium manganese EDTA), 5.0 g/L selenium (as sodium selenite) and 1.4 g/L cyanocobalamin (vitamin B12) indicated for administration to beef and dairy cattle deficient in and/or responsive to zinc, copper, manganese, selenium and/or vitamin B12 supplementation

Application no.	141960
Product name	Multimin Evolution Plus Copper Injection for Sheep
Active constituents	40 g/L zinc as disodium zinc EDTA, 10 g/L copper as disodium copper EDTA, 10 g/L manganese as disodium manganese EDTA, 3 g/L selenium as sodium selenite
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	15 February 2024
Product registration no.	94271
Label approval no.	94271/141960
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 g/L zinc as disodium zinc EDTA, 10 g/L copper as disodium copper EDTA, 10 g/L manganese as disodium manganese EDTA and 3 g/L selenium as sodium selenite product to treat sheep deficient in and/or responsive to zinc, copper, manganese and/or selenium

Application no.	140613
Product name	Vetsense Fluverm 50 mg/g Oral Premix Pig and Poultry Wormer
Active constituent	50 mg/g flubendazole
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of registration	20 February 2024
Product registration no.	93835
Label approval no.	93835/140613
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 50 mg/g flubendazole powder product as an oral wormer for pigs and chickens

Application no.	141982
Product name	Multimin Evolution Copper-free Injection for Sheep and Cattle
Active constituents	40 g/L zinc as disodium zinc EDTA, 10 g/L manganese as disodium manganese EDTA, 5 g/L selenium as sodium selenite
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	20 February 2024
Product registration no.	94279
Label approval no.	94279/141982
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 g/L zinc as disodium zinc EDTA, 10 g/L manganese as disodium manganese EDTA and 5 g/L selenium as sodium selenite product to treat sheep and cattle deficient in and/or responsive to zinc, manganese and/or selenium

Table 5: Variations of registration – veterinary chemical products

Application no.	141734
Product name	Elanco AH0498 Extinosad Aerosol for Wounds
Active constituents	2.8 g/kg spinosad, 0.39 g/kg chlorhexidine digluconate
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	6 February 2024
Product registration no.	56734
Label approval no.	56734/141734
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by adding a new pack size, and changing the instructions of use to align the label with the current Veterinary Labelling Code

Application no.	141867
Product name	Equipalazone Anti-inflammatory Oral Paste
Active constituent/s	200 mg/mL phenylbutazone
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	7 February 2024
Product registration no.	68896
Label approval no.	68896/141867
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the product registration and label to vary the distinguishing product name and the name that appears on the label from ‘Equibute’ to ‘Equipalazone Anti-Inflammatory Oral Paste’, vary the side effects statement of the label and to align the label with the current Veterinary Labelling Code

Application no.	142808
Product name	Equipalazone Oral Paste
Active constituent/s	200 mg/mL phenylbutazone
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd.
Applicant ACN	614 716 700
Date of variation	8 February 2024
Product registration no.	68896
Label approval no.	68896/142808
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 ‘Equipalazone Anti-Inflammatory Oral Paste’ to ‘Equipalazone Oral Paste’

Application no.	138481
Product name	M+PAC Mycoplasma Hyopneumoniae Inactivated Vaccine for Pigs
Active constituent	A liquid adjuvanted bacterin consisting of ≥ 1.1 RP units inactivated mycoplasma hyopneumoniae strain J
Applicant name	Intervet Australia Pty Limited
Applicant ACN	008 467 034
Date of registration	14 February 2024
Product registration no.	62077
Label approval no.	62077/138481
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 the label by updating the instructions of use to align with the current Veterinary Labelling Code

Application no.	141484
Product name	Streptosulcin Forte Calf Scour Boluses
Active constituents	Each bolus contains: 2400 mg sulfadimidine, 2400 mg sulfadiazine, 350 mg dihydrostreptomycin (as the sulfate), 6 mg thiamine hydrochloride, 1.52 mg hyoscine (as methobromide)
Applicant name	Jurox Pty Ltd
Applicant ACN	000 932 230
Date of variation	21 February 2024
Product registration no.	36323
Label approval no.	36323/141484
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by changing the instructions of use to align the label with the current Veterinary Labelling Code

Application no.	139424
Product name	Gudair Vaccine
Active constituents	2.5 mg/mL mycobacterium avium subsp. paratuberculosis, strain 316F (inactivated), adjuvanted with mineral oil in a multiple emulsion
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	21 February 2024
Product registration no.	53839
Label approval no.	53839/139424
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 the label by updating the instructions of use on the label

Application no.	141831
Product name	Emperor Pour-On for Beef and Dairy Cattle and Deer
Active constituent/s	5 mg/mL eprinomectin
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	16 February 2024
Product registration no.	89116
Label approval no.	89116/141831
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and labelling relevant particulars to update to the current Veterinary Labelling Code

Application no.	142025
Product name	Zotel Lice Lousicide for Sheep Pour-On
Active constituent/s	20 g/L spinosad
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	16 February 2024
Product registration no.	92447
Label approval no.	92447/142025
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of product registration and label approval

Approved active constituents

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

Table 6: Approved active constituents

Application no.	140647
Active constituent	Glufosinate-ammonium
Applicant name	NACL Industries Limited
Applicant ACN	N/A
Date of approval	12 February 2024
Approval no.	93841
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent glufosinate-ammonium for use in agricultural chemical products

Application no.	142163
Active constituent	Nitroxynil
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	12 February 2024
Approval no.	94346
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent nitroxynil for use in veterinary chemical products

Application no.	138781
Active constituent	Fluralaner
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	13 February 2024
Approval no.	93352
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluralaner for use in veterinary chemical products

Application no.	140692
Active constituent	Saflufenacil
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	13 February 2024
Approval no.	93845
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.	140696
Active constituent	Prometryn
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	13 February 2024
Approval no.	93847
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent prometryn for use in agricultural chemical products

Application no.	141967
Active constituent	Acepromazine maleate
Applicant name	Randlab Australia Pty Ltd
Applicant ACN	114 948 837
Date of approval	13 February 2024
Approval no.	94276
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent acepromazine maleate for use in veterinary chemical products

Application no.	140727
Active constituent	Imazapyr
Applicant name	Liao Ning Cynda Group
Applicant ACN	N/A
Date of approval	14 February 2024
Approval no.	93863
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imazapyr for use in agricultural chemical products

Application no.	142342
Active constituent	Cephapirin benzathine
Applicant name	Bimeda (Australia) Pty Ltd
Applicant ACN	058 196 508
Date of approval	15 February 2024
Approval no.	94401
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cephapirin benzathine for use in veterinary chemical products

Application no.	138425
Active constituent/s	Flumetsulam
Applicant name	Liao Ning Cynda Group
Applicant ACN	N/A
Date of approval	16 February 2024
Approval no.	93230
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent flumetsulam for use in agricultural chemical products.

Application no.	142404
Active constituent	Clomipramine hydrochloride
Applicant name	Kato Laboratories Pty Ltd
Applicant ACN	000 397 240
Date of approval	16 February 2024
Approval no.	94427
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent clomipramine hydrochloride for use in veterinary chemical products

Application no.	138977
Active constituent	Metalaxyl-m
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	20 February 2024
Approval no.	93397
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent metalaxyl-m for use in agricultural chemical products

Application no.	139376
Active constituent	Maropitant citrate
Applicant name	Vetpharm Laboratories IP Pty Ltd
Applicant ACN	654 406 756
Date of approval	20 February 2024
Approval no.	93496
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent maropitant citrate for use in veterinary chemical products

Application no.	140078
Active constituent	Florpyrauxifen benzyl
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of approval	22 February 2024
Approval no.	93659
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent florpyrauxifen benzyl for use in agricultural chemical products.

Application no.	140771
Active constituent	Propamocarb hydrochloride
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	23 February 2024
Approval no.	93879
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent propamocarb hydrochloride for use in agricultural chemical products

Table 7: Variations of active constituent

Application no.	141396
Active constituent	Propofol
Applicant name	Ceva Animal Health Pty Ltd
Applicant ACN	002 692 426
Date of variation	12 February 2024
Approval no.	84364
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

Application no.	142001
Active constituent	Meloxicam
Applicant name	Randlab Australia Pty Ltd
Applicant ACN	114 948 837
Date of variation	12 February 2024
Approval no.	83792
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

Application no.	142002
Active constituent	Clenbuterol hydrochloride
Applicant name	Randlab Australia Pty Ltd
Applicant ACN	114 948 837
Date of variation	12 February 2024
Approval no.	83623
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

Application no.	141992
Active constituent	Ivermectin
Applicant name	Randlab Australia Pty Ltd
Applicant ACN	114 948 837
Date of variation	13 February 2024
Approval no.	85908
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

New veterinary chemical product containing a new veterinary active constituent

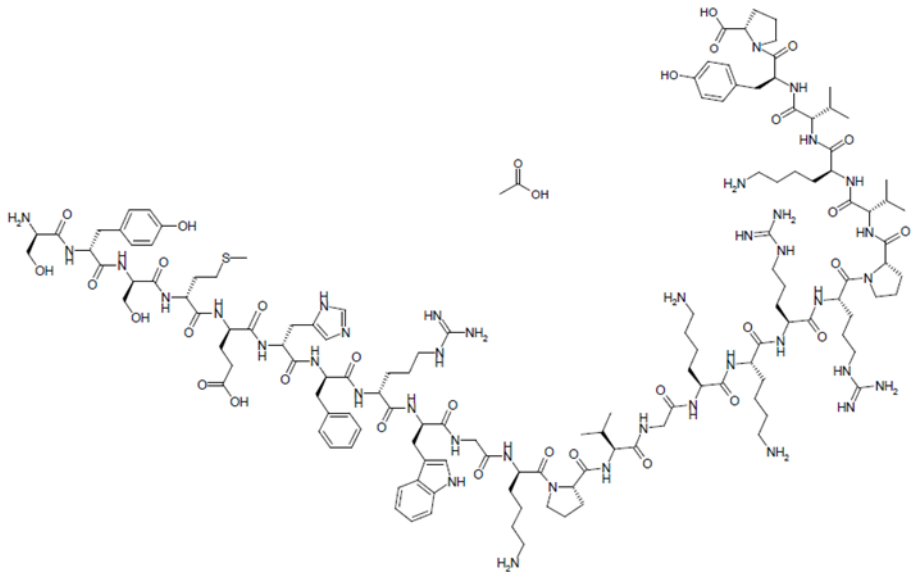
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, tetracosactide, and application for the registration of a new product containing the new active constituent, *CosACTHen 0.25 mg/mL Solution for Dogs*.

Dechra Regulatory B.V. is seeking the registration of the *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* containing 0.25 mg/mL of tetracosactide as the active constituent for use in the 'ACTH stimulation test', which is used for the evaluation of adrenocortical function in dogs.

Tetracosactide

As part of the application to register *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* containing tetracosactide, the APVMA has evaluated the safety of the new active constituent, tetracosactide.

Table 8: Particulars of the active constituent tetracosactide

Common name	Tetracosactide
IUPAC name	(2S)-1-[(2S)-2-[(2S)-2-[(2S)-6-amino-2-[(2S)-2-{[(2S)-1-[(2S)-2-[(2S)-2-[(2S)-6-amino-2-[(2S)-6-amino-2-{2-[(2S)-2-{[(2S)-1-[(2S)-6-amino-2-{2-[(2S)-2-[(2S)-2-[(2S)-2-[(2S)-2-[(2S)-2-[(2S)-2-[(2S)-2-[(2S)-2-amino-3-hydroxypropanamido]-3-(4-hydroxyphenyl)propanamido]-3-hydroxypropanamido]-4-(methylsulfanyl)butanamido]-4-carboxybutanamido]-3-(1H-imidazol-5-yl)propanamido]-3-phenylpropanamido]-5-carbamimidamidopentanamido]-3-(1H-indol-3-yl)propanamido]acetamido}hexanoyl]pyrrolidin-2-yl]formamido}-3-methylbutanamido]acetamido}hexanamido]hexanamido]-5-carbamimidamidopentanamido]-5-carbamimidamidopentanoyl]pyrrolidin-2-yl]formamido}-3-methylbutanamido]hexanamido]-3-methylbutanamido]-3-(4-hydroxyphenyl)propanoyl]pyrrolidine-2-carboxylic acid; acetate salt
CAS name	L-Seryl-L-tyrosyl-L-seryl-L-methionyl-L-glutamyl-L-histidyl-L-phenylalanyl-L-arginyl-L-tryptophanyl-glycyl-L-lysyl-L-prolyl-L-valyl-glycyl-L-lysyl-L-lysyl-L-arginyl-L-arginyl-L-prolyl-L-valyl-L-lysyl-L-valyl-L-tyrosyl-L-proline, acetate salt
CAS registry number	16960-16-0
Specified purity	90.0-102.0%
Molecular formula	$C_{136}H_{210}N_{40}O_{31}S$
Molecular weight	2931.6 g/mol
Structure	

Common name	Tetracosactide
Chemical family	Tetracosactide is a linear 24-amino acid peptide with a free amino group at the N-terminus and a free carboxyl group at the C-terminus.
Mode of action	Tetracosactide has the same physiological action as endogenous ACTH in stimulating the adrenal cortex to synthesise glucocorticoids, mineralocorticoids and (to a lesser extent) androgens.

Summary of the APVMA's evaluation of tetracosactide active constituent

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

Impurities of toxicological significance are not expected to occur in tetracosactide as a result of the raw materials and the synthetic route used.

Impurities of toxicological significance are not expected to occur in tetracosactide and concluded that there are no toxicological concerns regarding the approval of this active constituent. No ADI or ARfD was established, as tetracosactide is not currently proposed for use in food producing animals.

Based on its toxicity profile and intended use pattern, tetracosactide is listed in Schedule 4 in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

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

CosACTHen 0.25 mg/mL Solution for Injection for Dogs containing tetracosactide

In addition to the application to approve the new active constituent tetracosactide, the APVMA has under consideration an application to register a new product *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* containing tetracosactide for the evaluation of adrenocortical function in dogs.

Table 9: Particulars of the product

Proposed product name	CosACTHen 0.25 mg/mL Solution for Injection for Dogs
Applicant company	Dechra Regulatory B.V.
Name of active constituent	Tetracosactide
Signal heading	Schedule 4
Summary of proposed use	0.25 mg/mL of tetracosactide as the active constituent for use in the 'ACTH stimulation test', which is used for the evaluation of adrenocortical function in dogs
Pack sizes	1 mL
Withholding period	N/A

A summary of the APVMA's evaluation of *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994:*

1) The APVMA has evaluated the application and in its assessment in relation to whether the **safety criteria** have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:

i. The APVMA is satisfied that proposed use of *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* would not be an undue **health hazard to the safety of people** exposed to it during its handling and use.

   a. Risk management is achieved through consideration of the acute hazard of a product in conjunction with the systemic exposure expected through use of a product according to the label instructions.

   b. No acute oral, dermal or inhalational toxicity studies or dermal absorption studies on the active ingredient were provided, nor were there any short-term, sub-chronic, long-term studies, genotoxicity studies or reproductive toxicity/developmental toxicity studies.

   c. The toxicity data available on tetracosactide is related to the target animal safety study (TAS) conducted in dogs on *CosACTHen*. Significantly, the same product is used in humans for the same purpose and has been registered in Australia since 1991 and overseas for over 50 years. An understanding of the toxicity of the active ingredient can, to a considerable extent, be based on the clinical experience with, and the knowledge gained in the development of, this product.

   d. Only veterinarians and relevant support staff are expected to be exposed to the product during use, and not children or lay persons. The product may not be a high frequency of use product. The main potential routes of exposure are inhalation following aerosolization during syringe preparation and accidental self-injection.

   e. *CosACTHen* is neither a skin or eye irritant and is not a sensitiser to skin.

   f. Dermal absorption is expected to be negligible for a peptide of molecular weight >2 kg/mol, so self-injection (IM or subcutaneous (SC)) and inhalational exposure following aerosolization when adjusting the dose in the syringe (which may have the potential to elicit an anaphylactic reaction in susceptible individuals) are the most likely routes of systemic exposure. While exposure via ocular and oral routes is possible, the magnitude is likely to be negligible.

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

      Poisons Standard and Signal Heading

      Tetracosactide is listed in **Schedule 4** of the SUSMP (Health, 2023). This submission does not include a poison scheduling application. Since tetracosactide is a Schedule 4 poison, *CosACTHen 0.25 mg/mL*

Solution for Injection for Dogs requires a label signal header '**PRESCRIPTION ANIMAL REMEDY'** and '**KEEP OUT OF REACH OF CHILDREN'.**

First aid instructions

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

Safety directions

'Wash hands after use.'

The safety directions will also be listed in the FAISD handbook (APVMA 2023c)

Additional User Safety

Statements relating to hypersensitivity, pregnancy and lactation are appropriate. The APVMA has modified the applicant's suggested statements and came up with the following:

'Tetracosactide can cause **anaphylactic reactions** in people, particularly those with existing allergic disorders such as asthma. People with such allergic disorders, or a known hypersensitivity to tetracosactide, ACTH or any of the excipients, should avoid contact with the product. If you develop clinical symptoms following exposure, such as skin reactions, bradycardia or tachycardia, nausea, vomiting, oedema, vertigo and dizziness, or any signs of anaphylactic shock, you should seek medical advice immediately. **In case of accidental self-injection, seek medical advice immediately**.

Tetracosactide has not been tested in regulatory reproductive or developmental toxicity studies, but the pharmacological effects on the hypothalamic-pituitary-adrenal axis **may cause adverse effects** in pregnancy and be detrimental to the foetus **or newborn infant**. Therefore, the product should not be administered by pregnant or breastfeeding women.'

h. After consideration of the toxicological profile and likely human exposure associated with the use of *CosACTHen 0.25 mg/mL Solution for Injection for Dogs*, the APVMA concludes that the human health risks are acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act 1994* (as amended), for the proposed administration methods, provided the recommendations are noted and where relevant, incorporated on the product label, as above.

ii. The APVMA is satisfied that the proposed use of *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* containing the active constituent Tetracosactide would not be likely to have an unintended effect that is harmful to **animals, plants or the environment** if used according to the product label directions.

a. Based on the outcome of the assessment, no environmental protection statements are required. The following disposal statement is recommended that is in accordance with the Veterinary Labelling Code.

Disposal

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

iii. **Target Animal Safety** was demonstrated using laboratory and field trials and supportive data:

a. Tetracosactide, used to evaluate adrenocortical function in dogs via the ACHT stimulation test (ACTHst), has a long history of clinical use in both New Zealand and Australia with veterinarians accessing the human approved medicine, Synacthen, authorised in New Zealand in 1969 and in Australia in 1999. Globally the ACTHst has historically been conducted in dogs using human approved prescription medicines and the human approved diagnostic dose of 250 μg/person IV or IM.

b. Studies in rats showed it is rapidly distributed to the tissues within a few minutes of administration, while simultaneously disappearing from circulating blood. Following distribution into muscle, skin and intestine it is

extensively degraded. Based on these studies' rapid metabolism and elimination of tetracosactide via peptidase degradation is also expected to occur in the dog.

c. The systemic and local safety of *CosACTHen* administered via both the intravenous and intramuscular routes was first examined in a pharmacodynamic study at the proposed label dose rate of 5 μg/kg. Following this, safety was investigated in a repeat dose, margin of safety study. This pivotal study was conducted assuming a fixed recommended therapeutic dose (RTD) which equates to a dose range of 5 – 56 μg/kg BW. The highest dose of 56 μg/kg, which is 11X (11 times) greater than the proposed RTD of 5 μg/kg, was subsequently selected as the 1X therapeutic dose. *CosACTHen* had a good systemic safety profile when administered 3X, one week apart in beagle dogs from 5 months of age at 11.2X, 33.6X and 56X (IV) and 0, 11.2X, 22.4X (IM) the proposed RTD of 5 μg/kg.

d. Supportive data was also provided from field efficacy/safety studies. Additionally, a number of scientific papers were provided in which the safety of tetracosactide in the target animal was examined, typically following administration of an equivalent human medicine.

e. The application data discussed both primary and secondary pharmacodynamic effects, and specifically addressed safety of the active constituent with respect to the production of other adrenal steroid hormones post administration. International global pharmacovigilance data was also provided during this assessment.

f. No studies investigating the safety of the test product, or active constituent, in pregnant or lactating bitches were provided. A contraindication statement **'Do not use in pregnant or lactating animals'** will be included on the label.

iv. The APVMA is satisfied that the proposed use of *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* is not likely to have an unintended effect that is harmful to **target and other 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 demonstrated that if used according to the product label directions, the product is effective for its proposed uses.

ii. **Efficacy** of the product is supported by both product specific studies and published literature.

a. A pharmacodynamic study investigated the cortisol response in healthy dogs administered the test product (TP) via both the IM and IV routes at the recommended label dose of 5 μg/kg. Cortisol concentrations were assayed in all dogs administered the TP at 30, 60, 90 and 120 minutes post treatment.

b. A product specific field study was also supplied which investigated the diagnostic capability of the TP to assess adrenal function in the expected target population i.e., dogs with suspect Cushing's and Addison's disease.

c. Efficacy data generated in the pivotal safety study was provided. The dose rates used in this study were significantly higher than those proposed on the label. Though the study provided supportive evidence of the product's efficacy, it did not confirm the proposed dose rate will maximally stimulate adrenal tissue.

d. Information in the public domain was referenced to describe the pharmacokinetics and pharmacodynamics of the API. Technical arguments were supplied to support the assertion that extrapolation of data in the public domain was relevant to the test product.

3) The APVMA has considered the application, whether the **trade criteria** have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:

iii. The intended use is in companion animals only (dogs), therefore no assessment of residues or trade is required. The APVMA is satisfied that the proposed use of *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing Australian export commodities.

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether tetracosactide 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 *CosACTHen 0.25 mg/mL Solution for Injection for Dogs* should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

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

Please lodge your submission with a public submission coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Please send your written submission and coversheet by email or post to:

Email: casemanagement@apvma.gov.au

Post:
Case Management
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

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 licenses

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

Table 10: New licenses issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product typesError! Bookmark not defined.	Steps of manufacture	Date issued
Propharma Australia Pty Ltd	4025	004 983 984	6 Elliot Road Dandenong VIC 3175	Category 4: Premixes and supplements	Quality assurance (QA) of raw materials, formulation including blending, dry milling, filling, packaging, labelling, analysis and testing (physical), storage, and release for supply.	15 February 2024

Licence cancellations

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

Table 11: Licenses cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Acura Bio Pty Ltd	1086	074 656 509	2806 Ipswich Road Darra QLD 4076	12 February 2024
Farm Balance Pty Ltd	4018	007 368 069	229 Mountford Road Kerang VIC 3579	14 February 2024

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

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 (MRL Standard for Residues of Chemical Products) Instrument 2023*. 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 (MRL Standard for Residues of Chemical Products) Amendment Instrument* (No. 1) 2024.

The amendments will be incorporated into the compilation of the *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023.*

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 26 of APVMA Gazette No. 5, 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 2024 (No. 1)) 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

5 March 2024

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

Schedule 20 Maximum Residue Limits

[1] Section S20—3

Insert in alphabetical order the following chemicals, the corresponding residue definition(s), food

Agvet chemical: Bupivacaine	
Permitted residue: Bupivacaine	
Sheep fat	0.07
Sheep kidney	0.02
Sheep liver	0.02
Sheep muscle	0.0005

Agvet chemical: Lignocaine	
Permitted residue: Lignocaine	
Sheep fat	0.2
Sheep kidney	0.2
Sheep liver	0.1
Sheep muscle	0.15

[2] Section S20—3 (table entry for Agvet chemical: Ametoctradin)

Omit:

Basil	T20

Substitute:

Basil	T50

[3] Section S20—3 (table entry for Agvet chemical: Cypermethrin)

The maximum residue limit in the entry for each food commodity listed in the following table is amended as set out in the table:

Amendments relating to maximum residue limits			
Item	**Food commodity**	**Omit**	**Substitute**
1	Chives	T5	T8
2	Coriander (leaves, roots, stems)	T5	T8

Amendments relating to maximum residue limits			
Item	**Food commodity**	**Omit**	**Substitute**
3	Herbs	T5	T8

[4] Section S20—3 (table entry for Agvet chemical: Ethephon)

Omit:

Grapes	10

Substitute:

Grapes	6

[5] Section S20—3 (table entry for Agvet chemical: Fluxapyroxad)

Insert in alphabetical order:

Tea, green, black	T7

[6] Section S20—3 (table entry for Agvet chemical: Ipflufenoquin)

Insert the following food commodities and associated MRLs in alphabetical order:

Pome fruits	0.05
Wine-grapes	0.04

[7] Section S20—3 (table entry for Agvet chemical: Mefentrifluconazole)

Omit:

Tree nuts	0.2

Substitute:

Tree nuts	0.06

[8] Section S20—3 (table entry for Agvet chemical: Metalaxyl)

Insert in alphabetical order:

Almonds	T5

[9] Section S20—3 (table entry for Agvet chemical: Pyraclostrobin)

Insert in alphabetical order:

Tea, green, black	T7

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 2 April 2024 (28 days from date Gazette published). 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 public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

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

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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 12:

Table 12: 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
53015 / 0700 53015 / 07005	Taskforce Water Soluble Herbicide	Label	Vee Dri (Aust) Pty Ltd	May not meet labelling Criteria	27 February 2024
64625 / 0110	AW Scuffle Herbicide	Label	Agri West Pty Ltd	May not meet labelling Criteria	27 February 2024
64857 / 0410 64857 / 137863	AC Thwack Herbicide	Label	Axichem Pty Ltd	May not meet labelling Criteria	27 February 2024
82344 / 105479 82344 / 112110	Clethora 240EC Herbicide	Label	Nutrien Ag Solutions Limited	May not meet labelling Criteria	27 February 2024
84075 / 109646	Agroshine Imida600 Seed Treatment Insecticide	Label	Agroshine Australia Pty Ltd	May not meet labelling Criteria	27 February 2024

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 12.

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 12 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 12 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 12 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 12, 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 12 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 voluntary cancellations at the request of the holder on its website, and provides a subscription option to be notified by email when the list is updated.