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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

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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.	133437
Product name	AgMerch Tebuthiuron 200 GR Herbicide
Active constituent	200 g/kg tebuthiuron
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Date of registration	1 July 2022
Product registration no.	91775
Label approval no.	91775/133437
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/kg tebuthiuron granular formulation product for control of brigalow regrowth, tea tree regrowth, *Mimosa pigra* and certain problem woody weeds on grazing lands

Application no.	133411
Product name	Imtrade Noko 850 WG Herbicide
Active constituent	850 g/kg pyroxasulfone
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	1 July 2022
Product registration no.	91762
Label approval no.	91762/133411
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg pyroxasulfone water dispersible granule product for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops

Table 2: Variations of registration

Application no.	135796
Product name	Bar 750 WG Herbicide
Active constituent	750 g/kg metribuzin
Applicant name	Agro Life Science Corporation
Applicant ACN	N/A
Date of variation	9 June 2022
Product registration no.	67153
Label approval no.	67153/135796
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 'Novaguard Metribuzin 750 WG Herbicide' to 'Bar 750 WG Herbicide'

Application no.	135810
Product name	Orthene Xtra Insecticide
Active constituent	970 g/kg acephate (an anticholinesterase compound)
Applicant name	Arysta LifeScience North America LLC
Applicant ACN	N/A
Date of variation	14 June 2022
Product registration no.	50469
Label approval no.	50469/135810
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label to update the first aid instructions, storage and disposal statements and safety directions appearing on the label to reflect the current FAISD Handbook

Application no.	135831
Product name	Rancona Dimension Seed Treatment
Active constituents	25 g/L ipconazole, 20 g/L metalaxyl
Applicant name	Arysta LifeScience Australia Pty Ltd
Applicant ACN	005 225 507
Date of variation	16 June 2022
Product registration no.	67985
Label approval no.	67985 / 135831
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 and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	135858
Product name	Heist 960 EC Herbicide
Active constituent	960 g/L S-metolachlor
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	21 June 2022
Product registration no.	67715
Label approval no.	67715/135858
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 and safety directions appearing on a label to reflect the current FAISD Handbook.

Application no.	135865
Product name	Nufarm MCPA Amine 750 Herbicide
Active constituent	750 g/L MCPA present as the dimethylamine salt
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	22 June 2022
Product registration no.	60505
Label approval no.	60505/135865
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Nufarm Agritone 750 Selective Herbicide' to 'Nufarm MCPA Amine 750 Herbicide'

Application no.	135336
Product name	ADAMA 2,4-D Amine 625 Herbicide
Active constituent	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	23 June 2022
Product registration no.	55046
Label approval no.	55046/135336
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label, to update the timing restrictions for use in sugar cane

Application no.	135089
Product name	Trio Oxyfluorfen 240 EC Herbicide
Active constituent	240 g/L oxyfluorfen
Applicant name	CTS Chemicals Pty Ltd.
Applicant ACN	605 759 644
Date of variation	27 June 2022
Product registration no.	89919
Label approval no.	89919/135089
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registration particulars and label approval, to expand the pack size range and update the first aid and safety directions

Application no.	134923
Product name	ADAMA 2,4-D LV Ester 680 Herbicide
Active constituent	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	29 June 2022
Product registration no.	61895
Label approval no.	61895/134923
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to amend the timing restrictions for use in sugar cane

Application no.	134070
Product name	OzCrop Imidacloprid 350 SC Insecticide
Active constituent	350 g/L imidacloprid
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of variation	1 July 2022
Product registration no.	68445
Label approval no.	68445/134070
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to include new crops and pests from reference products

Table 3: Label approval

Application no.	135372
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 variation	23 June 2022
Product registration no.	90578
Label approval no.	90578/135372
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new Label for the existing product ‘Farmalinx Slay'em Trio Fungicide’ with the label name ‘ProForce Clean Sweep Trio Fungicide’

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.	128986
Product name	Multimin Chrome Injection for Cattle
Active constituent/s	40 g/L zinc as disodium zinc EDTA, 15 g/L copper as disodium copper EDTA, 10 g/L manganese as disodium manganese EDTA, 3 g/L selenium as sodium selenite, 5 g/L chromium as chromium chloride
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	1 July 2022
Product registration no.	90447
Label approval no.	90447/128986
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 mg/mL zinc as disodium zinc EDTA, 10 mg/mL manganese as disodium manganese EDTA, 15 mg/mL copper as disodium copper EDTA, 3 mg/mL selenium as sodium selenite and 5 mg/mL chromium as chromium chloride in an injectable formulation as a chelated trace mineral injection for beef and dairy cattle deficient in and/or responsive to manganese, zinc, selenium, chromium and/or copper supplementation

Application no.	133351
Product name	Carpromax Injection
Active constituent/s	50 mg/mL carprofen
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of registration	1 July 2022
Product registration no.	91746
Label approval no.	91746/133351
Description of the application and its purpose, including the intended use of the chemical product	Registration and label approval of a 50 mg/mL carprofen injectable solution product as a non-steroidal, anti-inflammatory and analgesic for use in horses, dogs and cats

Table 5: Variations of registration

Application no.	135822
Product name	Vetafarm Origins Insect and Mite Spray
Active constituent/s	6.25 g/L piperonyl butoxide, 1.25 g/L permethrin (40:60), 20 mg/L methoprene
Applicant name	Vetafarm Pty Ltd
Applicant ACN	059 895 153
Date of variation	15 June 2022
Product registration no.	60267
Label approval no.	60267/135822
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 'Vetafarm Insect and Mite Liquidator Residual Insecticide and Insect Growth Regulator Ready to Use' to 'Vetafarm Origins Insect and Mite Spray'

Application no.	134800
Product name	Independents Own Encore Pour-on Lousicide for Sheep
Active constituent/s	35 g/L imidacloprid
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	20 June 2022
Product registration no.	84054
Label approval no.	84054/134800
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the registration and the label

Application no.	132974
Product name	Ovastim Injection for Sheep
Active constituent/s	600 mg/L polyandroalbumin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	21 June 2022
Product registration no.	51133
Label approval no.	51133/132974
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of the registration and label approval to remove the precaution statement and update the general directions

Application no.	133251
Product name	Troy Chloromide Antiseptic Spray
Active constituent/s	8.0 g/L cetrimide, 2.4 g/L chloroxylenol, 0.8 g/L orthophenylphenol, 0.3 g/L pyrethrins
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	21 June 2022
Product registration no.	51610
Label approval no.	51610/133251
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the product and label to add a new pack size as well as variation of the conditions of label approval by aligning to the current Veterinary Labelling Code

Application no.	134799
Product name	Pastoral Ag Imidalab Pour-on Lice Treatment for Sheep
Active constituent/s	35 g/L imidacloprid
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	22 June 2022
Product registration no.	90295
Label approval no.	90295/134799
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the registration and the label

Application no.	134200
Product name	Bravecto 250 mg Fluralaner Spot-on Solution for Medium Cats
Active constituent/s	280 mg/mL fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	24 June 2022
Product registration no.	82806
Label approval no.	82806/134200
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the label by adding a side effects statement

Application no.	134201
Product name	Bravecto 112.5 mg Fluralaner Spot-on Solution for Small Cats
Active constituent/s	280 mg/mL fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	24 June 2022
Product registration no.	82807
Label approval no.	82807/134201
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the label by adding a side effects statement

Application no.	134205
Product name	Bravecto Plus Flea, Tick and Worm 250 mg Fluralaner and 12.5 mg Moxidectin Spot-on Solution for Medium Cats
Active constituent/s	280 mg/mL fluralaner, 14 mg/mL moxidectin
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	24 June 2022
Product registration no.	85416
Label approval no.	85416/134205
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the label to add a side effect statement

Application no.	134206
Product name	Bravecto Plus Flea, Tick and Worm 112.5 mg Fluralaner and 5.6 mg Moxidectin Spot-on Solution for Kittens and Small Cats
Active constituent/s	280 mg/mL fluralaner, 14 mg/mL moxidectin
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	24 June 2022
Product registration no.	85418
Label approval no.	85418/134206
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of label to add a side effect statement

Application no.	134871
Product name	Ilium Dermapred Topical Ointment
Active constituent/s	5 mg/g neomycin sulphate, 2.5 mg/g prednisolone acetate, 2 mg/g nitrofurazone
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	24 June 2022
Product registration no.	38601
Label approval no.	38601/134871
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 re-categorising the active constituents and updating the safety directions to align with the current FAISD Handbook

Application no.	134850
Product name	Prascend 1 mg Tablets for Horses
Active constituent/s	1 mg/tablet pergolide mesylate
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	28 June 2022
Product registration no.	69335
Label approval no.	69335/134850
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and particulars of label approval to amend the additional user safety directions

Application no.	134262
Product name	Apex Meloxicam Oral Suspension for Dogs
Active constituent/s	1.5 mg/mL meloxicam
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	30 June 2022
Product registration no.	63637
Label approval no.	63637/134262
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the label to update the side effect statements

Application no.	134847
Product name	Fasimec Cattle Oral Flukicide and Broad Spectrum Drench
Active constituent/s	120 g/L triclabendazole, 2 g/L ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	30 June 2022
Product registration no.	52406
Label approval no.	52406/134847
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of the label to align with the APVMA Veterinary Labelling Code

Application no.	134210
Product name	Aristopet Animal Health Mite & Lice Spray plus Insect Growth Regulator for Ornamental Birds
Active constituent/s	10 mg/L S-methoprene, 6.25 g/L piperonyl butoxide, 1.25 g/L permethrin 25:75: CIS:TRANS
Applicant name	Qpharma Pty Ltd
Applicant ACN	145 418 882
Date of variation	1 July 2022
Product registration no.	60061
Label approval no.	60061/134210
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 product formulation

Application no.	134263
Product name	Apex Meloxicam KG Oral Suspension for Dogs
Active constituent/s	Meloxicam 1.5 mg/mL
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	1 July 2022
Product registration no.	87621
Label approval no.	87621/134263
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the label to update the side effects statements and add an in-use shelf-life statement

Approved active constituents

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

Table 6: Active constituent

Application no.	126100
Active constituent/s	Metobromuron
Applicant name	Belchim Crop Protection NV
Applicant ACN	N/A
Date of approval	20 June 2022
Approval no.	89789
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent metobromuron for use in agricultural chemical products

Application no.	133032
Active constituent/s	Captan
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	21 June 2022
Approval no.	91661
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent captan for use in agricultural chemical products

Application no.	134966
Active constituent/s	Polyandroalbumin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	21 June 2022
Approval no.	92270
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent polyandroalbumin for use in veterinary chemical products

Application no.	132015
Active constituent	Chlorantraniliprole
Applicant name	Tagros Chemicals India Private Limited
Applicant ACN	N/A
Date of approval	24 June 2022
Approval no.	91374
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlorantraniliprole for use in agricultural chemical products

Application no.	133606
Active constituent	Bifenazate
Applicant name	Yun CropCare Co Ltd
Applicant ACN	N/A
Date of approval	27 June 2022
Approval no.	91832
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bifenazate for use in agricultural chemical products

Application no.	133764
Active constituent/s	Carprofen
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	30 June 2022
Approval no.	91879
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent carprofen for use in veterinary chemical products

Application no.	134225
Active constituent/s	Closantel
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of approval	30 June 2022
Approval no.	92029
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent closantel for use in veterinary chemical products

Application no.	128982
Active constituent/s	Chromium chloride hexahydrate
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	1 July 2022
Approval no.	90444
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent Chromium chloride hexahydrate for use in veterinary chemical products

Application no.	128984
Active constituent/s	Chromium chloride hexahydrate
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	1 July 2022
Approval no.	90445
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent Chromium chloride hexahydrate for use in veterinary chemical products

Application no.	128985
Active constituent/s	Disodium Manganese EDTA
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	1 July 2022
Approval no.	90446
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent Disodium Manganese EDTA for use in veterinary chemical products

Application no.	129120
Active constituent/s	Aminocyclopyrachlor
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of approval	1 July 2022
Approval no.	90494
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent aminocyclopyrachlor for use in agricultural chemical products

Application no.	129121
Active constituent/s	Aminocyclopyrachlor
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of approval	1 July 2022
Approval no.	90495
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent aminocyclopyrachlor for use in agricultural chemical products

Application no.	133674
Active constituent/s	Altrenogest
Applicant name	Curia Spain S.A.U.
Applicant ACN	N/A
Date of approval	1 July 2022
Approval no.	91850
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent altrenogest for use in veterinary chemical products

Application no.	134483
Active constituent/s	Oxytetracycline hydrochloride
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	1 July 2022
Approval no.	92092
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent oxytetracycline hydrochloride for use in veterinary chemical products

Application no.	134528
Active constituent/s	Flunixin meglumine
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	1 July 2022
Approval no.	92108
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent flunixin meglumine for use in veterinary chemical products

Application no.	134649
Active constituent/s	Acepromazine maleate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	1 July 2022
Approval no.	92134
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.	134723
Active constituent/s	Moxidectin
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	1 July 2022
Approval no.	92164
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent moxidectin for use in veterinary chemical products

Table 7: Variations of active constituent

Application no.	134280
Active constituent	Rimsulfuron
Applicant name	Production Agriscience (Australia) Pty Ltd
Applicant ACN	616 181 769
Date of variation	23 June 2022
Approval no.	65382
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.	133705
Active constituent	Spinosad manufacturing concentrate
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	24 June 2022
Approval no.	67860
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: BERANSA Solution for Injection for Dogs containing bedinvetmab

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent bedinvetmab, and applications for registration of a suite of new products containing the new active constituent. The products are BERANSA 30 mg, BERANSA 20 mg, BERANSA 15 mg, BERANSA 10 mg and BERANSA 5 mg Solution for Injection for Dogs for the alleviation of pain associated with osteoarthritis in dogs.

Table 8: Particulars of the active constituent

Common name	Bedinvetmab
CAS name	Immunoglobulin G2, anti-(*Canis familiaris* nerve growth factor) (*Canis familiaris* monoclonal ZTS-00508841 gamma2-chain), disulphide with *Canis familiaris* monoclonal ZTS-00508841 lambda-chain, dimer
CAS registry number	2171034-69-6
Molecular formula	$C_{6458}H_{9972}N_{1740}O_{2014}S_{44}$
Molecular weight	145,365.2 Da (without glycans and with all cysteines in disulphide bonds)
Structure	Heavy chain: EVQLVESGGD LVKPGGSLRL SCVASGFTFS SHGMHWVRQS PGKGLQWVAV 50’ INSGGSSTYY TDAVKGRFTI SRDNAKNTVY LQMNSLRAED TAMYYCAKES 100’ VGGWEQLVGP HFDYWGQGTL VIVSSASTTA PSVFPLAPSC GSTSGSTVAL 150’ ACLVSGYFPE PVTVSWNSGS LTSGVHTFPS VLQSSGLYSL SSMVTVPSSR 200’ WPSETFTCNV AHPASKTKVD KPVPKRENGR VPRPPDCPKC PAPEAAGAPS 250’ VFIFPPKPKD TLLIARTPEV TCVVVDLDPE DPEVQISWFV DGKQMQTAKT 300’ QPREEQFNGT YRVVSVLPIG HQDWLKGKQF TCKVNNKALP SPIERTISKA 350’ RGQAHQPSVY VLPPSREELS KNTVSLTCLI KDFFPPDIDV EWQSNGQQEP 400’ ESKYRTTPPQ LDEDGSYFLY SKLSVDKSRW QRGDTFICAV MHEALHNHYT 450’ QESLSHSPGK 460’ Light chain: QSVLTQPTSV SGSLGQRVTI SCSGSTNNIG ILGASWYQLF PGKAPKLLVY 50’ GNGNRPSGVP DRFSGADSGD SVTLTITGLQ AEDEADYYCQ SFDTTLGAHV 100’ FGGGTHLTVL GQPKASPSVT LFPPSSEELG ANKATLVCLI SDFYPSGVTV 150’ AWKADGSPVT QGVETTKPSK QSNNKYAASS YLSLTPDKWK SHSSFSCLVT 200’ HEGSTVEKKV APAECS 216’
Chemical family	Monoclonal antibody
Mode of action	Bedinvetmab is an IgG2 monoclonal antibody (mAb) directed at canine nerve growth factor (NGF). Binding of bedinvetmab with the NGF prevents NGF binding to its cellular receptor and prevents the activation of nociceptive neurons to transmit pain signals from the peripheral to the central nervous system. This is associated with pain reduction in degenerative joint disease (osteoarthritis) in dogs.

Summary of the APVMA's evaluation of bedinvetmab active constituent

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

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

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

Bedinvetmab is only for use in non-food producing animals (dogs), hence establishment of health-based guidance values such as acceptable daily intake (ADI) or acute reference dose (ARfD) are not required. The APVMA has considered the toxicological aspects of bedinvetmab and concluded that there are no toxicological concerns to the approval of this active constituent.

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

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

Table 9: Particulars of the product

Proposed product name(s):	BERANSA 5 mg Solution for Injection for Dogs BERANSA 10 mg Solution for Injection for Dogs BERANSA 15 mg Solution for Injection for Dogs BERANSA 20 mg Solution for Injection for Dogs BERANSA 30 mg Solution for Injection for Dogs
Applicant company:	Zoetis Australia Pty Ltd
Name of active constituent:	Bedinvetmab
Scheduling:	Schedule 4
Pharmaceutical form:	Injectable solution
Summary of proposed use:	For the alleviation of pain associated with osteoarthritis in dogs
Pack sizes:	1 × 1 mL vial of 5, 10, 15, 20 or 30 mg/mL 2 × 1 mL vials of 5, 10, 15, 20 or 30 mg/mL 6 × 1 mL vials of 5, 10, 15, 20 or 30 mg/mL

Proposed product name(s):	BERANSA 5 mg Solution for Injection for Dogs BERANSA 10 mg Solution for Injection for Dogs BERANSA 15 mg Solution for Injection for Dogs BERANSA 20 mg Solution for Injection for Dogs BERANSA 30 mg Solution for Injection for Dogs
Withholding period:	Not applicable

Summary of proposed product use

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

Dose and route of administration

Bedinvetmab in BERANSA Solution for Injection for Dogs is proposed to be administered subcutaneously to dogs at a dose rate of 0.5 to 1.0 mg/kg. For ease of administration the applicant recommends:

- 5 mg (1 mL) for dogs between 5.0 and 10.0 kg
- 10 mg (1 mL) for dogs between 10.1 and 20.0 kg
- 15 mg (1 mL) for dogs between 20.1 to 30.0 kg
- 20 mg (1 mL) for dogs between 30.1 to 40.0 kg
- 30 mg (1 mL) for dogs between 40.1 and 60.0 kg
- 40 mg (2 × 1 mL vials of 20 mg/mL) for dogs between 60.1 and 80.0 kg
- 50 mg (1 × 1 mL vial of 20 mg/mL and 1 x 1 mL vial of 30 mg/mL) for dogs between 80.1 and 100.0 kg
- 60 mg (2 × 1 mL vials of 30 mg/mL) for dogs between 100.1 and 120.0 kg.

The product is administered in monthly intervals.

Side effects: Mild reactions at the injection site (e.g. swelling and heat) may be uncommonly observed. In very rare cases, hypersensitivity type reactions (e.g. anaphylaxis, facial oedema and urticaria) may be observed. In such cases appropriate symptomatic treatment should be administered without delay.

Summary of the APVMA's evaluation of BERANSA 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, and proposes to determine that:

   i. The APVMA is satisfied that the proposed use of BERANSA Solution for Injection for Dogs would not be an undue hazard to the safety of people exposed to it during its handling and use.

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

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

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

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

The proposed product labelling includes appropriate first aid instructions, safety directions and the additional user safety statements. The product label will contain first aid statement: '*If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26'*. Safety directions of *'Pregnant women, women trying to conceive, and breastfeeding women should take extreme care to avoid accidental self-injection or needle stick injuries. Consult a medical practitioner if such an injection occurs. Wash hands after use'* and the additional user safety are included in the label to mitigate the risk.

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

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

Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection. Repeated self-administration may increase the risk of hypersensitivity reactions.

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

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

The product is for use in companion animals (dogs) only. BERANSA Solution for Injection for Dogs is unlikely to enter the food chain.

iii. The APVMA is satisfied that the proposed use of BERANSA Solution for Injection for Dogs containing the active constituent bedinvetmab is not likely to be harmful to human beings if used according to the product label directions.

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

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

v. The APVMA is satisfied that the proposed use of BERANSA Solution for Injection for Dogs is not likely to have an unintended effect that is harmful to dogs, plants or the environment if used according to the product label directions.

vi. For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.

vii. This Veterinary Medicinal Product will only be used in non-food animals. Hence, it satisfies the requirements of VICH phase 1. The APVMA is therefore satisfied that the proposed product meets the environmental safety criteria.

viii. Bedinvetmab is an immunological product and disposal instructions consistent with the Veterinary Labelling Code will be included on the label.

ix. The results of the target animal safety studies indicated that, at the proposed label dose rate of 0.5 to 1.0 mg/kg via a subcutaneous injection, BERANSA Solution for Injection for Dogs is unlikely to cause serious adverse reactions in dogs and appropriate, precautions, side effects and contraindication statements are included on the label.

x. The safety studies were conducted up to 181 days with the proposed dose administered at monthly intervals. A sufficient argument was provided that the product will be safe for long term use. A precautionary statement to mitigate potential risks has been included on the label as: 'Duration of treatment should be based on the individual response of each animal. If a positive response is not observed, consider alternative treatments'.

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

i. In relation to its assessment of efficacy under section 5B(2)(a), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for the proposed use.

The efficacy data submitted and assessed included clinical trials, scientific arguments and literature references on the use of the applicant's proposed product in dogs. The efficacy data package comprised of published literature, dose determination studies, dose confirmation studies, laboratory efficacy studies and field/clinical efficacy studies. The APVMA has concluded that the data generated from the efficacy studies support the claim: *'For the alleviation of pain associated with osteoarthritis in dogs'* when the product is administered subcutaneously to dogs at a dose rate of 0.5 to 1.0 mg/kg.

ii. The recommended minimum dose of BERANSA Solution for Injection for Dogs is 0.5 mg/kg bodyweight, administered subcutaneously once a month. Dogs will be treated according to the table below.

Table 10: Dosage and administration

					BERANSA strength (mg) to be administered
Bodyweight (kg)	5	10	15	20	30
5.0 to 10.0	1 vial				
10.1 to 20.0		1 vial			
20.1 to 30.0			1 vial		
30.1 to 40.0				1 vial	
40.1 to 60.0					1 vial
60.1 to 80.0				2 vials	
80.1 to 100.0				1 vial	1 vial
100.1 to 120.00					2 vials

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

   Review of the formulation indicates that the excipients are not novel, and the product is not for food producing animals (dogs). Therefore, there are no concerns from a trade perspective relating to the registration of this product.

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **bedinvetmab** 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 BERANSA 30 mg, BERANSA 20 mg, BERANSA 15 mg, BERANSA 10 mg and BERANSA 5 mg 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:

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

Email: enquiries@apvma.gov.au

Privacy

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

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. 4) 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 24 of APVMA Gazette No. 14, 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. 4)) 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

12 July 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: Myclobutanil	
Permitted residue: Myclobutanil	
Blackberries	2
Boysenberry	2
Raspberries, red, black	2

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Bulb vegetables [except garlic]	*0.01

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

Agvet chemical: Captan	
Permitted residue: Captan	
Tangelo, large-sized cultivars	T3

Agvet chemical: Emamectin	
Permitted residue: Sum of emamectin B1a and emamectin B1b	
Sorghum	*0.002

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*	
Bulb onions	0.07
Fruiting vegetables, cucurbits	0.5
Green onions	2
Macadamia nuts	0.2
Olives for oil production	3
Olive oil, crude	5
Peppers, sweet	0.3
Pistachio nut	0.2
Table olives	3

Agvet chemical: Myclobutanil	
Permitted residue: Myclobutanil	
Cane berries	2

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Bulb onions [except garlic]	0.07
Custard apple	2
Fruiting vegetables, cucurbits	0.5
Green onions	2
Olives for oil production	2
Olive oil, crude	5
Passionfruit	0.5
Peppers, sweet	0.5
Persimmon, American	2
Strawberry	2
Table olives	2
Tomato	0.5

Agvet chemical: Tetraniliprole	
Permitted residue: Tetraniliprole	
Cane berries	T0.5

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

Agvet chemical: Bupirimate	
Permitted residue: Bupirimate	
Tomato	T0.3

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Citrus fruits	0.2

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 9 August 2022 (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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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. 2) gazetted on 5 April 2022 (No. APVMA 7).

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 3, 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 Federal Register of Legislation.

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 no comment was received in response to that notice.

A copy of these variations has 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 3, 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 seventh day of July 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 3, 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] inserting in alphabetical order

Agvet chemical: Fluoxapiprolin	
Permitted residue: Fluoxapiprolin	
Dried grapes (=currants, raisins and sultanas)	0.5
Edible offal (mammalian)	*0.01
Eggs	*0.01
Grapes	0.15
Meat (mammalian) [in the fat]	*0.01
Milks	*0.01
Poultry, edible offal of	*0.01
Poultry meat [in the fat]	*0.01

Agvet chemical: Isotianil	
Permitted residue: Commodities of plant origin: Isotianil *Permitted residue: Commodities of animal origin: sum of isotianil and 3,4-dichloroisothiazole-5-carboxylic acid, expressed as isotianil*	
Banana	0.03
Edible offal (mammalian)	*0.02
Eggs	*0.02
Meat (mammalian)	*0.02
Milks	*0.02
Poultry, edible offal of	*0.02
Poultry meat	*0.02

Agvet chemical: Metobromuron	
Permitted residue: Commodities of plant origin: Sum of metobromuron and 4-bromophenylurea (CGA18237), expressed as metobromuron *Permitted residue: Commodities of animal origin: Sum of 4-bromo-2-hydroxyphenylurea (CGA 72905) and 4-bromophenyl urea (CGA18237), expressed as metobromuron*	
Edible offal (mammalian)	*0.02
Eggs	*0.02
Meat (mammalian)	*0.02
Milks	*0.02
Poultry, edible offal of	*0.02
Poultry meat	*0.02
Potato	*0.02

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

Agvet chemical: Glyphosate	
Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate	
Cereal grains [except barley; maize; popcorn, sorghum; wheat]	T*0.1

Agvet chemical: Maldison	
Permitted residue: Maldison	
Currant, black	T2

Agvet chemical: Mandestrobin	
Permitted residue: Mandestrobin	
Lettuce, leaf	7

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

Agvet chemical: Fluroxypyr	
Permitted residue: Fluroxypyr	
Rice bran, unprocessed	T0.3

Agvet chemical: Glyphosate	
Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate	
Cereal grains [except barley; maize; millet; popcorn; sorghum; wheat]	T*0.1
Millet	T15

Agvet chemical: Imidacloprid	
Permitted residue: Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid	
Poppy seed	T*0.05

Agvet chemical: Isofetamid	
Permitted residue: commodities of plant origin: Isofetamid	
Permitted residue: commodities of animal origin: Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2- carboxamido) propanoyl]phenoxy]propanoic acid (PPA), expressed as isofetamid	
Lettuce, head	30
Lettuce, leaf	30

Agvet chemical: Mandestrobin	
Permitted residue: Mandestrobin	
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	2
Leafy vegetables [except lettuce, head]	20
Onion, bulb	*0.01

Agvet chemical: Permethrin	
Permitted residue: Permethrin, sum of isomers	
Chervil	T30
Chives	T30
Coriander (leaves, roots, stems)	T30
Herbs	T30

Agvet chemical: Sethoxydim	
Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim	
Basil	T1
Basil, dry	T5
Hazelnut	T*0.03

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

Agvet chemical: Florpyrauxifen-benzyl	
Permitted residue: Sum of florpyrauxifen-benzyl and the XDE-848 acid metabolite [4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid] expressed as florpyrauxifen-benzyl	
Sorghum	*0.02

Agvet chemical: Glyphosate	
Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate	
Linseed	15
Poppy seed	20
Safflower seed	7
Sesame seed	20
Sunflower seed	20

Agvet chemical: Haloxyfop	
Permitted residue: Sum of haloxyfop, its esters and conjugates, expressed as haloxyfop	
Poppy seed	T0.5

Agvet chemical: Mandestrobin	
Permitted residue: Mandestrobin	
Lettuce, head	5

Agvet chemical voluntary recall: Black & Gold Value Everyday Ant Killer

Product name: Black & Gold Value Everyday Ant Killer

APVMA registration number: 63984

APVMA approved label number: 104424

Batch number: 210001, 210002 and 210003

Sold by: Metcash, nationally between January 2022 and June 2022

On 4 July 2022, Pascoe's Pty Ltd, ACN: 055 220 463, initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) in relation to the chemical product described above.

Reason for voluntary recall

The recall was initiated due to an out-of-specification result on tests of above batches. The recall is limited to the identified batches (see above).

Hazard

The product does not present any safety risks.

What to do if in possession of this chemical product

Check your product against the batch numbers above. A full refund of the purchase price is available by returning to the store in which it was purchased.

More information

Visit the APVMA website to view the notice of voluntary recall for the chemical product described above.

The APVMA publishes a list of agvet chemical recall notices on its website and provides a subscription option to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to:

Pascoe's Pty Ltd Consumer Advisory

Phone (toll-free): +1800 065 326
Email: pascoes.cs@pactgroup.com
Website: www.pascoes.com.au

Agvet chemical voluntary recall: First Force Fast Acting Ant Killer Powder

Product name: First Force Fast Acting Ant Killer Powder

APVMA registration number: 83896

APVMA approved label number: 109208

Batch number: 052104, 072105, 082106, 092107, 112108, 012103, 112109 and 012201

Sold by: Woolworths, nationally between April 2021 and April 2022

On 4 July 2022, Pascoe's Pty Ltd, ACN: 055 220 463, initiated a voluntary recall under section 106 of the *Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994* (Cth) in relation to the chemical product described above.

Reason for voluntary recall

The recall was initiated due to an out-of-specification result on tests of above batches. The recall is limited to the identified batches (see above).

Hazard

The product does not present any safety risks.

What to do if in possession of this chemical product

Check your product against the batch numbers above. A full refund of the purchase price is available by returning to the store in which it was purchased.

More information

Visit the APVMA website to view the notice of voluntary recall for the chemical product described above.

The APVMA publishes a list of agvet chemical recall notices on its website and provides a subscription option to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to:

Pascoe's Pty Ltd Consumer Advisory

Phone (toll-free): +1800 065 326
Email: pascoes.cs@pactgroup.com
Website: www.pascoes.com.au

Agvet chemical voluntary recall: Hovex Permethrin Ant Killer

Product name: Hovex Permethrin Ant Killer

APVMA registration number: 55137

APVMA approved label number: 0409

Batch number: 210004, 210005, 210006, 210007 and 210008

Sold by: Coles, nationally between November 2021 and June 2022

On 29 June 2022, Pascoe's Pty Ltd, ACN: 055 220 463, initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) in relation to the chemical product described above.

Reason for voluntary recall

The recall was initiated due to an out-of-specification result on tests of above batches. The recall is limited to the identified batches (see above).

Hazard

The product does not present any safety risks.

What to do if in possession of this chemical product

Check your product against the batch numbers above. A full refund of the purchase price is available by returning to the store in which it was purchased.

More information

Visit the APVMA website to view the notice of voluntary recall for the chemical product described above.

The APVMA publishes a list of agvet chemical recall notices on its website and provides a subscription option to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to:

Pascoe's Pty Ltd Consumer Advisory

Phone (toll-free): +1800 065 326
Email: pascoes.cs@pactgroup.com
Website: www.pascoes.com.au

APVMA Gazette for 2,4-D label variations April 2022

2,4-D reconsideration final label variations April 2022

On 3 September 2020, the Australian Pesticides and Veterinary Medicines Authority (APVMA) sent holders, or nominated agents, of 2,4-D product registrations and label approvals notice of the final regulatory decision in relation to a reconsideration of 2,4-D that was conducted under Division 4, Part 2 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).

The notice outlined that the APVMA had decided to:

a. VARY under section 34A(1) of the Agvet Code the conditions of approved 2,4-D active constituents specified in Attachment B to require that the approved 2,4-D active constituent must contain no more than one part of total dioxins (i.e. the sum of the toxic equivalents of the 17 congeners of concern per billion parts of 2,4-D acid equivalent (no more than 1nanogram toxic equivalents of dioxins per gram of 2,4-D acid equivalent (ae)).

b. VARY under section 34A(1) of the Agvet Code, the relevant particulars of the approved 2,4-D chemical product labels specified in Attachment C of that notice, in the manner indicated in Attachment C of that notice;

and then

c. AFFIRM under section 34A(1) of the Agvet Code the 2,4-D active constituent approvals as varied in Attachment B of that notice;

d. AFFIRM under section 34A(1) of the Agvet Code the 2, 4-D chemical product label approval as varied in Attachment C; and

e. AFFIRM under section 34A(1) of the Agvet Code the product registrations as shown in Attachment C.

In the notice the APVMA advised that the labels of all registered products would be varied and affirmed and would be given a new label approval number. To facilitate the update, holders or nominated agents were invited to submit varied labels for approval and templates were included in the notice to facilitate the update of those labels.

As of 1 April 2022, the APVMA had not received submissions of product registrations and varied labels for verification and approval for the following products:

Table 11: Prior label approval numbers cancelled – varied label approval numbers

Product number (1)	Product name (2)	Holder (3)	Label approval number(s) cancelled (4)	Varied label approval number
54528	Halley 2,4-D Ipa 300 Herbicide	Halley International Enterprise (Australia) Pty Ltd	0214, 0805, 0901	54528/092020
54529	Halley 2,4-D Amine 500 Low Odour Herbicide	Halley International Enterprise (Australia) Pty Ltd	0214, 0801, 0805	54529/092020
54813	Halley LV Ester 600 Herbicide	Halley International Enterprise (Australia) Pty Ltd	0214, 0805, 0903, 1001	54813/092020
58811	Rygel Amine 625 Selective Herbicide	Profeng Australia Pty Ltd	0214, 0605	58811/092020
58914	Inca 625 Herbicide	Proterra Pty Ltd	0207, 0214, 0604, 0805	58914/092020
58917	Inca 300 Herbicide	Proterra Pty Ltd	0107, 0214, 0504, 0805	58917/092020
58925	Pacific 2,4-D Amine 625 Herbicide	Pacific Agriscience Pty Ltd	0609, 0805, 1004	58925/092020
58927	Pacific 2,4-D IPA 300 Herbicide	Pacific Agriscience Pty Ltd	0805, 1004, 50606	58927/092020
59600	Aminoz CT 300 Herbicide By Sanonda	Sanonda (Australia) Pty Ltd	0214, 0505	59600/092020
59795	Rygel 2,4-D IPA 300 Herbicide	Profeng Australia Pty Ltd	0214, 1105	59795/092020
61380	Rygel Low Volatile Ester 600 Herbicide	Profeng Australia Pty Ltd	0214, 0709	61380/092020
62347	Genfarm LV Ester 600 Herbicide	Nutrien Ag Solutions Limited	0214, 1107	62347/092020
62926	Weeds Out 300 Herbicide	Biotis Life Science Pty Ltd	0214, 0908	62926/092020
63272	Genfarm 2,4-D Amine 300 Herbicide	Nutrien Ag Solutions Limited	0310, 0608	63272/092020
63668	Biotis Amine 720 Selective Herbicide	Biotis Life Science Pty Ltd	0214, 0609	63668/092020
63775	Biotis Amine 625 Selective Herbicide	Biotis Life Science Pty Ltd	0214, 0309	63775/092020
64539	Macro Protect LV Ester 680 Herbicide	Nutrien Ag Solutions Limited	0310, 105820	64539/092020
65006	Biotis 2,4-D Ester 680 Herbicide	Biotis Life Science Pty Ltd	49857	65006/092020
65226	Pacific 2,4-D LVE 680 Herbicide	Pacific Agriscience Pty Ltd	50455	65226/092020
65849	Fosterra 2,4-D Amine 625 Selective Herbicide	Fosterra Pty Ltd	52169	65849/092020
67219	Easyfarm 2,4-D IPA 300 Herbicide	Easyfarm Pty Ltd	55481, 59784	67219/092020
69019	JNO 2,4-D Amine 625 Herbicide	Jno Investment Holdings Pty Ltd	59661	69019/092020
69020	JNO 2,4-D Ester 680 Herbicide	Jno Investment Holdings Pty Ltd	59662	69020/092020
69663	Agrocn 2,4-D 625 Sl Selective Herbicide	Shanghai Agrochina Chemical Co. Ltd.	61380	69663/092020
69835	Macro Protect 2,4-D Amine 625 Ac Herbicide	Nutrien Ag Solutions Limited	61859	69835/092020
69921	Oztec 2,4-D IPA 300 Herbicide	Oztec Rural Pty Ltd	62060	69921/092020

Product number (1)	Product name (2)	Holder (3)	Label approval number(s) cancelled (4)	Varied label approval number
86156	Emuag 2,4-D 680EC Herbicide	EmuAg Pty Ltd	114814	86156/092020
86157	Emuag 2,4-D 625 Selective Herbicide	EmuAg Pty Ltd	114815	86157/092020

As the previous labels were considered to be varied as per the notice of 3 September 2020, the APVMA has issued holders or nominated agents of registered products in Table 11 with a copy of the varied label as it appears in the register.

Please note that it is an offence under section 81(1A) for a registered chemical product to be supplied in a container bearing an unapproved label (a label with incorrect or incomplete relevant particulars, that is not consistent with the final regulatory decisions).