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Gazette

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**AGRICULTURAL AND
VETERINARY CHEMICALS**



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

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

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GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) 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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Erratum Notice

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, APVMA 23, Tuesday, 15 November 2016.

In the Notice, the product name 'Imtarde Haloxy 900 EC Herbicide' was spelt incorrectly.

The correct entry for the Notice of Registration for 'Imtrade Haloxy 900 EC Herbicide' is on page 4 of this gazette.

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.

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	107446
Product name:	Imtrade Haloxy 900 EC Herbicide
Active constituent/s:	900 g/L haloxyfop-p present as the haloxyfop-p-methyl ester
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use	For post-emergent control of a wide range of annual and perennial grass weeds in grain legume and oilseed crops, lucerne, medic and clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops
Date of registration/approval:	28 September 2016
Product registration no.:	83076
Label approval no.:	83076/107446
Application no.:	107762
Product name:	Apparent Festival 100 Plant Growth Regulator
Active constituent/s:	100 g/L gibberellic acid
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of use	For foliar spray application to certain varieties of grapes, citrus and prunes to promote desirable harvest effects
Date of registration:	2 November 2016
Product registration no.:	83226
Label approval no.:	83226/107762
Application no.:	106012
Product name:	Brunnings Weed Kill Concentrate Big Shots
Active constituent/s:	360 g/L glyphosate present as the isopropylamine salt
Applicant name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of use	For control of weeds in the home garden
Date of registration:	3 November 2016
Product registration no.:	82535
Label approval no.:	82535/106012
Application no.:	104798
Product name:	Accolade 250 SC Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of use	For the control of various diseases of grapes, potatoes, tomatoes, cucurbits, avocados, mangoes, passionfruit and poppies
Date of registration:	9 November 2016
Product registration no.:	82017
Label approval no.:	82017/104798

Application no.:	104420
Product name:	Voliam Targo Insecticide
Active constituent/s:	18 g/L abamectin, 45 g/L chlorantraniliprole
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	For control of certain mite and insect pests on pome fruit
Date of registration:	14 November 2016
Product registration no.:	81921
Label approval no.:	81921/104420
Application no.:	107304
Product name:	Relyon Paraquick Force 350 Herbicide
Active constituent/s:	350 g/L paraquat present as paraquat dichloride
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of a wide range of grasses and broadleaf weeds
Date of registration:	16 November 2016
Product registration no.:	83010
Label approval no.:	83010/107304
Application no.:	103465
Product name:	Accensi Acetamiprid RTU Insecticide
Active constituent/s:	0.05 g/L acetamiprid
Applicant name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of use	For the control of various pests with a ready to use contact, systemic and residual insecticide
Date of registration:	18 November 2016
Product registration no.:	81616
Label approval no.:	81616/103465
Application no.:	107614
Product name:	Relyon Prosumi 500SC Fungicide
Active constituent/s:	500 g/L procymidone
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of certain fungal diseases on various crops
Date of registration:	22 November 2016
Product registration no.:	83139
Label approval no.:	83139/107614
Application no.:	105119
Product name:	Efecto Fungicide
Active constituent/s:	500 g/L flutriafol
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser
Date of registration:	23 November 2016
Product registration no.:	82163
Label approval no.:	82163/105119

2. VARIATIONS OF REGISTRATION

Application no:	107992
Product name:	Huilong Chlorsulfuron 750 WDG Herbicide
Active constituent/s:	750 g/kg chlorsulfuron
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY CHLORSULFURON 750 WDG HERBICIDE' to 'HUILONG CHLORSULFURON 750 WDG HERBICIDE'
Date of variation:	27 September 2016
Product registration no.:	66294
Label approval no.:	66294/107992

Application no:	108065
Product name:	Huilong Tebuconazole 430 SC Fungicide
Active constituent/s:	430 g/L tebuconazole
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY TEBUCONAZOLE 430 SC FUNGICIDE' to 'HUILONG TEBUCONAZOLE 430 SC FUNGICIDE'
Date of variation:	27 September 2016
Product registration no.:	66297
Label approval no.:	66297/108065

Application no:	108063
Product name:	Huilong 2,4-D IPA 300 Herbicide
Active constituent/s:	300 g/L 2,4-D present as the isopropylamine salt
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY 2,4-D IPA 300 HERBICIDE' to 'HUILONG 2,4-D IPA 300 HERBICIDE'
Date of variation:	27 September 2016
Product registration no.:	67141
Label approval no.:	67141/108063

Application no:	108116
Product name:	Touch & Go General Purpose Insecticide Space Spray
Active constituent/s:	4.5 g/kg allethrin 20:80, 1 g/kg phenothrin 20:80
Applicant name:	Ecolab Pty Limited
Applicant ACN:	000 449 990
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'GIBSON GENERAL PURPOSE INSECTICIDE SPACE SPRAY TOUCH & GO' to 'TOUCH & GO GENERAL PURPOSE INSECTICIDE SPACE SPRAY'
Date of variation:	4 October 2016
Product registration no.:	32338
Label approval no.:	32338/108116

Application no:	105800
Product name:	Ultrathor Water-Based Termiticide and Insecticide
Active constituent/s:	100 g/L fipronil
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of variation:	To change product name from 'ULTRATHOR WATER-BASED TERMITICIDE' to 'ULTRATHOR WATER-BASED TERMITICIDE AND INSECTICIDE' and to extend use to include control of a range of urban pests in external areas and surrounds of domestic, commercial, public, and industrial buildings and structures
Date of variation:	2 November 2016
Product registration no.:	64449
Label approval no.:	64449/105800

Application no:	105687
Product name:	Foragemax Herbicide
Active constituent/s:	50 g/L aminopyralid present as triisopropanolamine salt, 100 g/L halauxifen-methyl
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To extend the label approval to include undersown grasses in forage brassica (rape and turnip) crops
Date of variation:	3 November 2016
Product registration no.:	68249
Label approval no.:	68249/105687

Application no:	107647
Product name:	Carboline Sea-Barrier 1000 Antifouling
Active c Active constituent/s:	44 g/L thiram, 332 g/L copper present as cuprous oxide
Applicant name:	Resene Paints (Australia) Limited
Applicant ACN:	050 034 529
Summary of variation:	To approve a new label for the product with the label name 'ALEX YATCH AND BOAT PAINT COASTAL COPPER'
Date of variation:	8 November 2016
Product registration no.:	64129
Label approval no.:	64129/107647

Application no:	107750
Product name:	Dupont Fontelis Fungicide
Active constituent/s:	200 g/L penthiopyrad
Applicant name:	Du Pont (Australia) Pty Ltd
Applicant ACN:	000 716 469
Summary of variation:	To update spray drift instructions
Date of variation:	22 November 2016
Product registration no.:	65510
Label approval no.:	65510/107750

Application no:	106153
Product name:	Conan Sticks 720 SC Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of variation:	To extend the use to include the control of fungal diseases in chickpeas and lentils
Date of variation:	22 November 2016
Product registration no.:	68458
Label approval no.:	68458/106153

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.

1. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	62542
Product name:	ProZinc Insulin Injection For Cats
Active constituent/s:	each mL contains 40IU human insulin
Applicant name:	Boehringer Ingelheim Pty Limited
Applicant ACN:	000 452 308
Summary of use	For the treatment of diabetes mellitus in cats
Date of registration:	17 November 2016
Product registration no.:	70112
Label approval no.:	62542/70112

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	102185
Product name:	Apramax Apramycin Soluble Powder
Active constituent/s:	595 mg/g apramycin
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use	For the treatment of infections caused by bacteria sensitive to apramycin in pigs, calves and broilers
Date of registration:	23 November 2016
Product registration no.:	81028
Label approval no.:	81028/102185

3. VARIATIONS OF REGISTRATION

Application no:	108109
Product name:	Websters 5 In 1 Se Vaccine
Active constituent/s:	contains aluminium adjuvanted toxoid and cellular antigen from clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL), Cl. hauvoei (EP 0361) and selenium (as sodium selenate) 0.5 mg/mL.contains 0.13 mg/mL thiomersal.
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'WEBSTERS 5 IN 1 VACCINE WITH SELENIUM FOR LAMBS' to 'WEBSTERS 5 IN 1 Se VACCINE'
Date of variation:	30 September 2016
Product registration no.:	47952
Label approval no.:	47952/108109

Application no:	108115
Product name:	Alto Lab Bug Shield Read For Use Insecticide
Active constituent/s:	1 mg/mL permethrin (25:75::CIS:TRANS), 4 mg/mL piperonyl butoxide
Applicant name:	Greg Grant Australia Pty Ltd
Applicant ACN:	000 764 492
Summary of variation:	To change the name that appears on the label from 'ALTO LAB BUG SHIELD READ FOR USE INSECTICIDE' to 'BLUE RIBBON READY FOR USE INSECTICIDE'
Date of variation:	4 October 2016
Product registration no.:	42018
Label approval no.:	42018/108115

Application no:	108111
Product name:	CCD Olaquinox 100
Active constituent/s:	100 g/kg olaquinox
Applicant name:	CCD Animal Health Pty Ltd
Applicant ACN:	151 737 950
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'OPTIVITE QUINDOX' to 'CCD OLAQUINOX 100'
Date of variation:	4 October 2016
Product registration no.:	42340
Label approval no.:	42340/108111

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.

1. ACTIVE CONSITUTENT

Application no.:	104364
Active constituent/s:	Human Insulin
Applicant name:	Boehringer Ingelheim Pty Ltd
Applicant ACN:	000 452 308
Summary of use:	For use in veterinary chemical products
Date of approval:	16 November 2016
Approval no.:	81896
Application no.:	106003
Active constituent/s:	Siduron
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use:	For use in agricultural chemical products
Date of approval:	17 November 2016
Approval no.:	82531
Application no.:	106025
Active constituent/s:	Bromochlorodimethylhydantoin
Applicant name:	Semal Pty Ltd T/A Consolidated Chemical Co
Applicant ACN:	005 056 502
Summary of use:	For use in agricultural chemical products
Date of approval:	21 November 2016
Approval no.:	82545
Application no.:	103280
Active constituent/s:	Peforelin
Applicant name:	Veyx-Pharm GmbH
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	22 November 2016
Approval no.:	81520
Application no.:	106275
Active constituent/s:	Boscalid
Applicant name:	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN:	000 045 590
Summary of use:	For use in agricultural chemical products
Date of approval:	22 November 2016
Approval no.:	82625

Approved Active Constituents—Veterinary

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, s14, 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.

1. ACTIVE CONSITUTENT

Application no.:	107700
Active constituent/s:	Canine Erythrocytes
Applicant name:	Plasvacc Pty Ltd
Applicant ACN:	099 547 841
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	83189

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	105203
Active constituent/s:	Closantel
Applicant name:	Meril Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	17 October 2016
Approval no.:	82197

Application no.:	106299
Active constituent/s:	Methandriol Dipropionate
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	18 October 2016
Approval no.:	82139

Application no.:	106306
Active constituent/s:	Testosterone Cypionate
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent.
Date of variation:	17 October 2016
Approval no.:	82153

Application no.:	106307
Active constituent/s:	Testosterone Propionate
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	17 October 2016
Approval no.:	82154

Application no.:	106293
Active constituent/s:	Nandrolone Phenylpropionate
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	17 October 2016
Approval no.:	82141

Application no.:	106087
Active constituent/s:	Gentamicin Sulfate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	18 October 2016
Approval no.:	82507

Application no.:	106112
Active constituent/s:	Amoxycillin Trihydrate
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	25 October 2016
Approval no.:	81892

Application no.:	106161
Active constituent/s:	Hydrocortisone
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	25 October 2016
Approval no.:	82096

Application no.:	106038
Active constituent/s:	Bacitracin Zinc
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	25 October 2016
Approval no.:	82060

Application no.:	106167
Active constituent/s:	Clindamycin Hydrochloride
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	25 October 2016
Approval no.:	82088

Application no.:	106125
Active constituent/s:	Azaperone
Applicant name:	Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd
Applicant ACN:	000 233 992
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	25 October 2016
Approval no.:	54728

Application no.:	106353
Active constituent/s:	Moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	26 October 2016
Approval no.:	81957

Application no.:	106303
Active constituent/s:	Stanozolol
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	3 November 2016
Approval no.:	56288

Application no.:	107015
Active constituent/s:	Enrofloxacin
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	3 November 2016
Approval no.:	82082

Application no.:	106947
Active constituent/s:	Methadone Hydrochloride
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	3 November 2016
Approval no.:	82317

Application no.:	106089
Active constituent/s:	Sodium Arsanilate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	3 November 2016
Approval no.:	82316

Application no.:	105464
Active constituent/s:	Dimethyl Pimelate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	18 November 2016
Approval no.:	59170

Application no.:	107997
Active constituent/s:	Carprofen
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	18 November 2016
Approval no.:	82092

Application no.:	106300
Active constituent/s:	Testosterone
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	18 November 2016
Approval no.:	82155

Application no.:	107061
Active constituent/s:	Ambroxol Hydrochloride
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	23 November 2016
Approval no.:	54688

Application no.:	108274
Active constituent/s:	Sodium Arsanilate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	23 November 2016
Approval no.:	82316

Approved Active Constituents—Veterinary

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, s14A, 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.

1. ACTIVE CONSITUTENT

Application no.:	30806
Active constituent/s:	Potassium Chloride
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	19 July 2016
Approval no.:	57514

Application no.:	30808
Active constituent/s:	Potassium Chloride Anhydrous
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	19 July 2016
Approval no.:	57515

Application no.:	105483
Active constituent/s:	Oxantel Embonate
Applicant name:	Aristopet Pty Ltd
Applicant ACN:	151 418 882
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	82349

Application no.:	106007
Active constituent/s:	Lactic Acid
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	82532

Application no.:	106028
Active constituent/s:	Glycerin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	82548

Application no.:	105983
Active constituent/s:	Phenoxyethanol
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	82520

Application no.:	105803
Active constituent/s:	Zolazepam Hydrochloride
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	82466

Application no.:	105798
Active constituent/s:	Tiletamine Hydrochloride
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	82463

Application no.:	106026
Active constituent/s:	Fipronil
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	13 October 2016
Approval no.:	82546

Application no.:	106547
Active constituent/s:	Apramycin Sulfate
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	14 October 2016
Approval no.:	82728

Application no.:	106461
Active constituent/s:	Ceftiofur Hydrochloride
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	14 October 2016
Approval no.:	82682

Application no.:	106332
Active constituent/s:	Phenylpropanolamine Hydrochloride
Applicant name:	Ausrichter Pty Ltd
Applicant ACN:	000 908 529
Summary of use:	For use in veterinary chemical products
Date of approval:	14 October 2016
Approval no.:	82639

Application no.:	106317
Active constituent/s:	Ceftiofur Hydrochloride
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	14 October 2016
Approval no.:	82633

Application no.:	106249
Active constituent/s:	Pyrantel Pamoate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	14 October 2016
Approval no.:	82612

Application no.:	106023
Active constituent/s:	Doramectin
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	14 October 2016
Approval no.:	82543

Application no.:	105343
Active constituent/s:	Biotin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	17 October 2016
Approval no.:	82274

Application no.:	106488
Active constituent/s:	3,5-Dinitro-O-Toluamide
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	17 October 2016
Approval no.:	82686

Application no.:	106246
Active constituent/s:	Bacitracin Zinc
Applicant name:	Huvepharma EOOD
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	17 October 2016
Approval no.:	82610
Application no.:	106499
Active constituent/s:	Nicarbazin
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	18 October 2016
Approval no.:	82696
Application no.:	106495
Active constituent/s:	Zinc Bacitracin
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	18 October 2016
Approval no.:	82692
Application no.:	106351
Active constituent/s:	Nicotinamide
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	18 October 2016
Approval no.:	82648
Application no.:	106494
Active constituent/s:	Monensin Sodium 40%
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	18 October 2016
Approval no.:	82691
Application no.:	108240
Active constituent/s:	Meloxicam
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	20 October 2016
Approval no.:	83425

Application no.:	106014
Active constituent/s:	Albendazole
Applicant name:	Argenta Manufacturing Limited
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	20 October 2016
Approval no.:	82537
Application no.:	106496
Active constituent/s:	Oxytetracycline HCL
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	21 October 2016
Approval no.:	82693
Application no.:	106265
Active constituent/s:	Thiamine Nitrate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	21 October 2016
Approval no.:	82620
Application no.:	106401
Active constituent/s:	Moxidectin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	24 October 2016
Approval no.:	82668
Application no.:	106497
Active constituent/s:	Oxytetracycline Dihydrate
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	25 October 2016
Approval no.:	82694
Application no.:	106498
Active constituent/s:	Tylosin Phosphate
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	25 October 2016
Approval no.:	82695

Application no.:	106503
Active constituent/s:	Olaquinox 98%
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	25 October 2016
Approval no.:	82700

Application no.:	106542
Active constituent/s:	Meloxicam
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	25 October 2016
Approval no.:	82725

Application no.:	106545
Active constituent/s:	Salinomycin Sodium
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	25 October 2016
Approval no.:	82726

Application no.:	106500
Active constituent/s:	Bambermycin 8%
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82697

Application no.:	106501
Active constituent/s:	Bambermycin 4%
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82698

Application no.:	106506
Active constituent/s:	Monensin Sodium 20%
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82703

Application no.:	106504
Active constituent/s:	Chlortetracycline HCL 20%
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82701

Application no.:	106503
Active constituent/s:	Salinomycin Sodium 12%
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82699

Application no.:	107140
Active constituent/s:	Moxidectin
Applicant name:	Vetafarm Pty.Ltd.
Applicant ACN:	059 895 153
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82927

Application no.:	107012
Active constituent/s:	Abamectin
Applicant name:	Chemvet Australia Pty Ltd
Applicant ACN:	138 711 289
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82866

Application no.:	106546
Active constituent/s:	Monensin Sodium
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	26 October 2016
Approval no.:	82727

Application no.:	106854
Active constituent/s:	Pectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use:	For use in veterinary chemical products
Date of approval:	3 November 2016
Approval no.:	82818

Application no.:	106016
Active constituent/s:	Calcium Gluconate Monohydrate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	3 November 2016
Approval no.:	82539

Application no.:	107151
Active constituent/s:	Halofuginone Lactate
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of use:	For use in veterinary chemical products
Date of approval:	3 November 2016
Approval no.:	82934

Application no.:	107021
Active constituent/s:	Tylosin Phosphate
Applicant name:	Dox-Al Italia S.P.A.
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	3 November 2016
Approval no.:	82871

Application no.:	106493
Active constituent/s:	Tylosin Tartrate
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	3 November 2016
Approval no.:	82690

Application no.:	106920
Active constituent/s:	Abamectin
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	3 November 2016
Approval no.:	82843

Application no.:	106706
Active constituent/s:	Meloxicam
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	3 November 2016
Approval no.:	82763

Application no.:	108305
Active constituent/s:	Sodium Selenate
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2016
Approval no.:	83454

Application no.:	108304
Active constituent/s:	Moxidectin
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use:	For use in veterinary chemical products
Date of approval:	14 November 2016
Approval no.:	83453

Application no.:	108322
Active constituent/s:	Chlortetracycline Hydrochloride
Applicant name:	Zamira Life Sciences Pty Ltd
Applicant ACN:	130 641 502
Summary of use:	For use in veterinary chemical products
Date of approval:	18 November 2016
Approval no.:	83467

Application no.:	106861
Active constituent/s:	Clorsulon
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For use in veterinary chemical products
Date of approval:	18 November 2016
Approval no.:	82824

Application no.:	106870
Active constituent/s:	Moxidectin
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For use in veterinary chemical products
Date of approval:	18 November 2016
Approval no.:	82829

Application no.:	106872
Active constituent/s:	Amitraz
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For use in veterinary chemical products
Date of approval:	18 November 2016
Approval no.:	82830

Application no.:	106875
Active constituent/s:	Magnesium Hypophosphite
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For use in veterinary chemical products
Date of approval:	22 November 2016
Approval no.:	82832

Application no.:	106880
Active constituent/s:	Levamisole Base
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For use in veterinary chemical products
Date of approval:	22 November 2016
Approval no.:	82834

Application no.:	106573
Active constituent/s:	Flunixin Meglumine
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	22 November 2016
Approval no.:	82735

Application no.:	107824
Active constituent/s:	Ractopamine Hydrochloride
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	22 November 2016
Approval no.:	83240

Application no.:	107017
Active constituent/s:	Oxibendazole
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	23 November 2016
Approval no.:	82868

Application no.:	107156
Active constituent/s:	Procaine Penicillin
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	23 November 2016
Approval no.:	82935

Application no.:	107106
Active constituent/s:	Levamisole Hydrochloride
Applicant name:	Chemvet Australia Pty Ltd
Applicant ACN:	138 711 289
Summary of use:	For use in veterinary chemical products
Date of approval:	23 November 2016
Approval no.:	82914

Application no.:	107019
Active constituent/s:	Salinomycin Sodium
Applicant name:	Dox-Al Italia S.P.A.
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	23 November 2016
Approval no.:	82869

Application no.:	105351
Active constituent/s:	Ferric Pyrophosphate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	24 November 2016
Approval no.:	82279

Application no.:	106302
Active constituent/s:	Boldenone Undecylenate
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of use:	For use in veterinary chemical products
Date of approval:	24 November 2016
Approval no.:	82135

Application no.:	106305
Active constituent/s:	Nandrolone Decanoate
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of use:	For use in veterinary chemical products
Date of approval:	24 November 2016
Approval no.:	82157

Application no.:	107215
Active constituent/s:	Albendazole
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	24 November 2016
Approval no.:	82960

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	106085
Active constituent/s:	DL-Methionine
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	18 October 2016
Approval no.:	82189

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 Instrument No. 4 (MRL Standard) 2012*. 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 Instrument No. 4 (MRL Standard) Amendment Instrument 2016 (No. 16)*.

The amendments will be incorporated into the compilation of the [Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#).

The *MRL Standard* is accessible via the ComLaw website www.comlaw.gov.au or the links above.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: enquiries@apvma.gov.au

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

In the previous notice, the APVMA gazetted amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*, have been made.

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 Instrument No. 4 (MRL Standard) Amendment Instrument 2016 (No. 16)*) 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 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 Government of Australia and the Government of New Zealand 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.

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

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 AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2016 (NO. 16))

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 sunseting.

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: Acetamiprid

Permitted residue—commodities of plant origin:
Acetamiprid

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

Pome fruits	T0.5
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Agvet chemical: Dithianon

Permitted residue: Dithianon

Fruits	2
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Agvet chemical: Novaluron

Permitted residue: Novaluron

Pome fruits	T1
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[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Acetamiprid

Permitted residue—commodities of plant origin:
Acetamiprid

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

Apple	0.2
Pear	0.3

Agvet chemical: Chlorantraniliprole

Permitted residue—plant commodities and animal commodities other than milk: Chlorantraniliprole

Permitted residue—milk: Sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole

Safflower seed	T0.5
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Agvet chemical: Dithianon

Permitted residue: Dithianon

Blueberries	T7
Fruits [except blueberries]	2

Agvet chemical: Novaluron

Permitted residue: Novaluron

Apple	0.3
Edible offal (mammalian)	*0.01
Eggs	*0.01
Meat (mammalian) (in the fat)	0.1
Milk fats	0.2
Milks	*0.01
Pear	0.3
Poultry, edible offal of	*0.01
Poultry meat (in the fat)	*0.01

Agvet chemical: Spirotetramat

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

Blueberries	T2
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[1.3] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Trifloxystrobin

Permitted residue: Sum of trifloxystrobin and its acid metabolite ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl)-ethylideneaminooxymethyl]phenyl] acetic acid), expressed as trifloxystrobin equivalents

Chard (silver beet)	T10
Chicory leaves	T10
Endive	T10
Spinach	T10

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, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

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: 6 pm (ADST) 27 December 2016

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT

Submissions received after this date will only be considered 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.

For further information please contact:

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KINGSTON ACT 2604

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Email: enquiries@apvma.gov.au

Variations to Schedule 20 of the Australia 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. 11) gazetted on 23 August 2016 (No. APVMA 17).

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 17, 2016) 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 available on the Legislation website at www.legislation.gov.au/

Based on dietary exposure assessments and current health standards, the APVMA and 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 Government of Australia and the Government of New Zealand 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.

Food Standards Australia New Zealand (FSANZ) made Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) in relation to these variations and no comment was received in response to that notice.

A copy of these variations have been given to FSANZ.

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

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

For further information please contact:

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Australian Pesticides and Veterinary Medicines Authority
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KINGSTON ACT 2604

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Email: enquiries@apvma.gov.au



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

***Australia New Zealand Food Standards
Code—Schedule 20—Maximum residue
limits Variation Instrument
No. APVMA 11, 2016***

I, Matthew O'Mullane, Executive Director, Scientific Assessment and Chemical Review and 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*.

Matthew O'Mullane
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this Twenty Third day of November 2016

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 11, 2016*.

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 No. APVMA 24, of 29 November 2016.

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: Pyriofenone

Permitted residue: Pyriofenone

All other foods	0.05
Dried grapes (currants, raisins and sultanas)	2
Edible offal (mammalian)	*0.01
Eggs	*0.01
Fruiting vegetables, cucurbits	0.7
Grapes	0.5
Meat (mammalian)	*0.01
Milks	*0.01
Poultry, edible offal of	*0.01
Poultry meat	*0.01

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

Agvet chemical: Azoxystrobin

Permitted residue: Azoxystrobin

Beans [except broad and soya bean]	2
Meat (mammalian)	*0.01
Peas (pods and succulent, immature seeds)	2

Agvet chemical: Propachlor

Permitted residue: Sum of propachlor and metabolites hydrolysable to N-isopropylaniline, expressed as propachlor

Lettuce, head	*0.02
Lettuce, leaf	*0.02

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

Agvet chemical: Azoxystrobin

Permitted residue: Azoxystrobin

Legume vegetables	3
Lupin (dry)	T0.05
Meat (mammalian) (in the fat)	0.02

Agvet chemical: Boscalid

Permitted residue—commodities of plant origin:
Boscalid

Permitted residue—commodities of animal origin:
Sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl) nicotinamide and the glucuronide conjugate of 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl) nicotinamide, expressed as boscalid equivalents

Lupin (dry)	T3
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[1.4] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Azoxystrobin

Permitted residue: Azoxystrobin

Edible offal (mammalian)	0.03
Fruiting vegetables, cucurbits	2

Cancellation of a Label Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the label approval 81930/104446 of the following product

Product no	Product name	Label approval number	Approval holder	Date of effect
81930	GroChem Phosphorous Acid	81930/104446	Agrinova New Zealand Limited T/A Gro-Chem	4 November 2016

The following instructions set out how a person can deal with the cancelled product label approval.

SUPPLY

A person may supply or cause to be supplied products manufactured prior to 4 November 2017 at wholesale and retail level, until the 4 November 2017.

After 4 November 2017 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the label 81930/104446 with the intention to supply, or to supply the product.

USE

A person may continue to use the product according to its label instructions until 4 November 2017.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing the label 81930/104446 in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product after the registration has been cancelled until 4 November 2017.

The supply and use of the product must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product listed in the table 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
PO Box 6182
SYMONSTON ACT 2609
Phone: +61 2 6210 4749
Fax: +61 2 6210 4773
Email: chemicalreview@apvma.gov.au

Extension of the Suspension of Quintozene Active Constituent Approval Number 53706 and Certain Product Registrations and Label Approvals

The APVMA has decided to extend the suspension of the quintozene active constituent approval number 53706 (see table 1). This decision was made under s.41(1)(a) of the Agvet Code¹. The extended suspension is in effect for 12 months from 14 November 2016 to 12 November 2017.

The APVMA has decided to extend the suspension of the registration of seven quintozene products as outlined in table 2 below. This decision was made under s.44(1). The extended suspension of these product registrations is in effect for 12 months from 14 November 2016 to 12 November 2017.

The APVMA has decided to extend the suspension of all associated label approvals for products containing quintozene as outlined in table 2 below. This decision was made under s.44(2). The extended suspension of these label approvals is in effect for 12 months from 14 November 2016 to 12 November 2017.

Table 1—Active constituent subject to extended suspension

Approval number	Active name	Holder
53706	Quintozene	AMVAC C.V.

Table 2—Products and label approvals subject to extended suspension

Product number	Product name	Holder	Label approval(s)
45883	Uniroyal Chemical Terraclor Super-X E.C. Soil Fungicide	Amgrow Pty Ltd	45883/0903
47211 ²	Barmac Chloroturf Dg Fungicide	Amgrow Pty Ltd	47211/1102 47211/3427
48308 ²	Barmac Rhysol Dg Turf Fungicide	Amgrow Pty Ltd	48308/01 48308/0400
50787	Uniroyal Chemical Cotton Planter Box Protectant	Amgrow Pty Ltd	50787/0498 50788/0603
50789	Uniroyal Chemical Terraclor Cotton Seed Protectant	Amgrow Pty Ltd	50789/0300 50789/0498
53533 ²	Terraclor Soil Fungicide	Amgrow Pty Ltd	53533/0201 53533/0403 53533/0702 53533/0703 53533/1100 53533/1206
55743	Terraclor Seed Treatment	Amgrow Pty Ltd	55743/0105 55743/1106

¹ For the purposes of this document, the term 'Agvet Code', and all references to the legislation refers to the Agricultural and Veterinary Chemicals Code schedules to the Agricultural and Veterinary Chemicals Code Act 1994 unless otherwise specified.

² Subject to permit; PER12493.

REASONS FOR EXTENDING THE SUSPENSIONS

Under s.41(1)(a), the APVMA may suspend the approval of an active constituent if it appears to the APVMA that the constituent may not meet the safety criteria.

The APVMA became aware of information in 2009 indicating the presence of undeclared dioxins as impurities in products that contain quintozene as the active constituent. Dioxins are classified by the APVMA as compounds of toxicological concern (see apvma.gov.au/node/10706).

As a result of the presence of undeclared dioxin impurities, the APVMA considers that the quintozene active constituent approval number 53706 may be an undue hazard to the safety of people exposed to it during its handling and may have an effect that is harmful to human beings. Consequently, the APVMA has suspended quintozene active constituent approval number 53706 under s.41(1)(a) from 9 April 2010 until 13 November 2015. The APVMA has decided to extend this suspension for a further 12-months from 14 November 2016 to 12 November 2017.

If the APVMA suspends the approval of an active constituent for a chemical product, it must also suspend any registration of that product under s.44(1). If the APVMA suspends the registration of a chemical product, it must also suspend any approval relating to a label for containers for the product under s.44(2). Consequently, the APVMA suspended the registration of products containing quintozene and label approvals for products containing quintozene from 9 April 2010 until 14 November 2016. The APVMA has decided to continue the suspensions for the product registrations and label approvals outlined in table 2 for a further 12 months from 14 November 2016 to 12 November 2017.

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH QUINTOZENE ACTIVE CONSTITUENT, PRODUCT, OR PRODUCT CONTAINING THE QUINTOZENE LABEL³

Unless authorised by the APVMA, the following instructions apply to persons having possession or custody of stocks, and are considering using or otherwise dealing with suspended active constituent and product during the period of suspension.

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH SUSPENDED ACTIVE CONSTITUENTS AND PRODUCTS

Possession and custody

Possession and custody of existing stocks of quintozene active constituent and/or products is permitted.

Supply

Supply of the active constituent quintozene and/or any product that contains it as an active constituent is not permitted.

Use

Use of suspended product containing quintozene is not permitted.

³ Subject to permit; PER12493.

WARNING

The active constituent listed in table 1 is not approved, the products listed in table 2 are not registered and the labels listed in table 2 are not approved during the period of suspension.

A person must not possess with the intent to supply, or deal with any of these active constituents, products or products containing the label during this period except in accordance with the instructions contained in this notice. A failure to comply with these instructions will result in an offence against the Agvet Codes and the APVMA will take appropriate compliance action including a penalty of 300 penalty units as specified under s.45C(5). It is an offence for any person to supply, possess with the intent to supply, use or deal with the active constituent or products after 9 April 2010, unless authorised to do so by the APVMA.

APVMA CONTACT

For further information please contact:

Chemical Review Liaison Officer
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4749

Fax: +61 2 6210 4840

Email: chemicalreview@apvma.gov.au

Sero-X Insecticide Containing Clitoria Ternatea Extract

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing the new active constituent clitoria ternatea extract. The product is Sero-X Insecticide.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Sero-X Insectide
Applicant company:	Innovate Ag Pty Limited
Name of active constituent:	Clitoria ternatea extract
Signal heading:	Schedule 6
Summary of proposed use:	For the control or suppression of green mirid, silverleaf whitefly (biotype B) and heliothis in cotton.
Pack sizes:	1 L – 1000 L
Withholding period:	Harvest: Not required when used as directed

SUMMARY OF THE APVMA'S EVALUATION OF SERO-X INSECTICIDE 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 Sero-X Insecticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The then Office of Chemical Safety (OCS) in the Department of Health conducted a risk assessment on the product and concluded that there should be no adverse effects on human health from the use of Sero-X Insecticide when used in accordance with the label directions. OCS has recommended first aid and safety directions which have been incorporated into the label particulars.

Clitoria ternatea extract is included in Appendix B, Part 3 of the SUSMP as an agricultural substance considered not to require control by scheduling due to its low toxicity.

- (ii) The APVMA is satisfied that the proposed use of Sero-X Insecticide will not be an undue hazard to the safety of people using anything containing its residues.

An ADI for clitoria ternatea extract is not considered necessary as no effects were observed in a 90 day oral toxicity study in rats at the NOEL of 1000 mg/kg bw/d.

- (iii) The APVMA is satisfied that the proposed use of Sero-X Insecticide containing the active constituent clitoria ternatea extract is not likely to be harmful to human beings if used according to the product label directions.
- (iv) The APVMA is satisfied that the proposed use of Sero-X Insecticide is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

Environmental risks posed by the use of this product are acceptable to terrestrial vertebrates and invertebrates, soil organisms and terrestrial plants, as no adverse effects are expected. In a worst-case scenario of direct overspray, risk was shown to the aquatic environment. However, with a downwind no-spray zone of 5 m to aquatic and wetland areas, this risk was considered acceptable.

The APVMA has considered these findings and accepts these conclusions.

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 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the Sero-X Insecticide adequately demonstrate that if used according to the product label directions, the product is effective for its proposed use for the control or suppression of green mirid, silverleaf whitefly (Biotype B) and heliothis in cotton.
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:
 - (ii) The APVMA is satisfied that the proposed use of Sero-X Insecticide would not adversely affect trade between Australia and overseas markets.

Clitoria ternatea extract is a biological extract manufactured from clitoria ternatea plant material. The residues relating to the proposed use of clitoria ternatea extract in Sero-X Insecticide will not occur in foods and animal feeds above background levels of similar compounds naturally present in the environment. The extract components are the same or closely similar to those found in food. The trade risk associated with the proposed use of clitoria ternatea extract on cotton is considered to be low and not undue.

It is recommended that a Table 5 entry be established for the use of clitoria ternatea extract on food and non-food producing crops, as clitoria ternatea extract is indistinguishable from natural food components and is of no toxicological significance.

The following label statements have been proposed to manage the trade risks associated with the proposed use:

WITHHOLDING PERIODS:

Harvest: Not required when used as directed

Comment is sought from the relevant industry groups on the perceived level of risk and whether any industry-initiated strategies are required to manage that risk.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, www.apvma.gov.au/consultation/public or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Sero-X Insecticide 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.

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

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Email: enquiries@apvma.gov.au