

Commonwealth of Australia

Gazette

No. APVMA 25, Tuesday, 12 December 2017

Published by The Australian Pesticides and Veterinary Medicines Authority

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,

www.apvma.gov.au/news-and-publications/publications/gazette

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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 7, Tuesday, 4 April 2017.

In the Notice the summary of use was incorrect. The correct entry for the Notice of Registration for 'FOSTERA PCV MH' is on page 18 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.: 106394

Product name: Taratek LT Antisapstain Fungicide

Active constituent/s: 133 g/L 4,5-dichloro-2-n-octyl-3(2h)-isothiazolone, 33 g/L propiconazole, 33 g/L

tebuconazole

Applicant name:Zelam Pty LtdApplicant ACN:082 428 028

Summary of use: For the control of sapstain and mould on fresh timber

Date of registration: 3 November 2017

Product registration no.: 82666 Label approval no.: 82666/106394

Application no.: 112313

Product name: Raystar Bromoxynil 200 EC Herbicide

Active constituent/s: 200 g/L bromoxynil present as the n-octanoyl ester

Applicant name: Raystar Cropprotection Pty Ltd

Applicant ACN: 610 946 784

Summary of use: For the control of weeds in wheat, oats, barley, cereal rye and triticale (alone or undersown),

linseed, clover and lucerne pastures, turf, fallow, non-crop, roadsides and right-of-way

Date of registration: 20 November 2017

Product registration no.: 85116

Label approval no.: 85116/112313

Application no.: 112652

Product name: Huilong Chlorothalonil 720 SC Fungicide

Active constituent/s: 720 g/L chlorothalonil

Applicant name: Huilong Agrochemicals Australia Pty Ltd

Applicant ACN: 165 921 031

Summary of use: For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries,

faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes, turf and

vegetables

Date of registration: 20 November 2017

Product registration no.: 85213
Label approval no.: 85213/112652

Application no.: 109210

Product name: Kenso Agcare Pavo 250 EC Fungicide

Active constituent/s: 250 g/L pyraclostrobin

Applicant name: Kenso Corporation (M) Sdn. Bhd

Applicant ACN: N/A

Summary of use: For the control of leaf speckle and leaf spot in bananas and downy and powdery mildew in

grapevines, husk spot in macadamia and rust in almond

Date of registration: 20 November 2017

Product registration no.: 83897

Label approval no.: 83897/109210

Product name: DecayStop Rods for Timber Preservation

Active constituent/s: 254 g/kg boron (B) present as disodium octaborate anhydrous

Applicant name: Timber Restoration Systems Pty Ltd

Applicant ACN: 145 174 269

Summary of use: For the pre-treatment of sound timber and remedial treatment of decaying or insect

attacked timber

Date of registration: 20 November 2017

Product registration no.: 85215

Label approval no.: 85215/112654

Application no.: 112820

Product name: Raystar Triadimefon 125 EC Fungicide

Active constituent/s: 125 g/L triadimefon

Applicant name: Raystar Cropprotection Pty Ltd

Applicant ACN: 610 946 784

Summary of use: For the control of fungal diseases of wheat, barley, peas, grapevines, cucurbits and

sugar cane

Date of registration: 22 November 2017

Product registration no.: 85283

Label approval no.: 85283/112820

Application no.: 112936

Product name: AgProtect Chlorothalonil 720 SC Fungicide

Active constituent/s: 720 g/L chlorothalonil

Applicant name: Agprotect Australasia Pty Ltd

Applicant ACN: 621 073 023

Summary of use: For the control of fungal diseases on almonds, bananas, cucurbits, grapes, ornamentals,

peanuts, stone fruit, tobacco and vegetables

Date of registration: 22 November 2017

Product registration no.: 85325

Label approval no.: 85325/112936

Application no.: 112179

Product name: Raystar Imazethapyr WG Herbicide

Active constituent/s: 700 g/kg imazethapyr

Applicant name: Raystar Cropprotection Pty Ltd

Applicant ACN: 610 946 784

Summary of use: For the pre or post-emergence control of certain weeds in centrosema (cavalcade),

chickpeas, faba beans, field peas, lucerne, mung beans, peanuts, serradella, soy beans and

subterranean clover

Date of registration: 22 November 2017

Product registration no.: 85046

Label approval no.: 85046/112179

Application no.: 112301

Product name: Kelpie P-Quat 300 SL Herbicide

Active constituent/s: 300 g/L paraquat present as paraquat dichloride

Applicant name: Sinochem International Australia Pty Ltd

Applicant ACN: 160 164 616

Summary of use: For the control of a wide range of grasses and broadleaf weeds

Date of registration: 23 November 2017

Product registration no.: 85110
Label approval no.: 85110/112301

Product name: Accensi Bitertanol 300 EC Fungicide

Active constituent/s: 300 g/L bitertanol
Applicant name: Accensi Pty Ltd
Applicant ACN: 079 875 184

Summary of use: For control of rust on beans and ornamentals, black spot on roses, and powdery

mildew on begonias, eucalyptus seedlings and roses

Date of registration: 23 November 2017

Product registration no.: 83930

Label approval no.: 83930/109261

Application no.: 112686

Product name: Profeng Lambda-Cyhalothrin 250 CS Insecticide

Active constituent/s: 250 g/L lambda-cyhalothrin

Applicant name: Profeng Australia Pty Ltd

Applicant ACN: 156 055 533

Summary of use: For the control of certain insect pests in cotton, barley, wheat, and various field crops

Date of registration: 23 November 2017

Product registration no.: 85230

Label approval no.: 85230/112686

Application no.: 112637

Product name: Sharda Bensulfuron 600 Herbicide

Active constituent/s: 600 g/kg bensulfuron present as the methyl ester

Applicant name: Sharda Cropchem Espana S.L.

Applicant ACN: N/A

Summary of use: For the control of arrowhead, dirty dora and star fruit in aerially sown rice

Date of registration: 23 November 2017

Product registration no.: 85202

Label approval no.: 85202/112637

Application no.: 112715

Product name: Andiuron 900 WG Herbicide

Active constituent/s: 900 g/kg diuron

Applicant name: Ancom Australia Pty Limited

Applicant ACN: 080 066 708

Summary of use: For the control of weeds in asparagus, bananas, cereals, cotton, lupins and sugar cane

Date of registration: 23 November 2017

Product registration no.: 85240

Label approval no.: 85240/112715

Application no.: 112719

Product name: Starlet 100EC Insecticide

Active constituent/s: 100 g/L bifenthrin

Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of use: For the control of a number of insect pests in various agricultural crops

Date of registration: 23 November 2017

Product registration no.: 85244

Label approval no.: 85244/112719

Product name: Collaborate Insecticide and Adjuvant

Active constituent/s: 788 g/L paraffinic oil

Applicant name: Adjuvant Technical & Marketing Services Pty Ltd

Applicant ACN: 609 196 009

Summary of use: For the control or suppression of certain pests in various broadacre crops and cotton, a

carrier for ULV insecticides, and a defoliation aid for cotton

Date of registration: 24 November 2017

Product registration no.: 84116

Label approval no.: 84116/109730

Application no.: 112288

Product name: Evopure Stabilised Chlorine

Active constituent/s: 630 g/kg chlorine (CI) present as sodium dichloroisocyanurate

Applicant name: Evolution Water and Lighting Solutions Pty Ltd

Applicant ACN: 606 601 147

Summary of use: For the control of bacteria and algae in swimming pools

Date of registration: 24 November 2017

Product registration no.: 85098

Label approval no.: 85098/112288

Application no.: 112296

Product name: Sinon Haloxyfop 520 EC Herbicide

Active constituent/s: 520 g/L haloxyfop present as the haloxyfop-r-methyl ester

Applicant name: Sinon Australia Pty Limited

Applicant ACN: 102 741 024

Summary of use: For the 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: 27 November 2017

Product registration no.: 85106

Label approval no.: 85106/112296

Application no.: 107340

Product name:

Active constituent/s:

Applicant name:

Cutek Wood Preservative

11.88 g/L oxine copper

Chemisys Cutek Pty Ltd

Applicant ACN: 610 127 654

Summary of use: For pre-treatment and remedial treatment of exterior wood to resist damage caused by

fungal decay, mould and termites, in industrial and domestic situations by commercial

operators only

Date of registration: 28 November 2017

Product registration no.: 83026

Label approval no.: 83026/107340

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Product name: Stop Insect Natural Pyrethrum Aerosol Insecticide

Active constituent/s: 50 g/kg piperonyl butoxide, 10 g/kg pyrethrins

Applicant name: C Rudduck Proprietary Limited

Applicant ACN: 004 411 312

Summary of use: For the control of a range insect pests in indoor situations

Date of registration: 28 November 2017

Product registration no.: 84202

Label approval no.: 84202/109878

Application no.: 105627

Product name:

Biosmarte Pantry Moth Pheromone Glue Trap

Active constituent/s:

4.9 g/kg (z,e)-9,12-tetradecadien-1-yl acetate

Applicant name: Smartec Solutions Ltd

Applicant ACN: N/A

Summary of use: For use in food storage areas to attract and capture pantry moths including almond

moth, Indian meal moth and raisin moth

Date of registration: 28 November 2017

Product registration no.: 82387

Label approval no.: 82387/105627

Application no.: 109902

Product name: Freezone Ratshot G QuickShot Rodenticide

Active constituent/s: 0.05 g/kg brodifacoum

Applicant name: Freezone Public Health Pty Ltd

Applicant ACN: 132 080 098

Summary of use: For control of rats and mice in commercial, agricultural and domestic buildings

Date of registration: 28 November 2017

Product registration no.: 84215

Label approval no.: 84215/109902

Application no.: 112738

Product name: Ster-EO 100 Fumigant
Active constituent/s: 1000 g/kg ethylene oxide

Applicant name: Stereo Pty Ltd
Applicant ACN: 166 569 857

Summary of use: For sterilisation and fumigation in various situations

Date of registration: 29 November 2017

Product registration no.: 85248

Label approval no.: 85248/112738

Application no.: 112773

Product name: Pyshield2 Metered Insect Spray

Active constituent/s: 60 g/kg piperonyl butoxide, 14 g/kg pyrethrin

Applicant name: Eureka! Agresearch Pty Ltd

Applicant ACN: 086 194 738

Summary of use: For use with automatic metered dispensers for control of flying and crawling insects

Date of registration: 29 November 2017

Product registration no.: 85261

Label approval no.: 85261/112773

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Product name: Weed Force Diffufenican 500 SC Selective Herbicide

Active constituent/s: 500 g/L diflufenican
Applicant name: Weed Force Pty Ltd
Applicant ACN: 602 207 152

Summary of use: For the control of certain weeds in clover-based pasture, field peas, lentils, lupins and

oilseed poppies

Date of registration: 29 November 2017

Product registration no.: 85161

Label approval no.: 85161/112429

Application no.: 112265

Product name: Sinon S-Meto 960 EC Herbicide

Active constituent/s: 960 g/L s-metolachlor
Applicant name: Sinon Australia Pty Limited

Applicant ACN: 102 741 024

Summary of use: For the control of certain annual grasses and broadleaf weeds in certain crops

Date of registration: 29 November 2017

Product registration no.: 85088

Label approval no.: 85088/112265

Application no.: 106372

Product name: Kenso Agcare Kenpanil NF 360 Herbicide

Active constituent/s: 360 g/L propanil

Applicant name: Kenso Corporation (M) Sdn. Bhd

Applicant ACN: N/A

Summary of use: For post-emergence control of barnyard grass in rice

Date of registration: 29 November 2017

Product registration no.: 82651

Label approval no.: 82651/106372

Application no.: 112801

Product name:
Oxifen Herbicide
240 g/L oxyfluorfen

Applicant name: Industrial Quimica Key, S.A

Applicant ACN: N/A

Summary of use: For the selective control of certain broadleaf and grass weeds in cropping and forestry

situations

Date of registration: 30 November 2017

Product registration no.: 85272

Label approval no.: 85272/112801

Application no.: 112890

Product name: AgProtect 2,4-D Amine 625 Herbicide

Active constituent/s: 625 g/L 2,4-d present as the dimethylamine and diethanolamine salts

Applicant name: Agprotect Australasia Pty Ltd

Applicant ACN: 621 073 023

Summary of use: For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals

and pastures; and in cereal crops, pastures, sugarcane, peanuts, and non-agricultural

areas

Date of registration: 1 December 2017

Product registration no.: 85316

Label approval no.: 85316/112890

Product name: Surefire Cannonade 212 EC Herbicide

Active constituent/s: 212 g/L fluazifop-p present as the butyl ester

Applicant name: PCT Holdings Pty Ltd

Applicant ACN: 099 023 962

Summary of use: For the control of certain grasses in crops

Date of registration: 1 December 2017

Product registration no.: 85320

Label approval no.: 85320/112899

Application no.: 112837

Product name:

Active constituent/s:

Applicant name:

Diflukey Herbicide

500 g/L diflufenican

Industrial Quimica Key, S.A

Applicant ACN: N/A

Summary of use: For control of certain weeds in clover-based pasture, field peas, lentils, lupins, and

oilseed poppy

Date of registration: 1 December 2017

Product registration no.: 85293
Label approval no.: 85293/112837

Application no.: 112939

Product name: AgProtect Chlorthal 750 WG Herbicide

Active constituent/s: 750 g/kg chlorthal-dimethyl
Applicant name: Agprotect Australasia Pty Ltd

Applicant ACN: 621 073 023

Summary of use: For pre-emergent weed control in certain vegetable crops including onions, beans,

cabbages, cauliflowers, potatoes, and carrots, and for weed control in strawberries,

cotton, lucerne, perennial grass crops, lawns and ornamentals

Date of registration: 1 December 2017

Product registration no.: 85327

Label approval no.: 85327/112939

Application no.: 112935

Product name: AgProtect Alpha-Cypermethrin 100 Duo Insecticide

Active constituent/s: 100 g/L alpha-cypermethrin
Applicant name: Agprotect Australasia Pty Ltd

Applicant ACN: 621 073 023

Summary of use: For the control of insect pests including heliothis (helicoverpa spp.) on various crops,

red legged earth mite and blue oat mite on certain field crops and pastures, and certain

pests on fruit and vegetable crops

Date of registration: 1 December 2017

Product registration no.: 85324

Label approval no.: 85324/112935

Application no.: 112850

Product name: Fortin Max Plus Herbicide

Active constituent/s: 450 g/L glyphosate present as the isopropylamine salt

Applicant name: Industrial Quimica Key, S.A

Applicant ACN: N/A

Summary of use: For the control of a broad range of annual and perennial weeds

Date of registration: 1 December 2017

Product registration no.: 85297

Label approval no.: 85297/112850

Product name: AgProtect Atrazine 900 WG Herbicide

Active constituent/s: 900 g/kg atrazine

Applicant name: Agprotect Australasia Pty Ltd

Applicant ACN: 621 073 023

Summary of use: For the control of weeds and grasses in sorghum, maize, sugar cane, TT canola, and

lucerne, and for fallow area maintenance and other situations

Date of registration: 4 December 2017

Product registration no.: 85323

Label approval no.: 85323/112934

2. VARIATIONS OF REGISTRATION

Application no.: 111908

Product name: Sprayquick Herbicide

Active constituent/s: 135 g/L paraquat present as paraquat dichloride, 115 g/L diquat present as diquat

dibromide

Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'RELYON SPRAYQUICK HERBICIDE' to 'SPRAYQUICK HERBICIDE'

Date of variation:19 July 2017Product registration no.:81790

Label approval no.: 81790/111908

Application no.: 111903

Product name: Ammo 625 Herbicide

Active constituent/s: 625 g/L 2,4-D present as the dimethylamine and diethanolamine salts

Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'RELYON AMMO 625 HERBICIDE' to 'AMMO 625 HERBICIDE'

Date of variation:19 July 2017Product registration no.:82448Label approval no.:82448/111903

Application no.: 112404

Product name: Agsure Ammonium Sulphate Herbicide Adjuvant Spray Grade

Active constituent/s: 980 g/kg ammonium sulphate

Applicant name: Elders Rural Services Australia Limited

Applicant ACN: 004 045 121

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'AGSURE AMMONIUM SULPHATE ADJUVANT' to 'AGSURE AMMONIUM SULPHATE

HERBICIDE ADJUVANT SPRAY GRADE'

Date of variation: 4 September 2017

Product registration no.: 84443

Label approval no.: 84443/112404

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Product name: FREEZONE Clothing Moth Killer, Kills the Clothing Moths that lay eggs, Breaks the Life Cycle

Active constituent/s: 3 g/kg transfluthrin

Applicant name: Bio-Logix Laboratories Ltd

Applicant ACN:

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'HOVEX VAPORGUARD MOTH MEMBRANE' to 'FREEZONE CLOTHING MOTH KILLER,

KILLS THE CLOTHING MOTHS THAT LAY EGGS, BREAKS THE LIFE CYCLE'

Date of variation: 12 September 2017

Product registration no.: 69875

Label approval no.: 69875/112615

Application no.: 112646

Product name: Fipforce Aqua Termiticide & Insecticide

Active constituent/s: 100 g/L fipronil

Applicant name: Sherwood Chemicals Public Company Limited

Applicant ACN: N/A

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'FIPFORCE 100 g/L SC TERMITICIDE & INSECTICIDE' to 'FIPFORCE AQUA TERMITICIDE

& INSECTICIDE'

Date of variation: 14 September 2017

Product registration no.: 63789

Label approval no.: 63789/112646

Application no.: 112691

Product name: Baythroid Advanced Insect Killer For Gardens

Active constituent/s: 25 g/L beta-cyfluthrin

Applicant name: Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'BAYER ADVANCED LAWN AND GARDEN INSECTICIDE' to 'BAYTHROID ADVANCED INSECT KILLER FOR GARDENS' and to remove the use on lawns, around and inside

buildings and structures

Date of variation: 19 September 2017

Product registration no.: 60602 Label approval no.: 60602/112691

Application no.: 112706

Product name: Performa M Herbicide

Active constituent/s: 340 g/L MCPA (present as the dimethylamine salt), 80 g/L dicamba (present as the

dimethylamine salt)

Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'RELYON PERFORMA M HERBICIDE' to 'PERFORMA M HERBICIDE'

Date of variation: 20 September 2017

Product registration no.: 81885

Label approval no.: 81885/112706

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Product name: Veteran C Seed Dressing Liquid
Active constituent/s: 25 g/L flutriafol, 4 g/L cypermethrin

Applicant name: Nufarm Australia Limited

Applicant ACN: 004 377 780

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'CROP CARE VETERAN C SEED DRESSING LIQUID' to 'VETERAN C SEED

DRESSING LIQUID'

Date of variation: 28 September 2017

Product registration no.: 60146

Label approval no.: 60146/112783

Application no.: 112901

Product name:

Active constituent/s:

Applicant name:

Quizon 100EC Herbicide
99.5 g/L quizalofop-p-ethyl
Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'RELYON QUIZON 100EC HERBICIDE' to 'QUIZON 100EC HERBICIDE'

Date of variation: 9 October 2017

Product registration no.: 81996

Label approval no.: 81996/112901

Application no.: 112909

Product name: Pea Beu Flying Insect Killer Fast Kill Low Irritant Lemon Fresh

Active constituent/s: 1.08 g/kg tetramethrin 20:80, 0.25 g/kg phenothrin 20:80, 2.17 g/kg piperonyl butoxide,

3.18 g/kg n-octyl bicycloheptene dicarboximide

Applicant name: Reckitt Benckiser (Australia) Pty Limited

Applicant ACN: 003 274 655

Summary of variation: To change the distinguishing product name and the name that appears on the label from 'PEA

BEU INSECT KILLER FAST KILL LOW IRRITANT LEMON FRESH' to 'PEA BEU FLYING

INSECT KILLER FAST KILL LOW IRRITANT LEMON FRESH'

Date of variation: 10 October 2017

Product registration no.: 53238

Label approval no.: 53238/112909

Application no.: 112964

Product name: Pea Beu Flying Insect Killer Fast Kill Low Irritant Odourless

Active constituent/s: 1.08 g/kg tetramethrin, 0.25 g/kg d-phenothrin, 2.17 g/kg piperonyl butoxide, 3.18 g/kg

n-octyl bicycloheptene dicarboximide

Applicant name: Reckitt Benckiser (Australia) Pty Limited

Applicant ACN: 003 274 655

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'PEA BEU INSECT KILLER FAST KILL LOW IRRITANT ODOURLESS' to 'PEA BEU

FLYING INSECT KILLER FAST KILL LOW IRRITANT ODOURLESS'

Date of variation: 11 October 2017

Product registration no.: 67874

Label approval no.: 67874/112964

Product name: Mortein Mozzie Zapper Mosquito & Fly Control

Active constituent/s: 7.13 g/L transfluthrin

Applicant name: Reckitt Benckiser (Australia) Pty Limited

Applicant ACN: 003 247 655

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'MORTEIN PEACEFUL NIGHTS REPELLER MOSQUITO & FLY PLUG IN' to 'MORTEIN

MOZZIE ZAPPER MOSQUITO & FLY CONTROL'

Date of variation: 19 October 2017

Product registration no.: 64992

Label approval no.: 64992/113117

Application no.: 111583

Product name: Arsenal Super Herbicide

Active constituent/s: 240 g/L imazapyr present as isopropylamine salt

Applicant name: BASF Australia Ltd
Applicant ACN: 008 437 867

Summary of variation: To provide clear instructions when controlling weeds with hand gun and knapsack

application equipment

Date of variation: 20 November 2017

Product registration no.: 68618

Label approval no.: 68618/111583

Application no.: 112191

Product name:

Active constituent/s:

Applicant name:

Applicant ACN:

Smart Silver 800 Herbicide
800 g/L prosulfocarb
Crop Smart Pty Ltd
093 927 961

Summary of variation:To amend plant back periods from six to nine months

Date of variation: 21 November 2017

Product registration no.: 84227

Label approval no.: 84227/112191

Application no.: 110831

Product name: Warden 100SC Insecticide

Active constituent/s: 100 g/L fipronil

Applicant name: Adama Australia Pty Ltd

Applicant ACN: 050 328 973

Summary of variation: To change the distinguishing product name and the name that appears on the label from

WARDEN RESIDUAL TERMITICIDE' to 'WARDEN 100SC INSECTICIDE' and to extend use to include control of argentine stem weevil, mole crickets and funnel ants in turf

Date of variation: 22 November 2017

Product registration no.: 67463 Label approval no.: 67463/110831

Product name: Pettit Marine Paint Vivid Antifouling Paint

Active constituent/s: Black

247 g/L copper present as cuprous thiocyanate, 48.5 g/L zinc pyrithione

Red

226 g/L copper present as cuprous thiocyanate, 44.6 g/L zinc pyrithione

Blue

228 g/L copper present as cuprous thiocyanate, 43.7 g/L zinc pyrithione

White

251 g/L copper present as cuprous thiocyanate, 49.5 g/L zinc pyrithione

Applicant name: Resene Paints (Australia) Limited

Applicant ACN: 050 034 529

Summary of variation: To approve a new label for the product 'PETTIT MARINE PAINT VIVID ANTIFOULING PAINT'

with the label name 'CARBOLINE SEA BARRIER ALLOY 100 AU'

Date of variation: 23 November 2017

Product registration no.: 66263

Label approval no.: 66263/113203

Application no.: 108317

Product name: Paramite Selective Miticide

Active constituent/s: 110 g/L etoxazole

Applicant name: Sumitomo Chemical Australia Pty Limited

Applicant ACN: 081 096 255

Summary of variation: To extend use for the control of couch mite and other mites affecting turf

Date of variation: 23 November 2017

Product registration no.: 56791

Label approval no.: 56791/108317

Application no.: 110506

Product name: Imtrade Jetti Duo Herbicide

Active constituent/s: 350 g/L trifluralin, 550 g/L triallate

Applicant name: Imtrade Australia Pty Ltd

Applicant ACN: 090 151 134

Summary of variation: To add uses for chickpeas, lupins, peas and canola and add a pack size range

Date of variation: 24 November 2017

Product registration no.: 68009

Label approval no.: 68009/110506

Application no.: 112413

Product name: Regular Roundup Ready To Use Weedkiller

Active constituent/s: 21 g/L nonanoic acid, 7.2 g/L glyphosate present as the isopropylamine salt

Applicant name: Monsanto Australia Ltd

Applicant ACN: 006 725 560

Summary of variation: To approve a new label for the product 'REGULAR ROUNDUP READY TO USE

WEEDKILLER' with the label name 'ROUNDUP A WEEDKILLER'

Date of variation: 27 November 2017

Product registration no.: 67857

Label approval no.: 67857/112413

Product name: Roundup Ready PL Herbicide

Active constituent/s: 540 g/L glyphosate present as the potassium salt

Applicant name: Monsanto Australia Ltd

Applicant ACN: 006 725 560

Summary of variation: To amend the directions for use in roundup ready flex cotton to remove an application

restriction and allow the application between 22 nodes to 60% boll open stage

Date of variation: 27 November 2017

Product registration no.: 81975

Label approval no.: 81975/111241

Application no.: 108668

Product name: Nufarm Metham Soil Fumigant

Active constituent/s: 423 g/L metham present as sodium salt

Applicant name: Nufarm Australia Limited

Applicant ACN: 004 377 780

Summary of variation: To extend use to include control of phytophora species in gravel in quarry situations

Date of variation: 27 November 2017

Product registration no.: 34049

Label approval no.: 34049/108668

Application no.: 112263

Product name: Barmac Chloroturf DG Fungicide

Active constituent/s: 750 g/kg quintozene
Applicant name: Amgrow Pty Ltd
Applicant ACN: 100 684 786

Summary of variation: To remove uses in tomato, lettuce, beans, peanuts, cotton, cotton seed, potato, cabbage,

cauliflower, broccoli and apples and remove 7.25 kg (1.44g x 5) pack size

Date of variation: 29 November 2017

Product registration no.: 47211

Label approval no.: 47211/112263

Application no.: 108781

Product name:

Active constituent/s:

Applicant name:

Dupont Benevia Insecticide
100 g/L cyantraniliprole
Du Pont (Australia) Pty Ltd

Applicant ACN: 000 716 469

Summary of variation: To extend use to include control of various insect pests in bulb vegetables, potatoes and

strawberries and to amend advice in relation to type of adjuvant

Date of variation: 29 November 2017

Product registration no.: 66684 Label approval no.: 66684/108781

Application no.: 109811

Product name: Mortein Home Expert Multi Insect Killer

Active constituent/s: 0.7 g/kg imiprothrin, 1 g/kg esbiothrin, 0.3 g/kg permethrin

Applicant name: Reckitt Benckiser (Australia) Pty Limited

Applicant ACN: 003 274 655

Summary of variation: To add pack sizes and amend the statement of claims

Date of variation: 29 November 2017

Product registration no.: 83812

Label approval no.: 83812/109811

Product name: Terraclor Soil Fungicide
Active constituent/s: 750 g/kg quintozene
Applicant name: Amgrow Pty Ltd
Applicant ACN: 100 684 786

Summary of variation: To remove uses in tomato, lettuce, beans, peanuts, cotton, potato, cabbage, cauliflower,

broccoli and apples

Date of variation: 29 November 2017

Product registration no.: 53533

Label approval no.: 53533/112269

Application no.: 112327

Product name: Overture Fungicide

Active constituent/s: 125 g/L epoxiconazole

Applicant name: Sipcam Pacific Australia Pty Ltd

Applicant ACN: 073 176 888

Summary of variation: To extend the diseases to include powdery mildew in wheat, and net form of net blotch, leaf

scald, and powdery mildew in barley

Date of variation: 30 November 2017

Product registration no.: 63994 Label approval no.: 63994/112327

Application no.: 112969

Product name: Apparent Procymidone 500 Fungicide

Active constituent/s: 500 g/L procymidone
Applicant name: Apparent Pty Ltd
Applicant ACN: 143 724 136

Summary of variation: To correct the rate for faba beans in the directions for use table

Date of variation: 30 November 2017

Product registration no.: 69208

Label approval no.: 69208/112969

Application no.: 112675

Product name: Amgrow Chemspray Weed Control Bin-Die Selective Lawn Weeder

Active constituent/s: 200 g/L bromoxynil present as the n-octanoyl ester, 200 g/L MCPA present as the 2-ethyl

hexyl ester

Applicant name:Amgrow Pty LtdApplicant ACN:100 684 786

Summary of variation: To include additional pack sizes of 100 mL-2 L, and to update label directions

Date of variation: 1 December 2017

Product registration no.: 31456

Label approval no.: 31456/112675

Application no.: 112865

Product name: Choice Dicamba 500 Herbicide

Active constituent/s: 500 g/L dicamba (present as the dimethylamine salt)

Applicant name: Grow Choice Pty Limited

Applicant ACN: 161 264 884

Summary of variation: To amend plant-back period tables

Date of variation: 1 December 2017

Product registration no.: 63603

Label approval no.: 63603/112865

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 EXISTING ACTIVE CONSTITUENTS

Application no.: 102864

Product name: Fostera PCV MH

Active constituent/s: 1 RP mycoplasma hyopneumoniae vaccine, 1 RP cpcv 1–2 inactivated suspension

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 156 476 425

Summary of use: For vaccination of healthy pigs 3 weeks of age or older for aid in the reduction of PCV2

viraemia, virus shedding and aid in the control of PCV associated disease (PCVAD). Also as an aid in reducing enzootic pneumonia caused by mycoplasma hyopneumoniae

Date of registration: 22 March 2017

Product registration no.: 81347

Label approval no.: 81347/102864

Application no.: 112678

Product name: Bismoseal

Active constituent/s: 650 mg/g bismuth subnitrate

Applicant name: Norbrook Laboratories Australia Pty Limited

Applicant ACN: 080 972 596

Summary of use: For the prevention of mastitis in dairy cows during the non-lactating (dry) period and

early post-calving

Date of registration: 21 November 2017

Product registration no.: 85228

Label approval no.: 85228/112678

Application no.: 112747

Product name: Nemesis Pour-On Lousicide For Sheep

Active constituent/s: 35 g/L imidacloprid

Applicant name: Abbey Laboratories Pty Ltd

Applicant ACN: 156 000 430

Summary of use: For the control of susceptible body lice, bovicola ovis on shorn sheep up to 7 days off-shears

and unshorn lambs up to 2 months of age

Date of registration: 22 November 2017

Product registration no.: 85254

Label approval no.: 85254/112747

Application no.: 112674

Product name: Cloxicure

Active constituent/s: 600 mg cloxacillin (as benzathine salt)

Applicant name: Norbrook Laboratories Australia Pty Limited

Applicant ACN: 080 972 596

Summary of use: For the control of mastitis in dairy cows caused by *streptococcus* spp, *staphylococcus* spp

(including penicillin resistant strains), arcanobacterium spp, and other organisms susceptible

to cloxacillin

Date of registration: 24 November 2017

Product registration no.: 85227

Label approval no.: 85227/112674

Application no.: 111277

Product name: Flyban Insecticidal And Repellent Spray

Active constituent/s: 3 g/L n-octyl bicycloheptene dicarboximide, 6 g/L di-n-propyl isocinchomeronate,

2.7 g/L piperonyl butoxide, 1.5 g/L pyrethrins

Applicant name: The Hunter River Company Pty Limited

Applicant ACN: 133 798 615

Summary of use: For repelling flies and mosquitos on horses, dogs, cattle and pigs and for controlling

fleas and lice on dogs and cats

Date of registration: 27 November 2017

Product registration no.: 84739

Label approval no.: 84739/111277

2. LISTED REGISTRATIONS

Application no.: 111675

Product name: Stride

Active constituent/s: 6000 mg/50 g chondroitin sulfate (avian cartilage), 6000 mg/50 g glucosamine

hydrochloride (vegetable source)

Applicant name: Thoroughbred Remedies Manufacturing Ltd (TRM)

Applicant ACN: N/A

Summary of use: For the long term use to help improve joint health and function in horses

Date of registration: 1 December 2017

Product registration no.: 84877

Label approval no.: 84877/111675

3. VARIATIONS OF REGISTRATION

Application no.: 112788

Product name: Independents Own Venus Sheep Blowfly Treatment

Active constituent/s: 500 g/L cyromazine
Applicant name: Apparent Pty Ltd
Applicant ACN: 143 724 136

Summary of variation:To change the distinguishing product name and the name that appears on the label from

'INDEPENDENTS OWN URANUS SHEEP BLOWFLY TREATMENT' to 'INDEPENDENTS OWN VENUS SHEEP BLOWFLY TREATMENT'

Date of variation: 28 September 2017

Product registration no.: 66589

Label approval no.: 66589/112788

No. APVMA 25, Tuesday, 12 December 2017

Product name: Independents Own Venus Spray-On Sheep Blowfly Treatment

Active constituent/s: 60 g/L cyromazine Applicant name: Apparent Pty Ltd **Applicant ACN:** 143 724 136

Summary of variation: To change the distinguishing product name and the name that appears on the label from

'INDEPENDENTS OWN URANUS SPRAY-ON SHEEP BLOWFLY TREATMENT' to 'INDEPENDENTS OWN VENUS SPRAY-ON SHEEP BLOWFLY TREATMENT'

Date of variation: 28 September 2017

65089 Product registration no.:

Label approval no.: 65089/112789

Application no.: 111795

Product name: Cerenia Injectable Solution

Active constituent/s: 10 mg/ml maropitant as maropitant citrate

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 156 476 425

Summary of variation: To extend label claim to include the prevention of perioperative nausea and vomiting and

improvement in recovery from general anaesthesia after use of the μ-opiate receptor

agonist morphine

Date of variation: 28 November 2017

61840 Product registration no.:

Label approval no.: 61840/111795

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 CONSTITUENT

Application no.: 110124
Active constituent/s: Flumioxazin

Applicant name: Shandong Binnong Technology Co., Ltd

Applicant ACN: N/A

Summary of use: For use in agricultural chemical products

Date of approval: 8 November 2017

Approval no.: 84333

Application no.: 107959
Active constituent/s: Prometryn

Applicant name: Syngenta Australia Pty Ltd

Applicant ACN: 002 933 717

Summary of use: For use in agricultural chemicals products

Date of approval: 23 November 2017

Approval no.: 83314

Application no.: 110441
Active constituent/s: Clomazone

Applicant name: UPL Australia Limited

Applicant ACN: 066 391 384

Summary of use: For use in agricultural chemicals products

Date of approval: 23 November 2017

Approval no.: 84457

Application no.: 110394
Active constituent/s: Pinoxaden

Applicant name: Jiangsu Agrochem Laboratory Co Ltd

Applicant ACN: N/A

Summary of use: For use in agricultural chemicals products

Date of approval: 24 November 2017

Approval no.: 84431

Application no.: 110395
Active constituent/s: Amicarbazone

Applicant name: Jiangsu Agrochem Laboratory Co Ltd

Applicant ACN: N/A

Summary of use: For use in agricultural chemicals products

Date of approval: 24 November 2017

Active constituent/s: Clodinafop-Propargyl
Applicant name: Foison Scitech Co., Limited

Applicant ACN: N/A

Summary of use: For use in agricultural chemical products

Date of approval: 1 December 2017

Approved Active Constituents—s14A

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 CONSTITUENT

Application no.: 109725
Active constituent/s: Progesterone
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2017

Approval no.: 84111

Application no.: 110494
Active constituent/s: Glycine

Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2017

Approval no.: 84479

Application no.: 110438

Active constituent/s: Infectious Bronchitis Virus Ingham Strain

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2017

Approval no.: 84454

Application no.: 112064
Active constituent/s: Cedarwood Oil

Applicant name: National Machinery Traders (NSW) Pty Ltd

Applicant ACN: 158 517 983

Summary of use: For use in agricultural chemical products

Date of approval: 6 September 2017

Approval no.: 85017

Application no.: 112065
Active constituent/s: Rosemary Oil

Applicant name: National Machinery Traders (NSW) Pty Ltd

Applicant ACN: 158 517 983

Summary of use: For use in agricultural chemical products

Date of approval: 6 September 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Haemophilus Parasuis Serovar 5, Strain 1a84-29755 (Inactivated)

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 7 September 2017

Approval no.: 84597

Application no.: 110891

Active constituent/s: Haemophilus Parasuis Serovar 4, Strain 2170b (Inactivated)

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 7 September 2017

Approval no.: 84598

Application no.: 109345

Active constituent/s: Feline Calicivirus—Inactivated
Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 11 September 2017

Approval no.: 83967

Application no.: 108151
Active constituent/s: Oxfendazole

Applicant name: Landmark Operations Limited

Applicant ACN: 008 743 217

Summary of use: For use in veterinary chemical products

Date of approval: 12 September 2017

Approval no.: 83377

Application no.: 109844

Active constituent/s: Oxytetracycline Hydrochloride

Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 13 September 2017

Approval no.: 84177

Application no.: 109970

Active constituent/s: Cyanocobalamin

Applicant name: Troy Laboratories Pty Ltd

Applicant ACN: 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 18 September 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Sulfacetamide Sodium
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 18 September 2017

Approval no.: 83597

Application no.: 109744

Active constituent/s: Miconazole Nitrate
Applicant name: Apex Laboratories Pty Ltd

Applicant ACN: 614 716 700

Summary of use: For use in veterinary chemical products

Date of approval: 18 September 2017

Approval no.: 84129

Application no.: 109864

Active constituent/s: Propylene Glycol
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 19 September 2017

Approval no.: 84189

Application no.: 108149
Active constituent/s: Eprinomectin

Applicant name: Landmark Operations Limited

Applicant ACN: 008 743 217

Summary of use: For use in veterinary chemical products

Date of approval: 20 September 2017

Approval no.: 83376

Application no.: 107206
Active constituent/s: Eprinomectin

Applicant name: Norbrook Laboratories Australia Pty Limited

Applicant ACN: 080 972 596

Summary of use: For use in veterinary chemical products

Date of approval: 20 September 2017

Approval no.: 82956

Application no.: 110064
Active constituent/s: Sulfadiazine

Applicant name: CCD Animal Health Pty Ltd

Applicant ACN: 151 737 950

Summary of use: For use in veterinary chemical products

Date of approval: 20 September 2017

No. APVMA 25, Tuesday, 12 December 2017

Application no.: 110029
Active constituent/s: Nicotinamide
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 21 September 2017

Approval no.: 84272

Application no.: 109910

Active constituent/s: Detomidine Hydrochloride

Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 21 September 2017

Approval no.: 84221

Application no.: 110121

Active constituent/s: Polymyxin B Sulfate
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 27 September 2017

Approval no.: 84332

Application no.: 110036

Active constituent/s: Dihydrostreptomycin Sulfate

Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 27 September 2017

Approval no.: 84278

Application no.: 110039

Active constituent/s: Pyrantel Embonate

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 27 September 2017

Approval no.: 84280

Application no.: 109684

Active constituent/s: Phenylbutazone

Applicant name: Apex Laboratories Pty Ltd

Applicant ACN: 614 716 700

Summary of use: For use in veterinary chemical products

Date of approval: 10 October 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Morantel Citrate

Applicant name: CCD Animal Health Pty Ltd

Applicant ACN: 151 737 950

Summary of use: For use in veterinary chemical products

Date of approval: 10 October 2017

Approval no.: 84947

Application no.: 110107

Active constituent/s: Spectinomycin Sulfate Tetrahydrate

Applicant name: Abbey Laboratories Pty Ltd

Applicant ACN: 156 000 430

Summary of use: For use in veterinary chemical products

Date of approval: 10 October 2017

Approval no.: 84323

Application no.: 112569
Active constituent/s: Iron Dextran

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 11 October 2017

Approval no.: 85179

Application no.: 110291
Active constituent/s: Praziquantel

Applicant name: Bocko P/L & Flexsky P/L In Partnership

Applicant ACN: 078 722 371

Summary of use: For use in veterinary chemical products

Date of approval: 13 October 2017

Approval no.: 84384

Application no.: 112910
Active constituent/s: Iron Dextran

Applicant name: Troy Laboratories Pty Ltd

Applicant ACN: 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 13 October 2017

Approval no.: 85322

Application no.: 110303
Active constituent/s: Sorbitol
Applicant name: Delaval Pty Ltd
Applicant ACN: 004 210 459

Summary of use: For use in veterinary chemical products

Date of approval: 13 October 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Lignocaine Hydrochloride
Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 17 October 2017

Approval no.: 84359

Application no.: 108862

Active constituent/s: Piperonyl Butoxide
Applicant name: Mavlab Pty Ltd
Applicant ACN: 009 708 187

Summary of use: For use in veterinary chemical products

Date of approval: 18 October 2017

Approval no.: 83702

Application no.: 108866

Active constituent/s: Phenobarbitone
Applicant name: Mavlab Pty Ltd
Applicant ACN: 009 708 187

Summary of use: For use in veterinary chemical products

Date of approval: 18 October 2017

Approval no.: 83706

Application no.: 108867

Active constituent/s: Permethrin 25:75
Applicant name: Mavlab Pty Ltd
Applicant ACN: 009 708 187

Summary of use: For use in veterinary chemical products

Date of approval: 18 October 2017

Approval no.: 83707

Application no.: 110502
Active constituent/s: Prednisolone

Applicant name: Apex Laboratories Pty Ltd

Applicant ACN: 614 716 700

Summary of use: For use in veterinary chemical products

Date of approval: 18 October 2017

Approval no.: 84486

Application no.: 110943
Active constituent/s: Abamectin

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 19 October 2017

Application no.: 111420
Active constituent/s: Abamectin

No. APVMA 25, Tuesday, 12 December 2017

Applicant name: Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd

Applicant ACN: 000 233 992

Summary of use: For use in veterinary chemical products

Date of approval: 20 October 2017

Approval no.: 84779

Application no.: 110201

Active constituent/s: Phenylbutazone

Applicant name: CEVA Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 24 October 2017

Approval no.: 84362

Application no.: 110197

Active constituent/s: Neomycin Sulphate

Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 24 October 2017

Approval no.: 84361

Application no.: 110555
Active constituent/s: Ivermectin

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 25 October 2017

Approval no.: 84516

Application no.: 112136

Active constituent/s: Potassium Clavulanate
Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 156 476 425

Summary of use: For use in veterinary chemical products

Date of approval: 26 October 2017

Approval no.: 85036

Application no.: 112798

Active constituent/s: Sodium Chloride

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 26 October 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Sodium Selenate

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 26 October 2017

Approval no.: 85268

Application no.: 112797

Active constituent/s: Sodium Selenate

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 26 October 2017

Approval no.: 85268

Application no.: 110024

Active constituent/s: Sodium Selenate
Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 156 476 425

Summary of use: For use in veterinary chemical products

Date of approval: 27 October 2017

Approval no.: 84267

Application no.: 110182

Active constituent/s: Magnesium Sulphate Heptahydrate

Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 31 October 2017

Approval no.: 84358

Application no.: 110176

Active constituent/s: Di-Isopropylamine Dichloroacetate
Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 31 October 2017

Approval no.: 84354

Application no.: 110503

Active constituent/s: Hydrocortisone Acetate
Applicant name: Apex Laboratories Pty Ltd

Applicant ACN: 614 716 700

Summary of use: For use in veterinary chemical products

Date of approval: 31 October 2017

Application no.: 110292
Active constituent/s: L-Menthol

No. APVMA 25, Tuesday, 12 December 2017

Applicant name: Bocko P/L & Flexsky P/L In Partnership

Applicant ACN: 078 722 371

Summary of use: For use in veterinary chemical products

Date of approval: 2 November 2017

Approval no.: 84385

Application no.: 110966

Active constituent/s: Newcastle Disease Strain V-4 Virus

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 15 November 2017

Approval no.: 84628

Application no.: 110955

Active constituent/s: Mycobacterium Paratuberculosis

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 15 November 2017

Approval no.: 84624

Application no.: 110973

Active constituent/s: Infectious Bursal Disease Virus Strain V877 (Live)

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 15 November 2017

Approval no.: 84633

Application no.: 111022

Active constituent/s: Canine Parvovirus (Inactivated)

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 15 November 2017

Approval no.: 84642

Application no.: 111026

Active constituent/s: Canine Adenovirus Type 2 Live (Cav Ii)

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 15 November 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Bovine Herpes virus 1
Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 16 November 2017

Approval no.: 84651

Application no.: 111071

Active constituent/s: Live Marek's Disease Virus Serotype 3

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 16 November 2017

Approval no.: 84659

Application no.: 111072

Active constituent/s: Mannheimia Haemolytica Strain NL 1009

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 16 November 2017

Approval no.: 84660

Application no.: 111080

Active constituent/s: Clindamycin Hydrochloride
Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 16 November 2017

Approval no.: 84666

Application no.: 111083

Active constituent/s: Marek's Disease Virus, Serotype 3, HVT Strain FC 126

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 16 November 2017

Approval no.: 84669

Application no.: 110444

Active constituent/s: Dextrose Monohydrate

Applicant name: Delaval Pty Ltd
Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 21 November 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Gonadorelin Acetate
Applicant name: Randlab Australia Pty Ltd

Applicant ACN: 114 948 837

Summary of use: For use in veterinary chemical products

Date of approval: 24 November 2017

Approval no.: 84902

Application no.: 110166
Active constituent/s: Doramectin

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: 24 November 2017

Approval no.: 84347

Application no.: 111145

Active constituent/s: Cyanocobalamin

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 24 November 2017

Approval no.: 84693

Application no.: 110654

Active constituent/s: Chlortetracycline Hydrochloride as Calcium Complex

Applicant name: Abbey Laboratories Pty Ltd

Applicant ACN: 156 000 430

Summary of use: For use in veterinary chemical products

Date of approval: 24 November 2017

Approval no.: 84540

Application no.: 110288

Active constituent/s: Triclabendazole
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 29 November 2017

Approval no.: 84381

Application no.: 110294

Active constituent/s: Naphthalophos

Applicant name: Landmark Operations Limited

Applicant ACN: 008 743 217

Summary of use: For use in veterinary chemical products

Date of approval: 29 November 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Dextrose Monohydrate
Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 29 November 2017

Approval no.: 84350

Application no.: 110177

Active constituent/s: Ethanolamine Phosphoric Acid
Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 29 November 2017

Approval no.: 84355

Application no.: 111253
Active constituent/s: Praziquantel

Applicant name: Shanghai Neway Animal Health Co., Ltd

Applicant ACN: N/A

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84732

Application no.: 110565

Active constituent/s: Dibutyl Phthalate

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84521

Application no.: 110542
Active constituent/s: Maduramicin

Applicant name: Dox-Al Australia Pty Ltd

Applicant ACN: 079 454 265

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84509

Application no.: 111160

Active constituent/s: Cloprostenol Sodium

Applicant name: Bayer Australia Ltd (Animal Health)

Applicant ACN: 000 138 714

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Zinc Bacitracin

Applicant name: Dox-Al Australia Pty Ltd

Applicant ACN: 079 454 265

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84499

Application no.: 111043

Active constituent/s: L-Arginine Monohydrochloride
Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84649

Application no.: 111274

Active constituent/s: Cloprostenol Sodium

Applicant name: Vetoquinol Australia Pty Ltd

Applicant ACN: 006 949 480

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84738

Application no.: 111381

Active constituent/s: Fluoxetine Hydrochloride
Applicant name: Nexcyon Pharmaceuticals, Inc

Applicant ACN: 71-1034788

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84763

Application no.: 111273

Active constituent/s: Cloprostenol Sodium

Applicant name: Vetoquinol Australia Pty Ltd

Applicant ACN: 006 949 480

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84737

Application no.: 111391
Active constituent/s: Eprinomectin

Applicant name: Bimeda (Australia) Pty Limited

Applicant ACN: 058 196 508

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: RS-Methoprene
Applicant name: Mavlab Pty Ltd
Applicant ACN: 009 708 187

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 83763

Application no.: 111229
Active constituent/s: Tilmicosin

Applicant name: Elanco Australasia Pty Ltd

Applicant ACN: 076 745 198

Summary of use: For use in veterinary chemical products

Date of approval: 30 November 2017

Approval no.: 84725

Application no.: 110862

Active constituent/s: Tilmicosin Phosphate
Applicant name: Elanco Australasia Pty Ltd

Applicant ACN: 076 745 198

Summary of use: For use in veterinary chemical products

Date of approval: 1 December 2017

Approval no.: 84583

Application no.: 110500

Active constituent/s: Potassium Citrate
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of use: For use in veterinary chemical products

Date of approval: 1 December 2017

Approval no.: 84484

Application no.: 110534
Active constituent/s: Fipronil

Applicant name: Shanghai Neway Animal Health Co., Ltd

Applicant ACN: N/A

Summary of use: For use in veterinary chemical products

Date of approval: 7 December 2017

Approval no.: 84504

Application no.: 110652

Active constituent/s: Thiamine Hydrochloride
Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 7 December 2017

Application no.: 111427

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Sulfadimidine

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 7 December 2017

Approval no.: 84784

Application no.: 111432

Active constituent/s: Amoxycillin Trihydrate

Applicant name: Bimeda (Australia) Pty Limited

Applicant ACN: 058 196 508

Summary of use: For use in veterinary chemical products

Date of approval: 7 December 2017

Approval no.: 84784

Application no.: 110972

Active constituent/s: Vitamin D3 (Cholecalciferol)

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 7 December 2017

Approved Active Constituents—s14

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 CONSTITUENT

N/A

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.: 109692

Active constituent/s: Norethandrolone
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 1 September 2017

Approval no.: 54859

Application no.: 109690
Active constituent/s: Frusemide
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 12 September 2017

Approval no.: 55341

Application no.: 109708
Active constituent/s: Chlorophyll
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 13 September 2017

Approval no.: 55396

Application no.: 109658
Active constituent/s: Nicotinamide

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: 14 September 2017

Approval no.: 82021

Application no.: 109882
Active constituent/s: Oxfendazole
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 18 September 2017

Application no.: 109882

No. APVMA 25, Tuesday, 12 December 2017

Active constituent/s: Ephedrine Hydrochloride

Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 18 September 2017

Approval no.: 55107

Application no.: 112766

Active constituent/s: Imidocarb Dipropionate
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: 11 October 2017

Approval no.: 82037

Application no.: 111855

Active constituent/s: Imidocarb Dipropionate

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: 11 October 2017

Approval no.: 82037

Application no.: 110143
Active constituent/s: Sulfadiazine
Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 12 October 2017

Approval no.: 56230

Application no.: 113340

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: 17 November 2017

Approval no.: 82317

Application no.: 113365

Active constituent/s: Amprolium Hydrochloride

Applicant name: International Animal Health Products Pty Ltd

Applicant ACN: 003 185 699

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 29 November 2017

Application no.: 110186
Active constituent/s: Dicyclanil

No. APVMA 25, Tuesday, 12 December 2017

Applicant name: Jurox Pty Limited
Applicant ACN: 000 932 230

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 29 November 2017

Approval no.: 68023

Application no.: 110860

Active constituent/s: Tilmicosin Phosphate
Applicant name: Elanco Australasia Pty Ltd

Applicant ACN: 076 745 198

Summary of variation: Variation of relevant particulars or conditions of an approved active constituent

Date of variation: 30 November 2017

Licensing of Veterinary Chemical Manufacturers

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

For a comprehensive listing of all licensed manufacturers please see the APVMA's website www.apvma.gov.au.

1. NEW LICENCES

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

ELANCO AUSTRALASIA PTY LICENCE NO: 6212

LTD

112 Wharf Road • Category 6: Single step manufacture

WEST RYDE NSW 2114 Steps of manufacture: Release for supply

Licence issued: 21 November 2017

2. CHANGES TO EXISTING LICENCES

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

ALLTECH LIENERT LICENCE NO: 4085
AUSTRALIA PTY LTD

28 Durham Street • Category 4: Premixes, supplements

FORBES NSW 2871 Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation

including blending, pellet extrusion, filling, packaging, labelling, analysis and

testing (physical), storage and release for supply

Amended Licence Issued: 16 November 2017

ALLTECH LIENERT LICENCE NO: 4091
AUSTRALIA PTY LTD

8 Roseworthy Road • Category 4: Premixes, supplements and custom mixes

ROSEWORTHY SA 5371 Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, storage and release for supply

Amended Licence Issued: 17 November 2017

* Category 1: Immunobiologicals and sterile veterinary preparations

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

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: Single-step manufacturer

MARS AUSTRALIA PTY LTD

TRADING AS MARS
PETCARE AUSTRALIA

ACN: 008 454 313

1 Petcare Place

Product Types: *

LICENCE NO: 2106

Category 2: Palatable ingestible chews

WODONGA VIC 3690

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, filling, packaging, labelling, strip, blister or sachet packaging, microbiological reduction treatment (heat), analysis and testing

(physical), storage and release for supply

Amended Licence Issued: 21 November 2017

3. LICENCE CANCELLATIONS

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

Nil

4. LICENCE SUSPENSIONS

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

HY GAIN FEEDS PTY. LIMITED LICENCE NO: 6088

ACN: 006 198 821 **Period of Suspension:** 3 December 2017 to 2 March 2018

10 Hickson Road OFFICER VIC 3809

5. REVOCATION OF LICENCE CANCELLATION

The APVMA has revoked the cancellation of the following licences under subsection 127(7) of the Agvet Code:

Nil

6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agvet Code:

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

Phone: +61 2 6210 4899

Email: mls@apvma.gov.au

* Category 1: Immunobiologicals and sterile veterinary preparations

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

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: Single-step manufacturer

New Agricultural Active Constituent Bacillus Amyloliquefaciens Strain QST 713

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, *Bacillus amyloliquefaciens* strain QST 713, for use as a biofungicide in agricultural products.

Common name: Bacillus amyloliquefaciens strain QST 713

Species name: Bacillus amyloliquefaciens

Strain name: QST 713

Genus name: Bacillus

Family name: Bacillaceae

Group: Gram-positive eubacteria

Kingdom: Bacteria

Brief description: The strain originally known as Bacillus subtilis QST 713 was first isolated from soil in

a peach orchard in Fresno County, California (USA) in 1995. New taxonomic studies

revealed that Bacillus subtilis QST 713 should be reclassified as *Bacillus* amyloliquefaciens strain QST 713. It is a gram-positive, motile rod measuring

1.0 μ m × 3–5 μ m with peritrichous flagella

SUMMARY OF THE APVMA'S EVALUATION

The APVMA has evaluated the chemistry aspects of *Bacillus amyloliquefaciens* strain QST 713 active constituent (identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for *Bacillus amyloliquefaciens* strain QST 713 active constituent:

Constituent	Specification	Level
Bacillus amyloliquefaciens strain QST 713	Bacillus amyloliquefaciens strain QST 713	1.0 x E9 CFU/g minimum

Impurities of toxicological significance are not expected to occur in *Bacillus amyloliquefaciens* strain QST 713 as a result of the raw materials and the fermentation process used.

The APVMA has considered the toxicological aspects of *Bacillus amyloliquefaciens* strain QST 713, and concluded that there are no toxicological concerns to the approval of this active constituent. The organisms are not infective or pathogenic and were not toxic at limit doses in acute toxicity tests, consequently the establishment of an Acceptable Daily Intake (ADI), or of an Acute Reference Dose (ARfD), is not required.

Following a recommendation from the Advisory Committee on Chemical Substances (ACCS), the Scheduling Delegate for the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons*—SUSMP) has made a final decision regarding *Bacillus amyloliquefaciens* strain QST 713 to be listed in Appendix B of the Poisons Standard (substances considered not to require control by scheduling), as a result of its low toxicity, with an implementation date of 1 February 2018.

The APVMA is satisfied that the proposed importation and use of *Bacillus amyloliquefaciens* strain QST 713 would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of *Bacillus amyloliquefaciens* strain QST 713 should be granted. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

When making a submission please include a:

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

All personal and confidential commercial information (CCI)¹ material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Director of Chemistry and Manufacture
Scientific Assessment and Chemical Review Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4701 Fax: +61 2 6210 4721

Email: enquiries@apvma.gov.au

¹ A full definition of 'confidential commercial information' is contained in the <u>Agvet Code</u>.

Serenade Opti Biofungicide Containing the New Active Constituent Bacillus Amyloliquefaciens Strain QST 713

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is Serenade Opti Biofungicide.

PARTICULARS OF THE APPLICATION

Proposed product name(s): Serenade Opti Biofungicide

Bayer CropScience PTY LTD Applicant company:

Name of active constituent: Bacillus amyloliquefaciens strain QST 713

Signal heading: Not required—Appendix B

Summary of proposed use: For the control of Botrytis bunch rot in grapevines

Pack sizes: 0.1 kg-100 kg

Withholding period: Not required when used as directed

SUMMARY OF THE APVMA'S EVALUATION OF SERENADE OPTI BIOFUNGICIDE 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:
 - The APVMA is satisfied that the proposed use of Serenade Opti Biofungicide would not be an undue hazard to the (i) safety of people exposed to it during its handling and use.
 - The APVMA is satisfied that the proposed use of Serenade Opti Biofungicide will not be an undue hazard to the safety of people using anything containing its residues.
 - The APVMA is satisfied that the proposed use of Serenade Opti Biofungicide containing the active constituent Bacillus amyloliquefaciens strain QST 713 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 the new products Serenade Opti Biofungicide containing the active constituent Bacillus amyloliquefaciens strain QST 713, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.
- 2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

- 3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of Serenade Opti Biofungicide would not adversely affect trade between Australia and places outside Australia.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the 'Public Consultation' page at the APVMA website, www.apvma.gov.au/news-and-publications/public-consultations or by contacting the APVMA as indicated below.

MAKING A SUBMISSION

In accordance with section13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Serenade Opti Biofungicide 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)¹ 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

Phone: +61 2 6210 4701 **Fax:** +61 2 6210 4721

Email: enquiries@apvma.gov.au

¹ A full definition of 'confidential commercial information' is contained in the Agvet Code.

Cancellation of Registration and Label Approvals at the Request of the Holder

At the request of the holder, the APVMA has cancelled the registration and the associated label approvals of the following product:

Product no	Product name	Registrant/approval holder	Cancelled label approvals	Date of effect
37036	BUTASYL INJECTION PHENYLBUTAZONE 186 MG/ML AND SODIUM SALICYLATE 5 MG/ML	ELANCO AUSTRALASIA PTY LTD	37036/0909 37036/0499	27 November 2017

The following instructions set out how a person can deal with the cancelled product registration and the associated label approvals.

SUPPLY

A person may supply or cause to be supplied product and the associated label approvals manufactured prior to 27 November 2017 at wholesale and retail level, until the 27 November 2018.

After 27 November 2018 it will be an offence against the Agvet Codes to have possession or custody of the product with the intention to supply, or to supply the product and the associated label approvals listed in the table above.

USE

A person may continue to use the product and the associated label approvals according to its label instructions until 27 November 2018.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product and the associated label approvals listed in the table above 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 and associated label approvals listed in the table above after the registration has been cancelled until 27 November 2018.

The supply and use of the product and the associated label approvals listed in the table above 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 and associated label approvals 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 4776

Email: chemicalreview@apvma.gov.au

Cancellation of Product Label Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the product label approval of the following product:

Product no	Product name	Registrant/approval holder	Cancelled label approval	Date of effect
83385	Macspred Glymac Bio 510 SL Herbicide	Macspred Pty Ltd	83385/108159	1 December 2017

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

SUPPLY

A person may supply or cause to be supplied product bearing the cancelled label approval listed in the table above manufactured prior to 1 December 2017 at wholesale and retail level, until the 1 December 2018.

After 1 December 2018 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label approval with the intention to supply, or to supply product.

USE

A person may continue to use the product bearing the cancelled label approval listed in the table above according to its label instructions until 1 December 2018.

Any person who possesses, has custody of, uses, or otherwise deals with product bearing the cancelled label approval 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 bearing the cancelled label approval until 1 December 2018.

The supply and use of the product bearing the cancelled label approval listed in the table above 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 and the associated label approval listed in the table above 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 4729 **Fax:** +61 2 6210 4776

Email: chemicalreview@apvma.gov.au