

# Commonwealth of Australia

# Gazette

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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

If you would like to receive email notification when a new edition is published, please subscribe on the APVMA website.

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### **Agricultural Chemical Products and Approved Labels**

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

#### 1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.: 116026

Product name: Sinon Angle 750 Herbicide
Active constituent/s: 750 g/kg chlorsulfuron
Applicant name: Sinon Australia Pty Limited

**Applicant ACN:** 102 741 024

Summary of use: For the control of annual (wimmera) ryegrass and certain broadleaf weeds in wheat,

barley, oats, cereal rye and triticale

**Date of registration:** 3 September 2018

Product registration no.: 86552

**Label approval no.:** 86552/116026

Application no.: 116224

Product name: Arysta Lifescience Isoxaflutole 750 WG Herbicide

Active constituent/s: 750 g/kg isoxaflutole

Applicant name: Arysta Lifescience Australia Pty Ltd

**Applicant ACN:** 005 225 507

**Summary of use:** For the control and suppression of various broadleaf weeds and grasses in sugarcane

and chickpeas

**Date of registration:** 5 September 2018

Product registration no.: 86624 Label approval no.: 86624/116224

Application no.: 116698

Product name: Storm 960 Herbicide

Active constituent/s: 960 g/L s-metolachlor

Applicant name: Sunrise Crop Science Co Ltd

Applicant ACN: N/A

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

**Date of registration:** 5 September 2018

Product registration no.: 86836

**Label approval no.:** 86836/116698

Application no.: 116350

Product name: Maxunitech Thidiazuron 500SC Cotton Defoliant

Active constituent/s: 500 g/L thidiazuron

Applicant name: Max(Rudong) Chemicals Co Ltd

Applicant ACN: N/A

**Summary of use:** For the defoliation of cotton prior to harvest

**Date of registration:** 5 September 2018

Product registration no.: 86682 Label approval no.: 86682/116350

Product name: Fascinate 500 SG Herbicide

Active constituent/s: 500 g/kg glufosinate-ammonium

Applicant name: UPL Australia Limited

**Applicant ACN:** 066 391 384

Summary of use: For non-residual control of broadleaf and grass weeds in various situations

**Date of registration:** 5 September 2018

Product registration no.: 85197

**Label approval no.:** 85197/112629

Application no.: 111510

Product name: Imtrade Cyborg 25 EC Insecticide

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

Applicant name: Imtrade Australia Pty Ltd

**Applicant ACN:** 090 151 134

Summary of use: For the suppression of macadamia nut borer and fruit spotting bug in macadamias

**Date of registration:** 6 September 2018

Product registration no.: 84822

**Label approval no.:** 84822/111510

Application no.: 116358

Product name: Pulsar Infinity Slow Dissolve Pool Chlorine Tablet

Active constituent/s: 700 g/kg available chlorine (CI) present as calcium hypochlorite

Applicant name: Arch International Pty Limited

**Applicant ACN:** 074 240 707

Summary of use: For control of bacteria, viruses and protozoa in swimming pools

**Date of registration:** 10 September 2018

Product registration no.: 86686

**Label approval no.:** 86686/116358

Application no.: 116254

Product name: Glyphix Dry 700 Herbicide

Active constituent/s: 700 g/kg glyphosate present as the mono-ammonium salt

Applicant name: Ruralco Holdings Limited

**Applicant ACN:** 009 660 879

Summary of use: For the control of many annual and perennial weeds in certain situations

Date of registration: 10 September 2018

Product registration no.: 86644

Label approval no.: 86644/116254

Application no.: 116513

Product name: ACP Bison 440 Insecticide

Active constituent/s: 440 g/L buprofezin

Applicant name: Australis Crop Protection Pty Ltd

**Applicant ACN:** 150 711 185

Summary of use: For the control of various insect pests in citrus, grapes, pears, persimmons, custard

apple, passionfruit and mango as per the directions for use

Date of registration: 10 September 2018

Product registration no.: 86757

**Label approval no.:** 86757/116513

Product name: Sabakem Chlorothalonil 720 SC Fungicide

Active constituent/s: 720 g/L chlorothalonil
Applicant name: Sabakem Pty Ltd
Applicant ACN: 151 682 138

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

ornamentals, peanuts, stone fruit, tobacco and vegetables

**Date of registration:** 10 September 2018

Product registration no.: 86767

**Label approval no.:** 86767/116529

Application no.: 116625

Product name: Ozcrop Paraquat 360 SL Herbicide

Active constituent/s: 360 g/L paraquat present as paraquat dichloride

Applicant name:Ozcrop Pty LtdApplicant ACN:160 656 431

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

Date of registration: 10 September 2018

Product registration no.: 86801

**Label approval no.:** 86801/116625

Application no.: 116446

Product name: Maxiblock Sunscreen Australia Outbacker Insect Repellent Sunscreen SPF50+ Very High

Protection UVA/UVB Broad Spectrum 2 Hours Water Resistant Dual Protection Lotion for Face

and Body

Active constituent/s: 72.1 g/L diethyltoluamide (DEET), 1.0 g/L pyrethrins, 51.5 g/L n-octylbicycloheptene dicarboximide,

7.2 g/L piperonyl butoxide

Applicant name: Natuva Pty Ltd Applicant ACN: 169 208 735

**Summary of use:** For personal use as a sunscreen insect repellent

Date of registration: 10 September 2018

Product registration no.: 86717

Label approval no.: 86717/116446

Application no.: 116833

Product name: Methoxycrop 240 Insecticide
Active constituent/s: 240 g/L methoxyfenozide

Applicant name:Agricrop Pty LtdApplicant ACN:100 473 309

Summary of use: For the control of light brown apple moth on apples and pears, blueberries, citrus, grapevines

and kiwifruit, and for the control of various other lepidopteran pests of apples and pears, avocado, coffee, custard apple, eggplant, longan, lychee, peppers, okra, macadamia and

tomatoes

**Date of registration:** 10 September 2018

Product registration no.: 86853

**Label approval no.:** 86853/116833

Product name: Arysta Lifescience Imidacloprid 200 SC Insecticide

Active constituent/s: 200 g/L imidacloprid

Applicant name: Arysta Lifescience Australia Pty Ltd

Applicant ACN: 005 225 507

Summary of use: For the control of various insect pests of cotton, fruit, vegetables and ornamentals

Date of registration: 11 September 2018

Product registration no.: 86629

**Label approval no.:** 86629/116230

Application no.: 112704

Product name: Imtrade Fenhexamid 500 SC Fungicide

Active constituent/s: 500 g/L fenhexamid
Applicant name: Imtrade Australia Pty Ltd

**Applicant ACN:** 090 151 134

**Summary of use:** For the control of grey mould on strawberries

**Date of registration:** 13 September 2018

Product registration no.: 85234

Label approval no.: 85234/112704

Application no.: 111885

**Product name:**Allgon Timber Treatment for Borers and Termites

Active constituent/s: 87.5 g/L boron (B) present as boric acid

Applicant name: Allgon Pest Control Pty Ltd

Applicant ACN: 059 217 159

Summary of use: For industrial and domestic use in the pre-treatment of timber against insects

**Date of registration:** 13 September 2018

Product registration no.: 84950

**Label approval no.:** 84950/111885

Application no.: 112253

**Product name:** Fly Attract for Bug Zappers and Traps

Active constituent/s: 11 g/kg (z)-9 tricosene
Applicant name: The Kelly Company Pty Ltd

**Applicant ACN:** 001 729 693

Summary of use: For use with electronic insect killers and traps to attract flies

Date of registration: 13 September 2018

Product registration no.: 85083

Label approval no.: 85083/112253

Application no.: 112295

Product name: Fuhua Glufosinate Ammonium 150 SL Herbicide

Active constituent/s: 150 g/L glufosinate ammonium

Applicant name:Sichuan Leshan Fuhua Tongda Agro-Chemical Tech Co Ltd

Applicant ACN: N/A

Summary of use: For non-residual control of broadleaf and grass weeds

Date of registration: 13 September 2018

Product registration no.: 85105 Label approval no.: 85105/112295

#### 2. VARIATIONS OF REGISTRATION

Application no.: 117389

Product name: Spa Care by Lo-Chlor Spa Sanitiser

Active constituent/s: 504 g/kg available chlorine (CI) present as sodium dichloroisocyanurate,

Applicant name: M I International Pty Ltd

**Applicant ACN:** 002 869 089

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

'LO-CHLOR SPA SANITISER' to 'SPA CARE BY LO-CHLOR SPA SANITISER'

Date of variation: 31 August 2018

Product registration no.: 85547

**Label approval no.:** 85547/117389

Application no.: 115162

Product name:

Nufarm Tri-Base Blue Flowable Copper Fungicide

Active constituent/s:

190 g/L copper (Cu) present as tribasic copper sulphate

Applicant name: Nufarm Australia Limited

**Applicant ACN:** 004 377 780

Summary of variation: To vary label to use half rate application on grapevines

**Date of variation:** 5 September 2018

Product registration no.: 53568

Label approval no.: 53568/115162

Application no.: 114794

 Product name:
 Movento 240 SC Insecticide

 Active constituent/s:
 240 g/L spirotetramat

 Applicant name:
 Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of variation: To extend the use to include diamondback moth in brassicas and cotton mealybug in cotton

**Date of variation:** 10 September 2018

Product registration no.: 61864

**Label approval no.:** 61864/114794

Application no.: 115375

Product name: Kamba 750 Selective Herbicide

Active constituent/s: 750 g/L dicamba present as the dimethylamine and monomethlyamine salts

Applicant name: Nufarm Australia Limited

**Applicant ACN:** 004 377 780

Summary of variation: To extend use on rice to Queensland and Victoria and make other label updates

Date of variation: 11 September 2018

Product registration no.: 69302

**Label approval no.:** 69302/115375

Product name: Vaporph3os Phosphine Fumigant

Active constituent/s: 990 g/kg phosphine

Applicant name: Cytec Australia Holdings Pty Limited

**Applicant ACN:** 081 148 629

Summary of variation: To extend use to include fumigation of poultry housing for control of darkling beetle (lesser

mealworm)

Date of variation: 11 September 2018

Product registration no.: 51209

**Label approval no.:** 51209/111367

Application no.: 117055

Product name: Evergol Energy Seed Treatment And In-Furrow Fungicide

Active constituent/s: 76.8 g/L prothioconazole, 61.4 g/L metalaxyl, 38.4 g/L penflufen

Applicant name: Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of variation: To extend uses for suppression of crown rot and control of loose smut in wheat, barley, triticale

and oats, for control of covered smut in barley, for control of flag smut in wheat, for suppression of seed-borne head blight and crown rot in wheat and barley, and for suppression of white grain

disorder in wheat

**Date of variation:** 12 September 2018

Product registration no.: 83953

**Label approval no.:** 83953/117055

Application no.: 117456

Product name: Tokuthion Insecticide Spray

Active constituent/s: 500 g/L prothiofos (an anticholinesterase compound)

Applicant name: Arysta Lifescience North America LLC

Applicant ACN: N/A

Summary of variation: Variation of the label approval to remove the use on table grapes

Date of variation: 13 September 2018

Product registration no.: 33087

**Label approval no.:** 33087/117456

## **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. VARIATIONS OF REGISTRATION

Application no.: 116911

Product name: Promectin Plus LV Allwormer Paste For Horses (300 KG - 600 KG)

Active constituent/s: 238 mg/g praziquantel, 19 mg/g ivermectin

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

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

'PROMECTIN PLUS MINI ALLWORMER PASTE FOR HORSES (300 KG - 600 KG)' to 'PROMECTIN PLUS LV ALLWORMER PASTE FOR HORSES (300 KG - 600 KG)'

Date of variation: 30 July 2018 Product registration no.: 62378 Label approval no.: 62378/116911

Application no.:

Product name: Promectin Plus LV Allwormer Paste For Foals And Ponies (150KG - 300KG)

Active constituent/s: 238 mg/g praziquantel, 19 mg/g ivermectin

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

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

'PROMECTIN PLUS MINI ALLWORMER PASTE FOR FOALS AND PONIES (150KG - 300KG)' to

'PROMECTIN PLUS LV ALLWORMER PASTE FOR FOALS AND PONIES (150KG - 300KG)'

Date of variation: 30 July 2018 Product registration no.: 64400

Label approval no.: 64400/116910

117269 Application no.:

Product name: Covine Karma Pour-On Lousicide For Sheep

Active constituent/s: 35 g/L imidacloprid Applicant name: Ruralco Holdings Limited

**Applicant ACN:** 009 660 879

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

'COVINE VINDICATE POUR-ON LOUSICIDE FOR SHEEP' to 'COVINE KARMA POUR-ON

LOUSICIDE FOR SHEEP'

Date of variation: 24 August 2018

Product registration no.: 85811

Label approval no.: 85811/117269 Application no.: 117284
Product name: Aviax

Active constituent/s: 50 g/kg semduramicin (as semduramicin sodium 51.3 g/kg)

Applicant name: Phibro Animal Health Pty Limited

Applicant ACN: 093 869 991

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

'AVIAX BROAD SPECTRUM COCCIDIOCIDAL FEED ADDITIVE PREMIX' to 'AVIAX'

Date of variation: 24 August 2018

Product registration no.: 48882

Label approval no.: 48882/117284

Application no.: 117177

Product name: Purina Totalcare Flea Powder For Dogs

Active constituent/s: 10 g/kg rotenone, 10 g/kg piperonyl butoxide, 1 g/kg pyrethrins

Applicant name: Nestle Purina Petcare A Div Of Nestle Australia Ltd

**Applicant ACN:** 000 011 316

**Summary of variation:** To remove the use on cats from the label and instructions

Date of variation: 16 August 2018

Product registration no.: 63934

**Label approval no.:** 63934/117177

Application no.: 115927

Product name: Fasinex 240 Oral Flukicide For Cattle And Sheep

Active constituent/s: 240 g/L triclabendazole
Applicant name: Elanco Australasia Pty Ltd

**Applicant ACN:** 076 745 198

**Summary of variation:**To extend the use to sheep and to change the distinguishing product name and the name

that appears on the label from 'FASINEX 240 ORAL FLUKICIDE FOR CATTLE' to

'FASINEX 240 ORAL FLUKICIDE FOR CATTLE AND SHEEP'

**Date of variation:** 11 September 2018

Product registration no.: 51262

**Label approval no.:** 51262/115927

Application no.: 116488

Product name: Adaptil Spray

Active constituent/s: 15.72 mg/mL synthetic analogue of the canine appearing pheromone

Applicant name: Ceva Animal Health Pty Ltd

**Applicant ACN:** 002 692 426

Summary of variation: To approve a new label for the registered product 'ADAPTIL SPRAY' with the label

name 'ADAPTIL TRANSPORT SPRAY'

**Date of variation:** 13 September 2018

Product registration no.: 83354

Label approval no.: 83354/116488

### **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.: 113493

Active constituent/s: Prothioconazole

**Applicant name:** 4 Farmers Australia Pty Ltd

**Applicant ACN:** 160 092 428

Summary of use: For use in agricultural chemical products

Date of approval: 6 September 2018

Approval no.: 85517

Application no.: 114693
Active constituent/s: Chlorpyrifos

Applicant name: Krishi Rasayan Exports Pvt Ltd

Applicant ACN: N/A

**Summary of use:** For use in agricultural chemical products

Date of approval: 11 September 2018

#### 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.: 114166
Active constituent/s: Trimethoprim

Applicant name: Caledonian Holdings Distribution Pty Ltd

**Applicant ACN:** 122 162 190

Summary of use: For use in veterinary chemical products

Date of approval: 28 June 2018 Approval no.: 85855

Application no.: 114148

Active constituent/s: Dexamethasone Trimethylacetate

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 28 June 2018
Approval no.: 85842

Application no.: 114158

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

Summary of use: For use in veterinary chemical products

Date of approval: 28 June 2018
Approval no.: 85850

Application no.: 114159

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

**Summary of use:** For use in veterinary chemical products

Date of approval: 28 June 2018
Approval no.: 85851

Application no.: 114160

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

Summary of use: For use in veterinary chemical products

Date of approval: 28 June 2018
Approval no.: 85852

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

**Summary of use:** For use in veterinary chemical products

Date of approval: 29 June 2018 Approval no.: 85849

Application no.: 113814
Active constituent/s: Tryptophan

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: 29 June 2018
Approval no.: 85668

Application no.: 114167
Active constituent/s: NDV Clone 30

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 29 June 2018
Approval no.: 85856

Application no.: 114168

Active constituent/s: Feline Calicivirus (Live)
Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 29 June 2018
Approval no.: 85857

Application no.: 114169

Active constituent/s: Corynebacterium Pseudotuberculosis Toxiod and Inactivated Cells

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 29 June 2018 Approval no.: 85858

Application no.: 114182
Active constituent/s: Clorsulon

Applicant name: Norbrook Laboratories Australia Pty Limited

**Applicant ACN:** 080 972 596

**Summary of use:** For use in veterinary chemical products

Date of approval: 29 June 2018 Approval no.: 85867

Active constituent/s: Inactivated Infectious Bursal Disease Virus (Strain IBDV D78)

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 29 June 2018
Approval no.: 85853

Application no.: 114175
Active constituent/s: Praziquantel

Applicant name: Caledonian Holdings Distribution Pty Ltd

**Applicant ACN:** 122 162 190

**Summary of use:** For use in veterinary chemical products

Date of approval: 2 July 2018
Approval no.: 85864

Application no.: 114184

Active constituent/s: Flunixin Meglumine

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 2 July 2018 Approval no.: 85869

Application no.: 114171

Active constituent/s: Dinoprost Trometamol
Applicant name: Zoetis Australia Pty Ltd

**Applicant ACN:** 156 476 425

**Summary of use:** For use in veterinary chemical products

Date of approval: 2 July 2018 Approval no.: 85860

Application no.: 111486

Active constituent/s: Mometasone Furoate

Applicant name: Bayer Australia Ltd (Animal Health)

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 4 July 2018 Approval no.: 84814

Application no.: 112991

Active constituent/s: Piperonyl Butoxide

Applicant name: Bayer Australia Ltd (Animal Health)

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 4 July 2018
Approval no.: 85355

Active constituent/s: Cobalt Sulphate Heptahydrate
Applicant name: Argenta Manufacturing Limited

Applicant ACN: N/A

**Summary of use:** For use in veterinary chemical products

Date of approval: 4 July 2018 Approval no.: 85854

Application no.: 114173

Active constituent/s: Bovine Herpes Virus Type 1.2B (Inactivated)

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 4 July 2018
Approval no.: 85862

Application no.: 114172

Active constituent/s: Feline Herpes Virus Type 1 (Live)
Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 4 July 2018 Approval no.: 85861

Application no.: 114170

Active constituent/s: Feline Panleucopenia Virus (Live)
Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 4 July 2018 Approval no.: 85859

Application no.: 110869

Active constituent/s: Spectinomycin Sulfate Zoetis Australia Pty Ltd

**Applicant ACN:** 156 476 425

Summary of use: For use in veterinary chemical products

**Date of approval:** 5 July 2018 **Approval no.:** 84586

Application no.: 114194
Active constituent/s: Cyclosporin

Applicant name: Elanco Australasia Pty Ltd

**Applicant ACN:** 076 745 198

**Summary of use:** For use in veterinary chemical products

Date of approval: 5 July 2018
Approval no.: 85876

Active constituent/s: Piperazine Citrate

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 6 July 2018
Approval no.: 85901

Application no.: 114225
Active constituent/s: Frusemide

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 6 July 2018
Approval no.: 85900

Application no.: 114219

Active constituent/s: Salmonella Dublin (Inactivated)
Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 6 July 2018
Approval no.: 85894

Application no.: 114218

Active constituent/s: Salmonella Typhimurium (Inactivated)

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 6 July 2018 Approval no.: 85893

Application no.: 114177

Active constituent/s: Pyrantel Embonate

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 6 July 2018 Approval no.: 85865

Application no.: 114183

Active constituent/s: ILT Virus (Living, Attenuated)
Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 6 July 2018 Approval no.: 85868

Active constituent/s: Tolfenamic Acid

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 9 July 2018
Approval no.: 85907

Application no.: 114235

Active constituent/s: Riboflavin Sodium Phosphate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 9 July 2018
Approval no.: 85905

Application no.: 114232

Active constituent/s: Pyrantel Embonate

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 9 July 2018 Approval no.: 85904

Application no.: 114231

Active constituent/s: Ammonium Ferric Citrate (Brown)

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 9 July 2018 Approval no.: 85903

Application no.: 114220

Active constituent/s: Mannheimia Haemolytica (Inactivated), Strain X 387 (Leucotoxin Producing)

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 9 July 2018 **Approval no.:** 85895

Application no.: 114222

Active constituent/s: Mannheimia Haemolytica (Inactivated), Strain X 332

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 9 July 2018
Approval no.: 85897

Active constituent/s: Barium 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: 9 July 2018 Approval no.: 85694

Application no.: 116177
Active constituent/s: Amitraz

Applicant name: Landmark Operations Limited

**Applicant ACN:** 008 743 217

**Summary of use:** For use in veterinary chemical products

Date of approval: 9 July 2018
Approval no.: 86594

Application no.: 114198
Active constituent/s: Meloxicam

Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

Summary of use: For use in veterinary chemical products

Date of approval: 10 July 2018
Approval no.: 85880

Application no.: 114239
Active constituent/s: Guaiphenesin

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 10 July 2018 Approval no.: 85909

Application no.: 114240
Active constituent/s: Glycine

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 10 July 2018 Approval no.: 85910

Application no.: 114241

Active constituent/s: L-Lysine Hydrochloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 10 July 2018 Approval no.: 85911

Active constituent/s: Prednisolone Acetate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 10 July 2018 Approval no.: 85914

Application no.: 114245

Active constituent/s: Manganese Sulfate Monohydrate

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 10 July 2018
Approval no.: 85915

Application no.: 114246

Active constituent/s: Flunixin Meglumine
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 10 July 2018
Approval no.: 85916

Application no.: 114251
Active constituent/s: Nystatin

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 10 July 2018 Approval no.: 85921

Application no.: 114197

Active constituent/s: Hydroxocobalamin Acetate
Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

Summary of use: For use in veterinary chemical products

Date of approval: 11 July 2018
Approval no.: 85879

Application no.: 114196

Active constituent/s: Oxytetracycline Dihydrate
Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

Summary of use: For use in veterinary chemical products

Date of approval: 11 July 2018 Approval no.: 85878

Active constituent/s: Choline Chloride

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 11 July 2018 Approval no.: 85918

Application no.: 114249

Active constituent/s: Bromhexine Hydrochloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 11 July 2018
Approval no.: 85919

Application no.: 114176

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: 17 July 2018 Approval no.: 82703

Application no.: 114262
Active constituent/s: Castor Oil

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 17 July 2018 Approval no.: 85939

Application no.: 114250

Active constituent/s: Chlorpheniramine Maleate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 17 July 2018 **Approval no.:** 85920

Application no.: 110498

Active constituent/s: Calcium And Phosphorus (as Calcium Hydrogen Phosphate)

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

**Summary of use:** For use in veterinary chemical products

Date of approval: 23 July 2018 Approval no.: 84483

Active constituent/s: Triamcinolone Acetonide
Applicant name: Apex Laboratories Pty Ltd

**Applicant ACN:** 614 716 700

Summary of use: For use in veterinary chemical products

Date of approval: 25 July 2018
Approval no.: 85891

Application no.: 114294

Active constituent/s: Infectious Bronchitis Virus Living, Attenuated

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 26 July 2018 Approval no.: 85959

Application no.: 114347

Active constituent/s: Miconazole Nitrate
Applicant name: Dermcare-Vet Pty Ltd

**Applicant ACN:** 010 280 010

**Summary of use:** For use in veterinary chemical products

Date of approval: 30 July 2018
Approval no.: 85998

Application no.: 114356
Active constituent/s: Thiamazole

Applicant name: Dermcare-Vet Pty Ltd

**Applicant ACN:** 010 280 010

Summary of use: For use in veterinary chemical products

Date of approval: 30 July 2018
Approval no.: 86003

Application no.: 114030

Active constituent/s: Sulphadimidine

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: 30 July 2018 Approval no.: 85773

Application no.: 114185

Active constituent/s: Fowl Adenovirus, Living (Esurient Strain)

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 30 July 2018 Approval no.: 85870

Active constituent/s: Newcastle Disease Virus (NDV) Strain V4 (Living)

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 30 July 2018 Approval no.: 85871

Application no.: 114189

Active constituent/s: Whole Cell Actinobacillus Pleuropneumoniae Serotypes 1, 7 and 15 including Haemolysin

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 30 July 2018 Approval no.: 85874

Application no.: 114187

Active constituent/s: Vitamin B5 Calcium Salt = Calcium Pantothenate

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

Summary of use: For use in veterinary chemical products

Date of approval: 30 July 2018
Approval no.: 85872

Application no.: 114188

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

**Summary of use:** For use in veterinary chemical products

Date of approval: 30 July 2018 Approval no.: 85873

Application no.: 113932
Active constituent/s: Ivermectin

Applicant name: Caledonian Holdings Distribution Pty Ltd

**Applicant ACN**: 122 162 190

**Summary of use:** For use in veterinary chemical products

Date of approval: 31 July 2018
Approval no.: 85724

Application no.: 114199
Active constituent/s: Selamectin

Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

Summary of use: For use in veterinary chemical products

Date of approval: 31 July 2018 Approval no.: 85881

Active constituent/s: Iron Amino Acid Chelate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 31 July 2018 Approval no.: 85912

Application no.: 114336

Active constituent/s: Cobalt Sulphate Heptahydrate

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: 2 August 2018

Approval no.: 85987

Application no.: 114332

Active constituent/s: Magnesium Sulphate Heptahydrate

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: 2 August 2018

Approval no.: 85984

Application no.: 114353

Active constituent/s: Phenylpropanolamine Hydrochloride

Applicant name: Dermcare-Vet Pty Ltd

**Applicant ACN:** 010 280 010

Summary of use: For use in veterinary chemical products

Date of approval: 2 August 2018

Approval no.: 86000

Application no.: 114373

Active constituent/s: Calcium Chloride Dihydrate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 9 August 2018

Approval no.: 86015

Application no.: 113847

Active constituent/s: Calcium Chloride Dihydrate
Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

**Summary of use:** For use in veterinary chemical products

Date of approval: 9 August 2018

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

**Applicant ACN:** 156 476 425

Summary of use: For use in veterinary chemical products

Date of approval: 9 August 2018

Approval no.: 86038

Application no.: 114396

Active constituent/s: Morantel 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: 9 August 2018

Approval no.: 86036

Application no.: 114395
Active constituent/s: Sodium lodide

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: 9 August 2018

Approval no.: 86035

Application no.: 114546
Active constituent/s: Zeranol

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 9 August 2018

Approval no.: 86041

Application no.: 114550

Active constituent/s: Ampicillin (as Sodium Salt)

Applicant name: Norbrook Laboratories Australia Pty Limited

**Applicant ACN:** 080 972 596

Summary of use: For use in veterinary chemical products

Date of approval: 9 August 2018

Approval no.: 86043

Application no.: 116699
Active constituent/s: Ivermectin

Applicant name: Landmark Operations Limited

**Applicant ACN:** 008 743 217

Summary of use: For use in veterinary chemical products

Date of approval: 10 August 2018

Application no.: 116700
Active constituent/s: Ivermectin

Applicant name: Landmark Operations Limited

**Applicant ACN:** 008 743 217

Summary of use: For use in veterinary chemical products

Date of approval: 10 August 2018

Approval no.: 86838

Application no.: 114253

Active constituent/s: Butorphanol Tartrate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85923

Application no.: 114253
Active constituent/s: Ascorbic Acid

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85925

Application no.: 114256

Active constituent/s: Polymyxin B Sulfate
Applicant name: Troy Laboratories Pty Ltd

Applicant ACN: 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85926

Application no.: 114257
Active constituent/s: Menthol

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85927

Application no.: 114258

Active constituent/s: Heptaminol Hydrochloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 20 August 2018

Active constituent/s: Acepromazine Maleate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85929

Application no.: 114260

Active constituent/s: Thiamine Hydrochloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85930

Application no.: 114261
Active constituent/s: Trypsin

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85931

Application no.: 114263

Active constituent/s: Cephalexin Monohydrate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85933

Application no.: 114264

Active constituent/s: Thiopental Sodium

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 20 August 2018

Approval no.: 85934

Application no.: 114243

Active constituent/s: Ammonium Ferric Citrate (Green)

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 22 August 2018

Active constituent/s: Potassium Chloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 22 August 2018

Approval no.: 85844

Application no.: 114265
Active constituent/s: Folic Acid

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 22 August 2018

Approval no.: 85935

Application no.: 114266

Active constituent/s: Methadone Hydrochloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 22 August 2018

Approval no.: 85936

Application no.: 114267

Active constituent/s: Hydroxocobalamin Acetate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 22 August 2018

Approval no.: 85937

Application no.: 114268
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: 22 August 2018

Approval no.: 85938

Application no.: 114271
Active constituent/s: Selamectin

Applicant name: Shanghai Neway Animal Health Co., Ltd

Applicant ACN: N//

**Summary of use:** For use in veterinary chemical products

Date of approval: 22 August 2018

Application no.: 114272
Active constituent/s: Moxidectin

Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

**Summary of use:** For use in veterinary chemical products

Date of approval: 22 August 2018

Approval no.: 85940

Application no.: 114205
Active constituent/s: Pimobendan

Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

**Summary of use:** For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 85886

Application no.: 114206

Active constituent/s: Benazepril Hydrochloride
Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

**Summary of use:** For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 85887

Application no.: 114207

Active constituent/s: Flunixin Meglumine
Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

Summary of use: For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 85888

Application no.: 114208

Active constituent/s: Miconazole Nitrate
Applicant name: Belin Holdings Pty Ltd

**Applicant ACN:** 618 278 167

Summary of use: For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 85889

Application no.: 114275

Active constituent/s: Propylene Glycol
Applicant name: Vetsense Pty Ltd
Applicant ACN: 150 968 871

**Summary of use:** For use in veterinary chemical products

Date of approval: 23 August 2018

Application no.: 114567
Active constituent/s: Salicylic Acid
Applicant name: Vetsense Pty Ltd
Applicant ACN: 150 968 871

**Summary of use:** For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 86053

Application no.: 114568

Active constituent/s: Povidone (PVP) Iodine
Applicant name: Vetsense Pty Ltd
Applicant ACN: 150 968 871

**Summary of use:** For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 86054

Application no.: 114324
Active constituent/s: Moxidectin

Applicant name: Shanghai Neway Animal Health Co., Ltd

Applicant ACN: N/A

Summary of use: For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 85981

Application no.: 114331
Active constituent/s: Eprinomectin

Applicant name: Shanghai Neway Animal Health Co., Ltd

Applicant ACN: N/A

**Summary of use:** For use in veterinary chemical products

Date of approval: 23 August 2018

Approval no.: 85983

Application no.: 114276

Active constituent/s: Whole Cell Leptospira Interrogans Serovar Hardjo

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 28 August 2018

Approval no.: 85944

Application no.: 114280

Active constituent/s: Leptospira Interrogans Serovar Pomona

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 28 August 2018

Active constituent/s: Concentrated Antigens of Dichelobacter Nodosus, Serotype A, B1, B2, C, D, E, F, G, H and I

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 28 August 2018

Approval no.: 85947

Application no.: 114283

Active constituent/s: Whole Cell E. Coli including Fimbrial Antigens K88, K99 And 987P

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 28 August 2018

Approval no.: 85949

Application no.: 114284

Active constituent/s: Whole Cell E. Coli including Fimbrial Antigens K99

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 28 August 2018

Approval no.: 85950

Application no.: 114287

Active constituent/s: Whole Cell-Free Extract of K99 Pilus Type of Escherichia Coli

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 28 August 2018

Approval no.: 85953

Application no.: 114285
Active constituent/s: Vitamin K1

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: 30 August 2018

Approval no.: 85951

Application no.: 114286
Active constituent/s: Abamectin

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: 30 August 2018

Active constituent/s: Vitamin A Acetate = Retinyl Acetate

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

**Summary of use:** For use in veterinary chemical products

Date of approval: 30 August 2018

Approval no.: 85974

Application no.: 114316

Active constituent/s: Vitamin B1 Hydrochloride = Thiamine Hydrochloride

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

**Summary of use:** For use in veterinary chemical products

Date of approval: 30 August 2018

Approval no.: 85974

Application no.: 114359

Active constituent/s: Imidocarb Dipropionate
Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 6 September 2018

Approval no.: 86006

Application no.: 114202
Active constituent/s: Moxidectin

Applicant name: Ferrari Animal Health Pty Ltd

Applicant ACN: 162 206 671

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85883

Application no.: 114293

Active constituent/s: Triclabendazole

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85958

Application no.: 114297
Active constituent/s: Albendazole

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Active constituent/s: Leptospira Interrogans Serovar Pomona

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85954

Application no.: 114289

Active constituent/s: Porcine Parvovirus

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85955

Application no.: 114290

Active constituent/s: Fowl Pox Virus (Living, Attenuated)

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85956

Application no.: 114298
Active constituent/s: Ketoprofen

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85962

Application no.: 114299

Active constituent/s: Neomycin Sulfate

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85963

Application no.: 114301

Active constituent/s: Hyoscine Butylbromide
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 6 September 2018

Application no.: 114317
Active constituent/s: Glycerin

Applicant name: GEA Farm Technologies Australia Pty Ltd

**Applicant ACN:** 078 926 477

**Summary of use:** For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85975

Application no.: 114331

Active constituent/s: Menadione Sodium Bisulfite

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: 6 September 2018

Approval no.: 85988

Application no.: 114338

Active constituent/s: Sulfaquinoxaline

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:** 6 September 2018

Approval no.: 85989

Application no.: 114345

Active constituent/s: Fenbendazole

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

**Summary of use:** For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85996

Application no.: 114339

Active constituent/s: Magnesium Oxide

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: 6 September 2018

Approval no.: 85990

Application no.: 114302

Active constituent/s: Potassium Aspartate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 6 September 2018

Active constituent/s: Octyl Methoxycinnamate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 6 September 2018

Approval no.: 85968

Application no.: 114341
Active constituent/s: Malic Acid

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: 6 September 2018

Approval no.: 85992

Application no.: 114360

Active constituent/s: Disodium Edetate
Applicant name: Dermcare-Vet Pty Ltd

**Applicant ACN:** 010 280 010

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 7 September 2018

Approval no.: 86007

Application no.: 114342

Active constituent/s: Betamethasone Valerate
Applicant name: Dermcare-Vet Pty Ltd

**Applicant ACN:** 010 280 010

Summary of use: For use in veterinary chemical products

Date of approval: 7 September 2018

Approval no.: 85993

Application no.: 114355
Active constituent/s: Trilostane

Applicant name: Dermcare-Vet Pty Ltd

**Applicant ACN:** 010 280 010

**Summary of use:** For use in veterinary chemical products

Date of approval: 7 September 2018

Approval no.: 86002

Application no.: 114362

Active constituent/s: Trenbolone Acetate
Applicant name: Zoetis Australia Pty Ltd

**Applicant ACN:** 156 476 425

**Summary of use:** For use in veterinary chemical products

Date of approval: 7 September 2018

Active constituent/s: Vitamin D3 = Cholecalciferol

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

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 7 September 2018

Approval no.: 86017

Application no.: 114380

Active constituent/s: Permethrin (25:75 CIS:TRANS)

Applicant name: Vetsense Pty Ltd
Applicant ACN: 150 968 871

**Summary of use:** For use in veterinary chemical products

Date of approval: 7 September 2018

Approval no.: 86021

Application no.: 114384

Active constituent/s: Pyrantel Pamoate
Applicant name: Interchem Pty Ltd
Applicant ACN: 057 313 630

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 7 September 2018

Approval no.: 86025

Application no.: 114374

Active constituent/s: Sodium Selenate

Applicant name: Chemvet Australia Pty Ltd

**Applicant ACN:** 138 711 289

Summary of use: For use in veterinary chemical products

Date of approval: 7 September 2018

Approval no.: 86016

Application no.: 114376

Active constituent/s: Vitamin E-DI Acetate = Alpha Tocopherol Acetate

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

Summary of use: For use in veterinary chemical products

Date of approval: 10 September 2018

Approval no.: 86018

Application no.: 114385

Active constituent/s: Ketamine Hydrochloride
Applicant name: Interchem Pty Ltd
Applicant ACN: 057 313 630

**Summary of use:** For use in veterinary chemical products

Date of approval: 10 September 2018

Active constituent/s: Potassium Chloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 10 September 2018

Approval no.: 86023

Application no.: 114377

Active constituent/s: Cyanocobalamin

Applicant name: Chemvet Australia Pty Ltd

**Applicant ACN:** 138 711 289

Summary of use: For use in veterinary chemical products

Date of approval: 10 September 2018

Approval no.: 86019

Application no.: 114386

Active constituent/s: Piperazine Dihydrochloride

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: 10 September 2018

Approval no.: 86027

Application no.: 114602

Active constituent/s: Oxantel Embonate

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

Summary of use: For use in veterinary chemical products

Date of approval: 11 September 2018

Approval no.: 86079

Application no.: 114379

Active constituent/s: Triamcinolone Acetonide
Applicant name: Randlab Australia Pty Ltd

**Applicant ACN**: 114 948 837

**Summary of use:** For use in veterinary chemical products

Date of approval: 11 September 2018

Approval no.: 86020

Application no.: 114387

Active constituent/s: Phenylbutazone

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: 11 September 2018

Active constituent/s: Ranitidine Hydrochloride

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: 11 September 2018

Approval no.: 86030

Application no.: 114392
Active constituent/s: Trimethoprim

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: 12 September 2018

Approval no.: 86033

Application no.: 114273

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: 12 September 2018

Approval no.: 85941

Application no.: 114393

Active constituent/s: Sodium Propionate

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: 12 September 2018

Approval no.: 86034

Application no.: 114407

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

**Summary of use:** For use in veterinary chemical products

Date of approval: 12 September 2018

Approval no.: 86040

Application no.: 114551

Active constituent/s: Phytomenadione (Vitamin K1, Phytonadione, Phylloquinone) 5%

Applicant name: Mavlab Pty Ltd
Applicant ACN: 009 708 187

**Summary of use:** For use in veterinary chemical products

Date of approval: 12 September 2018

Active constituent/s: Closantel Sodium

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86096

Application no.: 114604

Active constituent/s: Oxantel Embonate

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86081

Application no.: 114625

Active constituent/s: Ketamine Hydrochloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 85086

Application no.: 114574

Active constituent/s: Pyrantel Embonate

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

Summary of use: For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86060

Application no.: 114589

Active constituent/s: Pyrantel Embonate

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86068

Application no.: 114594

Active constituent/s: Niclosamide, Anhydrous

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

Summary of use: For use in veterinary chemical products

Date of approval: 13 September 2018

Active constituent/s: Niclosamide, Anhydrous

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86071

Application no.: 114595
Active constituent/s: Mebendazole

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86072

Application no.: 114596
Active constituent/s: Praziquantel

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

Summary of use: For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86073

Application no.: 114363

Active constituent/s: Permethrin (25:75 CIS:Trans)

Applicant name: Dermcare-Vet Pty Ltd

**Applicant ACN:** 010 280 010

Summary of use: For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86010

Application no.: 114597
Active constituent/s: Nicotinic Acid

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86074

Application no.: 114598

Active constituent/s: Di-N-Propyl Isocinchomeronate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Active constituent/s: Cobalt (II) Sulfate

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86022

Application no.: 114600

Active constituent/s: Povidone-lodine

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86077

Application no.: 114601
Active constituent/s: Ivermectin

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

**Summary of use:** For use in veterinary chemical products

Date of approval: 13 September 2018

Approval no.: 86078

Application no.: 114565

Active constituent/s: Chlortetracycline Hydrochloride
Applicant name: CCD Animal Health Pty Ltd

**Applicant ACN:** 151 737 950

**Summary of use:** For use in veterinary chemical products

Date of approval: 14 September 2018

Approval no.: 86051

Application no.: 114566

Active constituent/s: Morantel Citrate Monohydrate
Applicant name: CCD Animal Health Pty Ltd

**Applicant ACN:** 151 737 950

Summary of use: For use in veterinary chemical products

Date of approval: 14 September 2018

Approval no.: 86052

Application no.: 114677
Active constituent/s: Closantel

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 14 September 2018

Active constituent/s: Ampicillin Trihydrate

Applicant name: Norbrook Laboratories Australia Pty Limited

**Applicant ACN:** 080 972 596

Summary of use: For use in veterinary chemical products

Date of approval: 14 September 2018

Approval no.: 86057

Application no.: 114572

Active constituent/s: Amoxycillin Trihydrate

Applicant name: Norbrook Laboratories Australia Pty Limited

**Applicant ACN:** 080 972 596

**Summary of use:** For use in veterinary chemical products

Date of approval: 14 September 2018

Approval no.: 86058

Application no.: 114390

Active constituent/s: Ferric Ammonium Citrate

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 September 2018

Approval no.: 86031

Application no.: 114552

Active constituent/s: Monensin Sodium Technical

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 September 2018

Approval no.: 86045

Application no.: 114553

Active constituent/s: Cloxacillin Benzathine

Applicant name: Norbrook Laboratories Australia Pty Limited

**Applicant ACN:** 080 972 596

Summary of use: For use in veterinary chemical products

Date of approval: 18 September 2018

Approval no.: 86046

Application no.: 114562

Active constituent/s: Cloxacillin (as Sodium Salt)

Applicant name: Norbrook Laboratories Australia Pty Limited

**Applicant ACN:** 080 972 596

**Summary of use:** For use in veterinary chemical products

Date of approval: 18 September 2018

Application no.: 114626
Active constituent/s: Oxybenzone

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 2018

Approval no.: 86087

Application no.: 114627
Active constituent/s: Cod Liver Oil

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 2018

Approval no.: 86088

Application no.: 114750

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

**Applicant ACN:** 156 476 425

**Summary of use:** For use in veterinary chemical products

Date of approval: 18 September 2018

Approval no.: 86129

Application no.: 114751

Active constituent/s: Cephalexin Sodium

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

Summary of use: For use in veterinary chemical products

Date of approval: 18 September 2018

Approval no.: 86130

Application no.: 114763

Active constituent/s: Trenbolone Acetate

Applicant name: Intervet Australia Pty Limited

Applicant ACN: 008 467 034

**Summary of use:** For use in veterinary chemical products

Date of approval: 18 September 2018

Approval no.: 86136

Application no.: 114603

Active constituent/s: Amoxycillin Trihydrate

Applicant name: Norbrook Laboratories Australia Pty Limited

**Applicant ACN:** 080 972 596

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

Application no.: 114383
Active constituent/s: Imidacloprid

Applicant name: Chemvet Australia Pty Ltd

**Applicant ACN:** 138 711 289

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86024

Application no.: 114721

Active constituent/s: Levothyroxine Sodium

Applicant name: Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 19 September 2018

Approval no.: 86119

Application no.: 114399

Active constituent/s: Framycetin Sulfate

Applicant name: Australian Pharmavet Contract Manufacturing Pty Ltd

**Applicant ACN:** 607 905 733

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86039

Application no.: 114784

Active constituent/s: Lignocaine Hydrochloride
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

**Date of approval:** 19 September 2018

Approval no.: 86142

Application no.: 114786

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

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86143

Application no.: 114874
Active constituent/s: Inositol

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 19 September 2018

Active constituent/s: Adenosine 5'-Monophosphate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86171

Application no.: 114888

Active constituent/s: Methylprednisolone Acetate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

**Date of approval:** 19 September 2018

Approval no.: 86173

Application no.: 114892
Active constituent/s: Nitrofurazone

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

**Date of approval:** 19 September 2018

Approval no.: 86175

Application no.: 114867

Active constituent/s: Calcium Gluconate

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86163

Application no.: 114951
Active constituent/s: Dipyrone

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86191

Application no.: 114971
Active constituent/s: Praziquantel

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

Application no.: 114972
Active constituent/s: L-Tryptophan

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86199

Application no.: 115015

Active constituent/s: Sodium Acetate Trihydrate
Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86210

Application no.: 115028
Active constituent/s: Chlorothymol

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86215

Application no.: 115144

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:** 19 September 2018

Approval no.: 86257

Application no.: 115146

Active constituent/s: Dexamethasone Sodium Phosphate

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of use: For use in veterinary chemical products

Date of approval: 19 September 2018

Approval no.: 86259

Application no.: 115147
Active constituent/s: Chloroxylenol

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

**Summary of use:** For use in veterinary chemical products

Date of approval: 19 September 2018

# 2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.: 116926
Active constituent/s: L-Isoleucine

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 August 2018

Approval no.: 84646

Application no.: 116922

Active constituent/s: N-Acetyl Glucosamine
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 August 2018

Approval no.: 84360

Application no.: 113844

Active constituent/s: Cobalt Sulphate Heptahydrate
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: 8 August 2018

Approval no.: 84352

Application no.: 114279

Active constituent/s: Milbemycin Oxime

Applicant name: Neove Pharma Australia Pty Limited

**Applicant ACN:** 140 367 442

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

Date of variation: 23 August 2018

Approval no.: 82961

Application no.: 117288

Active constituent/s: N-Acetyl Glucosamine
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: 30 August 2018

Approval no.: 84360

Application no.: 114307

Active constituent/s: Adenosine Triphosphate

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: 30 August 2018

Active constituent/s: Tylosin Tartrate

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:** 7 September 2018

Approval no.: 82690

Application no.: 114554

Active constituent/s: Monensin Sodium 40%

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: 10 September 2018

Approval no.: 82691

Application no.: 114559

Active constituent/s: L-Arginine Monohydrochloride
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 2018

Approval no.: 84649

Application no.: 113836

Active constituent/s: Oxytetracycline 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: 14 September 2018

# 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. VARIATIONS OF ACTIVE CONSTITUENT

Application no.: 114295
Active constituent/s: Diazepam

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:** 6 September 2018

Approval no.: 55040

Application no.: 114406
Active constituent/s: Nicarbazin

Applicant name: Nutriment Health Pty Ltd

**Applicant ACN:** 138 061 266

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

**Date of variation:** 7 September 2018

Approval no.: 82388

Application no.: 114404

Active constituent/s: Robenidine Hydrochloride
Applicant name: Nutriment Health Pty Ltd

**Applicant ACN:** 138 061 266

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

**Date of variation:** 7 September 2018

# **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:

Nil

# 2. CHANGES TO EXISTING LICENCES

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

Nil

# 3. LICENCE CANCELLATIONS

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

Pharmapak Technologies Pty LICENCE NO: 6107

Ltd

**ACN:** 093 794 104 **Date cancelled:** 3 August 2018

7 Inman Road

DEE WHY NSW 2099

Durablend Pty Ltd LICENCE NO: 3035

**ACN:** 094 764 315 **Date cancelled:** 31 August 2018

6 Garling Road

KINGS PARK NSW 2148

# 4. LICENCE SUSPENSIONS

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

Nil

# 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

# 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. 7) gazetted on 25 September 2018 (No. APVMA 19).

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 7, 2018) 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 Food Standards Australia and New Zealand (FSANZ) are satisfied that these MRLs are not harmful to public health. MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health by minimising residues in foods consistent with the effective control of pests and diseases.

The agreement between the Australian Government and the New Zealand Government concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

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:

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



# **Australian Government**

# Australian Pesticides and Veterinary Medicines Authority

# Australia New Zealand Food Standards Code—Schedule 20—Maximum residue limits Variation Instrument No. APVMA 7, 2018

I, Jason Lutze, 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*.

Jason Lutze

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

Dated this Twentieth day of September 2018

# 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 7, 2018.

# 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 19 of 25 September 2018.

# 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**

Swede Tomato

Turnip, garden

# 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: Metamitron	
Permitted residue: Metamitron	
Apple	0.01
Edible offal (Mammalian)	*0.05
Meat [mammalian]	*0.05
Milks	*0.05

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

T0.05

0.01 T0.05

	Agvet chemical: Emamectin  Permitted residue: Sum of emamectin B1a and emamectin B1b		
	Beetroot	T0.05	
	Egg plant	T0.1	
	Leafy vegetables [except lettuce, head;	T0.5	
	lettuce, leaf; mizuna]		
	Mizuna	T0.5	
	Parsnip	T0.05	
	Peppers, sweet	0.01	
	Podded pea (young pods) (snow and	T0.02	
	sugar snap)		
	Radish	T0.05	

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

AgVet chemical: Emamectin	
Permitted residue: Sum of emamectin B1a and emamectin B1b	
Fruiting vegetables, cucurbits	0.01
Fruiting vegetables, other than cucurbits [except mushrooms and sweet corn (corn-on-the-cob)]	0.1
Leafy vegetables [except lettuce, head and lettuce, leaf]	0.3
Legume vegetables	0.1
Root and tuber vegetables [except potato]	*0.01

Agvet chemical: Flumioxazin	
Permitted residue: Flumioxazin	
Carrot	T*0.05

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

# 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

Stone fruits [except cherries; plums] 1

# Agvet chemical: Emamectin

Permitted residue: Sum of emamectin B1a and emamectin B1b

0.05 Strawberry

# Etoxazole

Permitted residue: Etoxazole

Podded pea (young pods) (snow and T\*0.02 sugar snap)

# Agvet chemical: Propiconazole

Permitted residue: Propiconazole

Podded pea (young pods) (snow and T\*0.02 sugar snap)

Agvet chemical: Sedaxane	
Permitted residue: Sedaxane, sum of isome	ers
Podded pea (young pods) (snow and	T*0.02
sugar snap)	

# Di-Bak Parkinsonia Bioherbicide containing *Lasiodiplodia pseudotheobrom*ae, Neoscytalidium novaehollandiae, and Macrophomina phaseolina

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 Di-Bak Parkinsonia Bioherbicide (APVMA number 68348 / 58200)

# PARTICULARS OF THE APPLICATION

Proposed product name(s): Di-Bak Parkinsonia Bioherbicide

Applicant company: Bioherbicides Australia Pty Ltd

Name of active constituent: Lasiodiplodia pseudotheobromae, Neoscytalidium novaehollandiae, and

Macrophomina phaseolina

Signal heading: Schedule 0 (unscheduled)

Summary of proposed use: For the control of the woody weed Parkinsonia aculeata on grazing lands

**Pack sizes:** 100, 250, 500, 1000 or 5000 capsules

Withholding period: Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF DI-BAK PARKINSONIA BIOHERBICIDE 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 Di-Bak Parkinsonia Bioherbicide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety in the Department of Health and Ageing conducted a risk assessment on the product and concluded that it can be used safely. The three active constituents, belong to the family Botryosphaeriaceae are fungi isolated from plants afflicted with the naturally occurring disease known as Parkinsonia dieback. The product consists of sterile grain inoculated with the three active constituents, encased in a gelatine capsule. The concentration of each active constituent is 16 Colony Forming Unit (± 7%) per capsule. The product is to be inserted into a hole drilled in the stem of the parkinsonia tree and sealed to enhance infection while minimising exposure to end-users and the environment. The three active constituents are known to be native to and widely distributed throughout the Australian environment.

Noting the use of the product is in non-food producing situations, an ADI and ARfD have not been set for the active constituents. Based on the toxicological data evaluated the product is considered to have low pathogenic potential.

On 23 June 2016, the Delegate of the Secretary of the Department of Health published a decision listing the three active constituents *Lasiodiplodia pseudotheobromae*, *Neoscytalidium novaehollandiae*, and *Macrophomina phaseolina* in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons, with exemptions when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule. Therefore, the product Di-Bak Parkinsonia Bioherbicide is unscheduled and does not require control by scheduling.

The APVMA is satisfied that the use of Di-Bak Parkinsonia Bioherbicide will not be an undue health hazard to humans according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* 1994.

- (ii) The APVMA is satisfied that the proposed use of Di-Bak Parkinsonia Bioherbicide will not be an undue hazard to the safety of people using anything containing residues.
  - The proposed product is for exclusive use via stem insertion against the woody weed, *Parkinsonia aculeate*, in grazing lands of Australia. Consequently there are no residues or trade risks associated with its proposed use.
- (iii) The APVMA is satisfied that the proposed use of Di-Bak Parkinsonia Bioherbicide is not likely to be harmful to human beings when used according to label directions.
- (iv) The APVMA is satisfied that the proposed use of Di-Bak Parkinsonia Bioherbicide is not likely to have an unintended effect that is harmful to animals, plants or the environment when used according to label directions.

Environmental fate and effects studies, as well as relevant efficacy studies, were reviewed to assess the fate and behaviour of each fungal strain in the environment and their effects on non-target organisms. Particular consideration was given to environmental exposure relative to natural background levels.

All three organisms belong to a fungal family called the botryosphaeriaceae, the species and strains/isolates are native to Australian soils and are also found in soils throughout the world. Following insertion of the product as a capsule into tree trunks, the fungal species are not expected to enter the environment until the host tree has been colonised by one or more of the fungal species. Once colonization of the host plant occurs, the spread into the surrounding environment will be dependent on dispersal routes for each fungi. Botryosphaeriaceae fungi in woody hosts are predominately spread via horizontal transmission (i.e. spores). Their dispersal involves the physical movement of fungal spores produced in and around the tree. As trees die there is a succession of insects and other fungi that compete with fungal species for resources. Most of these fungi are basidiomycetes with the capacity to utilise cellulose and degrade lignin. These fungi out-compete ascomycetes (such as the botryosphaeriaceae fungi) and therefore, it is appropriate to assume that the poorly competitive botryosphaeriaceae fungi used in this product will be degraded by the more aggressive decomposer organisms.

It is expected that the three fungal species will be found in the soil after treatment. The fungi would grow from the inoculation site to the roots. There, the fungi would remain in situ in roots and be subject to attack by progressive wood decay fungi and bacteria. It is also generally considered that, although *M. phaseolina* may be able to survive considerable periods in soil as microsclerotia, it is a poor saprophytic competitor in terrestrial environments and will not proliferate without colonising a new host. It is likely that *L. pseudotheobromae* and *N. novaehollandiae* will also enter the soil through the root system of the infected parkinsonia plant. The fungi are expected to remain viable in the soil, as natural dieback infection is known to gradually spread through a stand of parkinsonia trees via root to root contact over several years. It is considered that accumulation of the species in soil would not be greater than that naturally found at treated sites.

No toxicity, infectivity or pathogenicity was observed in rats or mice following oral or intraperitoneal administration of the formulated product. No reports of adverse effects of these fungi to birds, fish, bees, non-target arthropods, invertebrates or soil macro-organisms such collembola, earthworms and nematodes were found in the literature. It is considered unlikely that the fungi would be able to proliferate/disseminate so much so that it enters into the aquatic environment (and survives in aquatic environment) in quantities large enough to effect aquatic species. The potential for the three fungal strains to cause infections (asymptotic or pathogenic) in non-target plants was also considered. Host range and specificity vary from broad 'host neutral' species to those limited to a single host genus. All three fungal species often act as latent pathogens, only becoming pathogenic under specific

environmental stress conditions. The disease front observed moving through affected parkinsonia populations suggests that plants may be infected from direct contact with other infected plants, or at the least from infected plants bearing spores within close proximity. Considering field observations the likelihood of infection is considered limited. In a field trial, the rate of infection movement through a parkinsonia population was 16 metres over 3 years. Field observations indicated that mortality was observed in parkinsonia trees, and not among the surrounding native vegetation. Natural dieback events in parkinsonia have been observed for more than 50 years in areas of Queensland and these events have been associated with botryosphaeriaceae fungi including L. pseudotheobromae.

The use of Di-Bak Parkinsonia Bioherbicide is intended to facilitate a natural dieback event. While this results in introducing the disease to areas previously unaffected, considering 50 years of field observations, risks to nontarget terrestrial plants would be considered no greater than areas where the disease occurs naturally. Nevertheless, to minimise exposure to known plants that are susceptible to disease caused by these fungal species, the applicant proposes that the product not be used within 500 metres of orchards or other agricultural crops or within 50 metres of stands of native tree species.

Based on available information, the APVMA is satisfied that the product is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (s5A(1)(c)), when used according to label directions.

- 2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
  - In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials (i) supporting the efficacy of the product adequately demonstrate that when used according to label directions, the product will be effective.

Review of efficacy information showed that parkinsonia trees inoculated with fungi developed the disease and deterioration in plant health was reported at 6 months, 12 months and by 18 months. Several studies monitored plant health out to 30 months after treatment. The fungi Lasiodiplodia pseudotheobromae, Macrophomina phaseolina and Neoscytalidium novaehollandiae present in the product are known to cause disease and in the trials presented, inoculated trees did develop disease.

The APVMA is satisfied that the product as a bio-herbicide will be effective as an aid for inducing dieback in the woody weed, P. aculeate.

- 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 Di-Bak Parkinsonia Bioherbicide would not adversely affect trade between Australia and places outside Australia as the product is not for use in food producing situations.

# **FURTHER INFORMATION**

# **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 Di-Bak Parkinsonia Bioherbicide 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)<sup>1</sup> 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

<sup>&</sup>lt;sup>1</sup> A full definition of 'confidential commercial information' is contained in the Agvet Code.

# New Agricultural Active Constituent Lasiodiplodia pseudotheobromae

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, *Lasiodiplodia pseudotheobromae*. *Lasiodiplodia pseudotheobromae* is an endophytic fungus that occurs on a variety of plant hosts causing dieback and canker diseases.

Common name: Lasiodiplodia pseudotheobromae

Scientific classification: Kingdom: fungi

Phylum: ascomycota
Class: dothideomycetes
Subclass: incertae sedis
Order: botryosphaeriales
Family: botryosphaeriaceae

Genus: lasiodiplodia

Species: lasiodiplodia pseudotheobromae

Mycological description: The organism is a thallus of fungal mycelium. In nature, lasiodiplodia

pseudotheobromae can exist as fungal mycelia generally within plant host material

producing conidia from pycnidia embedded in host plant material.

Etymology: Named for its resemblance to lasiodiplodia theobromae

# SUMMARY OF THE APVMA'S EVALUATION OF *LASIODIPLODIA PSEUDOTHEOBROMAE* ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of *Lasiodiplodia pseudotheobromae* active constituent (biological properties, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has completed a toxicological evaluation of Lasiodiplodia pseudotheobromae.

ADI and ARfD have not been established for the active constituent, noting the use of the product is in non-food producing situations.

Based on the toxicological evaluation on 23 June 2016, the Delegate of the Secretary of the Department of Health published a decision listing the active constituent *Lasiodiplodia pseudotheobromae* in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with exemptions when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule<sup>1</sup>.

It is not proposed to establish a standard for the active constituent Lasiodiplodia pseudotheobromae.

Other components of toxicological significance are not expected to occur in *Lasiodiplodia pseudotheobromae* technical active constituent.

<sup>&</sup>lt;sup>1</sup> It is noted that the use of CFU (colony-forming units) in this context refers to the number of inoculated millet seeds per capsule, and does not relate to the general use of the term 'colony-forming units' in microbiology, which refers to the number of viable cells that can grow a colony.

The APVMA is satisfied that there are no objections on human health grounds to the approval of the active constituent *Lasiodiplodia pseudotheobromae*.

# **MAKING A SUBMISSION**

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

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

When making a submission please include:

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

All personal and confidential commercial information (CCI)<sup>2</sup> material contained in submissions will be treated confidentially.

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

<sup>&</sup>lt;sup>2</sup> A full definition of 'confidential commercial information' is contained in the Agvet Code.

# New Agricultural Active Constituent Neoscytalidium novaehollandiae

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, *Neoscytalidium novaehollandiae*. *Neoscytalidium novaehollandiae* is an endophytic fungus that occurs on a variety of plant hosts causing dieback and canker diseases.

Common name: Neoscytalidium novaehollandiae

Scientific classification: Kingdom: fungi

Phylum: ascomycota
Class: dothideomycetes
Subclass: incertae sedis
Order: botryosphaeriales
Family: botryosphaeriaceae

Genus: neoscytalidium

Species: neoscytalidium novaehollandiae

**Mycological description:** The organism is a thallus of an asexual fungal mycelium containing arthrospores. In

nature, *Neoscytalidium novaehollandiae* can exist as fungal mycelia generally within plant host material producing conidia from pycnidial embedded in host plant material. Colonies are initially white to olivaceous-buff, becoming greenish-olivaceous to citrine from the middle of colonies within 7 days, and black (surface and beneath) with age,

with suppressed, moderately fluffy mycelium, and smooth edges.

# SUMMARY OF THE APVMA'S EVALUATION OF NEOSCYTALIDIUM NOVAEHOLLANDIAE ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of *Neoscytalidium novaehollandiae* active constituent (biological properties, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has completed a toxicological evaluation of Neoscytalidium novaehollandiae.

ADI and ARfD have not been established for the active constituent, noting the use of the product is in non-food producing situations.

Based on the toxicological evaluation on 23 June 2016, the Delegate of the Secretary of the Department of Health published a decision listing the active constituent *Neoscytalidium novaehollandiae* in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), except when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule<sup>1</sup>.

It is not proposed to establish a standard for active constituent Neoscytalidium novaehollandiae.

Other components of toxicological significance are not expected to occur in *Neoscytalidium novaehollandiae* technical active constituent.

<sup>&</sup>lt;sup>1</sup> It is noted that the use of CFU (colony-forming units) in this context refers to the number of inoculated millet seeds per capsule, and does not relate to the general use of the term 'colony-forming units' in microbiology, which refers to the number of viable cells that can grow a colony.

The APVMA is satisfied that there are no objections on human health grounds to the approval of the active constituent Neoscytalidium novaehollandiae.

# **MAKING A SUBMISSION**

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

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

When making a submission please include:

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

All personal and confidential commercial information (CCI)<sup>2</sup> material contained in submissions will be treated confidentially.

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

<sup>&</sup>lt;sup>2</sup> A full definition of 'confidential commercial information' is contained in the Agvet Code.

# New Agricultural Active Constituent Macrophomina phaseolina

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, *Macrophomina phaseolina*. *Macrophomina phaseolina* is an endophytic fungus that occurs on a variety of plant hosts causing dieback and canker diseases.

Common name: Macrophomina phaseolina

Scientific classification: Kingdom: fungi

Phylum: ascomycota
Class: dothideomycetes
Subclass: incertae sedis
Order: botryosphaeriales
Family: botryosphaeriaceae
Genus: macrophomina

Species: macrophomina phaseolina

**Mycological description:** The organism is a soil-borne anamorphic fungus with an optimum temperature for

growth around 33°C. It is typified by the production of dark, smooth, almost spherical microsclerotia and the lack of any conidiomata in culture. The sexual stage is unknown. In culture, different isolates can appear very different, differing in colony colour (greyish-white, blackish-grey, deep black and white), mycelial growth characteristics (copious and fluffy or limited and appressed), growth rate, media

preferences and size and number of microsclerotia.

# SUMMARY OF THE APVMA'S EVALUATION OF MACROPHOMINA PHASEOLINA ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of *Macrophomina phaseolina* active constituent (biological properties, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has completed a toxicological evaluation of Macrophomina phaseolina.

ADI and ARfD have not been established for the active constituent, noting the use of the product is in non-food producing situations.

Based on the toxicological evaluation on 23 June 2016, the Delegate of the Secretary of the Department of Health published a decision listing the active *Macrophomina phaseolina* in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), except when used as a herbicide in capsule preparations at a concentration of 16 CFU or less per capsule<sup>1</sup>.

It is not proposed to establish a standard for active constituent Macrophomina phaseolina.

<sup>&</sup>lt;sup>1</sup> It is noted that the use of CFU (colony-forming units) in this context refers to the number of inoculated millet seeds per capsule, and does not relate to the general use of the term 'colony-forming units' in microbiology, which refers to the number of viable cells that can grow a colony.

Other components of toxicological significance are not expected to occur in *Macrophomina phaseolina* technical active constituent.

The APVMA is satisfied that there are no objections on human health grounds to the approval of the active constituent *Macrophomina phaseolina*.

# **MAKING A SUBMISSION**

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

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

When making a submission please include:

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

All personal and confidential commercial information (CCI)<sup>2</sup> material contained in submissions will be treated confidentially.

Submissions should be addressed in writing to:

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<sup>&</sup>lt;sup>2</sup> A full definition of 'confidential commercial information' is contained in the Agvet Code.