

# Commonwealth of Australia

## Gazette

Agricultural and Veterinary Chemicals

No. APVMA 23, Tuesday, 17 November 2020

Published by the Australian Pesticides and Veterinary Medicines Authority



### **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.

© Commonwealth of Australia 2020

This work is copyright. Apart from any use as permitted under the Copyright Act 1968, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority. Requests and

inquiries concerning reproduction and rights should be addressed to:

Assistant Director, Communications

Australian Pesticides and Veterinary Medicines Authority

**GPO Box 3262** 

Sydney NSW 2001

Email: communications@apvma.gov.au

Website: apvma.gov.au

**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.

If you would like to subscribe to receive email notification when a new edition is published, please complete the subscription form.

**APVMA CONTACTS** 

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on the APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

#### **CONTENTS**

Agricultural Chemical Products and Approved Labels	4
Veterinary Chemical Products and Approved Labels	. 12
Approved Active Constituents	15
Amendments to the APVMA MRL Standard	17
Proposal to amend Schedule 20 in the Australia New Zealand Food Standards Code	18
Variations to Schedule 20 of the Australia New Zealand Food Standards Code	23

#### **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.: 126013

Product name: Apparent Atrazine 500 Flowable Herbicide

Active constituent/s: 500 g/L atrazine
Applicant name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574

Summary of use: For control of selected weeds in crops, Pinus radiata plantations and TT-canola

Date of registration: 26 October 2020

Product registration no.: 89758

**Label approval no.:** 89758/126013

Application no.: 127102

Product name: Apparent Alpha Omega 300 SC Insecticide

Active constituent/s: 300 g/L alpha-cypermethrin

Applicant name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574

Summary of use: For control of certain insect pests, including redlegged earth mite and blue oat mite in field crops

and pastures, fruit and vegetable crops

Date of registration: 26 October 2020

Product registration no.: 90030

**Label approval no.:** 90030/127102

Application no.: 127169

**Product name:** Titan Hexazinone 750 SG Herbicide

Active constituent/s: 750 g/kg hexazinone
Applicant name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574

Summary of use: For the control of certain sedges, perennial grasses, broadleaf and woody weeds in *Pinus radiata* 

forests, and industrial weed control situations

Date of registration: 29 October 2020

Product registration no.: 90042

**Label approval no.:** 90042/127169

Application no.: 127159

Product name: Choice Di Met 400 Insecticide

Active constituent/s: 400 g/L dimethoate (an anti-cholinesterase compound)

Applicant name: Grow Choice Pty Ltd

**Applicant ACN:** 161 264 884

Summary of use: For the control of a wide range of insect pests on pastures, cotton, lucerne, peanuts, peas and

ornamentals

Date of registration: 29 October 2020

Product registration no.: 90037

**Label approval no.:** 90037/127159

Product name: NAADCO MCPE LVE 570 Herbicide

Active constituent/s: 570 g/L MCPA present as the 2-ethylhexyl ester

Applicant name: New Australia Agricultural Development Company Pty Ltd

**Applicant ACN:** 138 055 553

Summary of use: For control of certain weeds in agricultural crops

Date of registration: 29 October 2020

Product registration no.: 90034

**Label approval no.:** 90034/127119

Application no.: 126628

Product name: Gro-Sure Spray Adjuvant

Active constituent/s: 704 g/L methyl and ethyl esters of free fatty acids derived from refined canola oil

Applicant name: Agritrading Pty Ltd
Applicant ACN: 134 291 295

Summary of use: For enhancing the effectiveness of certain herbicides

Date of registration: 30 October 2020

Product registration no.: 89976

Label approval no.: 89976/126628

Application no.: 127204

Product name: Green Diamond Dust Mite Killer

Active constituent/s: 150 g/kg eucalyptus oil

Applicant name: New Generation Aerosols Pty Ltd

**Applicant ACN:** 120 403 107

Summary of use: For the treatment of dust mites in rugs, pillows, bedding, curtains, couches and pet areas

Date of registration: 30 October 2020

Product registration no.: 90050

**Label approval no.:** 90050/127204

Application no.: 127758

Product name:

Active constituent/s:

Applicant name:

Glean Herbicide

750 g/kg chlorsulfuron

FMC Australasia Pty Ltd

**Applicant ACN:** 095 326 891

Summary of use: For control of annual (Wimmera) ryegrass and certain broadleaf weeds in winter cereal crops

**Date of registration:** 3 November 2020

Product registration no.: 90141

**Label approval no.:** 90141/127758

Application no.: 121600

Product name: MacPhersons KOMACHI Activator Herbicide

Active constituent/s: 80 g/L aminopyralid present as the tri-isopropanolamine salt

Applicant name: TGAC Australia Pty Ltd

**Applicant ACN:** 134 570 700

Summary of use: For the control of Eucalyptus spp. when mixed with a triclopyr and picloram herbicide

Date of registration: 4 November 2020

Product registration no.: 88528

**Label approval no.:** 88528/121600

#### 2. VARIATIONS OF REGISTRATION

Application no.: 128282

Product name: Eco-NemGuard

Active constituent/s: 1,280 g/L garlic extract containing a minimum 26 g/L total polysulfides

Applicant name: Hurlvess Pty Ltd t/a Organic Crop Protectants Pty Ltd

**Applicant ACN:** 003 149 719

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

'ECOguard Nematicide' to 'Eco-NemGuard'

Date of variation: 16 October 2020

Product registration no.: 88489

**Label approval no.:** 88489/128282

Application no.: 128329

Product name: Phostoxin Fumigation Blanket

Active constituent: 330 g/kg phosphine (ph3) present as aluminium phosphide

Applicant name: Detia Degesch GMBH

Applicant ACN: N/A

Summary of variation: To vary the distinguishing product name and the name that appears on the label from 'Detia Gas Ex

B Fumigation Blankets' to 'Phostoxin Fumigation Blanket'

Date of variation: 20 October 2020

Product registration no.: 63587

Label approval no.: 63587/128329

Application no.: 128363

Product name: Relyon Imazapyr 750 SG Herbicide

Active constituent/s: 750 g/kg imazapyr

Applicant name: Nutrien Ag Solutions Limited

**Applicant ACN:** 008 743 217

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

750SG Herbicide' to 'Relyon Imazapyr 750 SG Herbicide'

Date of variation: 21 October 2020

Product registration no.: 84768

Label approval no.: 84768/128363

Application no.: 128389

Product name: Relyon Chlorsulfuron 750 WG Herbicide

Active constituent/s: 750 g/kg chlorsulfuron
Applicant name: Nutrien Ag Solutions Limited

Applicant ACN: 008 743 217

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

750WG Herbicide' to 'Relyon Chlorsulfuron 750 WG Herbicide'

Date of variation: 22 October 2020

Product registration no.: 82041

Label approval no.: 82041/128389

Product name: Relyon Indoxacarb 300 WG Insecticide

Active constituent/s: 300 g/kg indoxacarb

Applicant name: Nutrien Ag Solutions Limited

**Applicant ACN:** 008 743 217

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

300WG Insecticide' to 'Relyon Indoxacarb 300 WG Insecticide'

Date of variation: 23 October 2020

Product registration no.: 83916

**Label approval no.:** 83916/128388

Application no.: 125840

Product name: Surefire Chlorantraniliprole 350 WG Insecticide

Active constituent/s: 350 g/kg chlorantraniliprole
Applicant name: PCT Holdings Pty Ltd

**Applicant ACN:** 099 023 962

**Summary of variation:** To add uses in certain pome fruit, stone fruit and grapevine crops

Date of variation: 26 October 2020

Product registration no.: 88598

**Label approval no.:** 88598/125840

Application no.: 125987

Product name: Sprayphos 620 Systemic Fungicide

Active constituent/s: 620 g/L phosphorus (phosphonic) acid present as mono and di potassium phosphite

Applicant name: Foliar Fertilizers Pty Ltd

**Applicant ACN:** 007 974 496

Summary of variation: For control of phytophthora in almond, macadamia, walnut and chestnuts

Date of variation: 26 October 2020

Product registration no.: 59052

**Label approval no.:** 59052/125987

Application no.: 125916

Product name: Enviroweeder

Active constituent/s: 244 g/L sodium chloride

Applicant name: Nontox Pty Ltd
Applicant ACN: 614 054 054

Summary of variation: To update safety directions and first aid instructions

**Date of variation:** 26 October 2020

Product registration no.: 82955

**Label approval no.:** 82955/125916

Product name: Accensi Simazine 900 WG Herbicide Active constituent/s: 900 g/kg simazine and related triazines

Applicant name: Accensi Pty Ltd **Applicant ACN:** 079 875 184

Summary of variation: To add the following uses: broadleaf weeds and grasses in almonds, various pests in pyrethrum

crops, weed control in walnuts, specified grass and broadleaf weeds in leeks, various pests and diseases in tea tree oil, broadleaf and grass weeds in ginger (Zingiber officinale), weed and sucker control in hazel nuts, various weeds in nursery stock (non-food), foliage, cut flowers and

wildflowers

Date of variation: 26 October 2020

55138 Product registration no.:

Label approval no.: 55138/127174

Application no.:

Product name: Kenso Agcare Metoken Gold Herbicide

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

Applicant name: Kenso Corporation (m) Sdn Bhd

Applicant ACN:

Summary of variation: To add the following use instructions for the control of various weeds in rhubarb, various

broadleaf and grass weeds in brassica leafy vegetables, multiple pests in mustard, various broadleaf and grass weeds in spinach, silverbeet, spring onions, shallots, green beans and navy

beans and various weeds in culinary herbs

26 October 2020 Date of variation:

Product registration no.: 68625

Label approval no.: 68625/127089

Application no.:

Product name: Laguna 430 Fungicide Active constituent/s: 430 g/L tebuconazole

Applicant name: Sipcam Pacific Australia Pty Ltd

**Applicant ACN:** 073 176 888

Summary of variation: To add uses in Duboisia, oil tea tree, anise myrtle, lemon myrtle, non-food producing plants and

vegetation, beetroot, beetroot leaves, chicory, endive, radish, silverbeet, spinach, carrots, mung

beans, faba beans, broad beans, soya beans, walnuts and garlic

Date of variation: 27 October 2020

Product registration no.: 59420

Label approval no.: 59420/127088

Application no.: 126068

Product name: Family Protection Aerogard Body Odourless Protection 6 Hours Protection Low Irritant\* Great For

Kids 12 Months+ Insect Repellent

Active constituent/s: 95 g/kg picaridin

Applicant name: RB (Hygiene Home) Australia Pty Ltd

**Applicant ACN:** 629 549 506

Summary of variation: To extend the protection period, vary the net contents, and amend the product name

Date of variation: 27 October 2020

Product registration no.: 61364

Label approval no.: 61364/126068

Product name: Campbell Magnate 750WG Fungicide
Active constituent/s: 750 g/kg imazalil present as the sulphate
Colin Campbell (Chemicals) Pty Ltd

**Applicant ACN:** 000 045 590

**Summary of variation:** To add use in mushroom to control green mould

Date of variation: 28 October 2020

Product registration no.: 52223

**Label approval no.:** 52223/127084

Application no.: 124103

Product name: Ozcrop Cyprofludox WG Fungicide
Active constituent/s: 375 g/kg cyprodinil, 250 g/kg fludioxonil

Applicant name: Ozcrop Pty Ltd
Applicant ACN: 160 656 431

Summary of variation: To include new crops and pests and to include those listed in the permit to label project

Date of variation: 28 October 2020

Product registration no.: 83349

Label approval no.: 83349/124103

Application no.: 127113

Product name: Sipcam Pacific Australia Pty Ltd

Active constituent/s: 25 g/L pyraflufen-ethyl

Applicant name: Sipcam Pacific Australia Pty Ltd

**Applicant ACN:** 073 176 888

Summary of variation: To add the cotton claim for defoliation and acceleration of boll opening when mixed with

thidiazuron and ethephon and either D-C-Tron Cotton or Hasten or Canopy Insecticide

Date of variation: 30 October 2020

Product registration no.: 83053

Label approval no.: 83053/127113

Application no.: 126585

Product name: Nufarm Pulse Penetrant

Active constituent/s: 1,000 g/L modified polydimethylsiloxane

Applicant name: Nufarm Australia Limited

**Applicant ACN:** 004 377 780

**Summary of variation:** To cross-label with numerous registered products

Date of variation: 2 November 2020

Product registration no.: 57279

**Label approval no.:** 57279/126585

Application no.: 127182

Product name: Imtrade Delta-Duo Insecticide

Active constituent/s: 27.5 g/L deltamethrin

Applicant name: Imtrade Australia Pty Ltd

**Applicant ACN:** 090 151 134

Summary of variation: To add control of bark eating weevil in oil tea tree

Date of variation: 3 November 2020

Product registration no.: 53118

**Label approval no.:** 53118/127182

Product name: Sipcam Simazine 900WDG Herbicide

Active constituent/s: 900 g/kg simazine

Applicant name: Sipcam Pacific Australia Pty Ltd

**Applicant ACN:** 073 176 888

Summary of variation: To add the following use instructions: broadleaf weeds and grasses in almonds, various pests in

pyrethrum crops, weed control in walnuts, specified grass and broadleaf weeds in leeks, various pests in tea tree oil, broadleaf and grass weeds in ginger (Zingiber officinale), weed and sucker control in hazel nuts, various weeds in nursery stock (non-food), foliage, cut flowers and

wildflowers

Date of variation: 3 November 2020

Product registration no.: 52710

**Label approval no.:** 52710/127194

Application no.: 127178

Product name: Choice Cure 430 Fungicide
Active constituent/s: 430 g/L tebuconazole
Applicant name: Grow Choice Pty Ltd

**Applicant ACN:** 161 264 884

Summary of variation: To add uses in Duboisia, oil tea tree, anise myrtle, lemon myrtle, non-food producing plants and

vegetation, beetroot, beetroot leaves, chicory, endive, radish, silverbeet, spinach, carrots, mung

beans, faba beans, broad beans, soya beans, walnuts and garlic

Date of variation: 3 November 2020

Product registration no.: 80627

**Label approval no.:** 80627/127178

Application no.: 127269

Product name: Barmac Tri-Max 480 Herbicide

Active constituent/s: 480 g/L trifluralin
Applicant name: Amgrow Pty Ltd
Applicant ACN: 100 684 786

Summary of variation: To add the uses for various broadleaf and grass weeds in chillies, paprika and eggplant, multiple

pests in mustard, winter grass in parsnips, pests and diseases and Cercospora leaf spot in Duboisia, weeds in swedes and turnips, selected grass weeds in quinoa, various pests and

diseases in tea tree oil and weeds in Industrial hemp

Date of variation: 4 November 2020

Product registration no.: 88601

**Label approval no.:** 88601/127269

Application no.: 127183

Product name: Chemag Sharp Shooter 500 SC

Active constituent/s: 500 g/L oryzalin

Applicant name: Imtrade Australia Pty Ltd

**Applicant ACN:** 090 151 134

Summary of variation: To add uses for broadleaf and grass weeds in ginger and Duboisia

Date of variation: 4 November 2020

Product registration no.: 60041

**Label approval no.:** 60041/127183

Product name: AC Fearsome 500 Fungicide

Active constituent/s: 500 g/L flutriafol
Applicant name: Axichem Pty Ltd
Applicant ACN: 131 628 594

Summary of variation: To add uses for the control of sugarcane smut and pineapple disease in sugarcane planting

material

Date of variation: 5 November 2020

Product registration no.: 68744

Label approval no.: 68744/125094

#### 3. LABEL APPROVAL

Application no.: 127305

Product name: Rid Australia Medicated Rid Insect Repellent Tropical Strength + Antiseptic Spray 6 Hours

Mosquito Protection Neutral Scent Protection Against Mosquitoes That May Carry Ross River

Virus & Dengue

Active constituent/s: 191 g/kg N,N-diethly-M-toluamide, 40 g/kg N-octyl bicycloheptene dicarboximide, 1 g/kg triclosan

Applicant name: Cavalieri Investing Pty Ltd

**Applicant ACN:** 162 722 625

Summary of variation: To approve a new label for the product 'Rid Australia Medicated Rid Insect Repellent Tropical

Strength + Antiseptic Spray 6 Hours Mosquito Protection Neutral Scent' with the label name 'Rid Australia Rid Outdoors Insect Repellent Spray Tropical Strength Protection for up to 6 Hours

Repels Against Mosquitoes, Flies, Sandflies, Ticks, Leaches, Fleas, Biting Midge'

Date of variation: 28 October 2020

Product registration no.: 53407

**Label approval no.:** 53407/127305

Application no.: 127304

Product name: Rid Australia Medicated Rid Insect Repellent Tropical Strength + Antiseptic Spray 6 Hours

Mosquito Protection Neutral Scent Protection Against Mosquitoes That May Carry Ross River

Virus & Dengue

Active constituent/s: 191 g/kg N,N-diethly-M-toluamide, 40 g/kg N-octyl bicycloheptene dicarboximide, 1 g/kg triclosan

Applicant name: Cavalieri Investing Pty Ltd

**Applicant ACN:** 162 722 625

Summary of variation: To approve a new label for the product 'Rid Australia Medicated Rid Insect Repellent Tropical

Strength + Antiseptic Spray 6 Hours Mosquito Protection Neutral Scent' with the label name 'Rid Australia Medicated Rid Insect Repellent Workforce Strength + Antiseptic 6 Hours Mosquito

Protection Neutral Scent'

Date of variation: 28 October 2020

Product registration no.: 53407

Label approval no.: 53407/127304

#### 4. VARIATION OF LABEL APPROVAL

Application no.: 128223

Product name: Hy-Clor Long Life Algaecide

Active constituent/s: 40 g/L copper (Cu) present as a cupric ammonium complex

Applicant name: Hy-Clor (Australia) Pty Ltd

**Applicant ACN:** 000 655 381

Summary of variation: To vary the name that appears on the label from 'Swim ABC Long Life Algaecide' to 'Swim Eze

Long Life Algaecide'

Date of variation: 15 October 2020

Product registration no.: 59579

Label approval no.: 59579/128223

#### **Veterinary Chemical Products and Approved Labels**

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

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

Application no.: 125845

Product name: Aleve Injection For Cattle And Pigs

Active constituent/s: 20 mg/mL meloxicam

Applicant name: Probus Pharmaceuticals Pty Ltd

**Applicant ACN:** 638 193 674

Summary of use: For inflammation and pain management in cattle and pigs

Date of registration: 26 October 2020

Product registration no.: 89704

**Label approval no.:** 89704/125845

Application no.: 126006

Product name: Aleve Oral Solution For Dogs

Active constituent/s: 1.5 mg/mL meloxicam

Applicant name: Probus Pharmaceuticals Pty Ltd

**Applicant ACN:** 638 193 674

Summary of use: For alleviation of inflammation and pain in both acute and chronic musculoskeletal disorders in

agob

Date of registration: 28 October 2020

Product registration no.: 89754

**Label approval no.:** 89754/126006

Application no.: 125470

Product name: Sed8 Aquatic Anaesthetic

Active constituent/s: 540 g/L isoeugenol (2-Methoxy-4-propenylphenol)

Applicant name: Aquatic Diagnostic Services International Pty Ltd

**Applicant ACN:** 067 814 466

Summary of use: For use as sedation/anaesthesia of salmonids in routine husbandry operations

Date of registration: 2 November 2020

Product registration no.: 89630

**Label approval no.:** 89630/125470

Application no.: 127090

Product name: Jurox Triple Drench

Active constituent/s: 40 g/L levamisole hydrochloride, 25 g/L albendazole, 1 g/L moxidectin

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

**Summary of use:** For the treatment and control of sensitive strains of gastrointestinal nematodes (roundworms),

including nematodes that have single, dual or triple resistance to macrocyclic lactones (including

abamectin resistant strains), benzimidazoles, imidazothiazoles (levamisole/morantel) or

monepantel

Date of registration: 4 November 2020

Product registration no.: 90020

**Label approval no.:** 90020/127090

Product name: Respotil 300mg/mL Tilmicosin Phosphate Solution For Injection

Active constituent/s: 300 mg/mL tilmicosin as tilmicosin phosphate

Applicant name: Probus Pharmaceuticals Pty Ltd

**Applicant ACN:** 638 193 674

Summary of use: For the treatment of Bovine Respiratory Disease (BRD) associated with Mannheimia haemolytica,

Pasteurella multocida and other organisms susceptible to tilmicosin

Date of registration: 4 November 2020

Product registration no.:

Label approval no.: 89712/125867

Application no.: 127317

Product name: Malabac Duo Medicated Shampoo

Active constituent/s: 20 g/L chlorhexidine gluconate, 20 g/L miconazole nitrate

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

Summary of use: For use in dogs and cats as a topical medicated shampoo against chlorhexidine-sensitive and

miconazole-sensitive bacteria, fungi and yeast

Date of registration: 4 November 2020

Product registration no.: 90081

Label approval no.: 90081/127317

#### 2. **VARIATIONS OF REGISTRATION**

Application no.: 125764

Product name: Ilium Temvet Injection

Active constituent/s: 300 ug/mL buprenorphine as buprenorphine hydrochloride

Applicant name: Troy Laboratories Pty Ltd

**Applicant ACN:** 000 283 769

Summary of variation: To extend product use to include horses

Date of variation: 30 October 2020

67612 Product registration no.:

67612/125764 Label approval no.:

#### **VARIATION OF LABEL APPROVAL**

Application no.: 127020

Product name: Panapex Ointment

Active constituent/s: 100,000 units/mL nystatin, 2,500 units/mL thiostrepton, 2.5 mg/mL neomycin as sulfate,

1 mg/mL triamcinolone acetonide

Applicant name: Dechra Veterinary Products (Australia) Pty Ltd

**Applicant ACN:** 

Summary of variation: To update instructions for use and user safety information

29 October 2020 Date of variation:

Product registration no.: 85780

Label approval no.: 85780/127020

Product name: Purina Totalcare Flea Control Kills Fleas (Ctenocephalides Spp) Shampoo For Dogs

Active constituent/s: 10 g/L piperonyl butoxide, 8 g/L melaleuca oil, 2 g/L permethrin (25:75)

Applicant name: Nestle Purina Petcare a Div of Nestle Australia Ltd

**Applicant ACN:** 000 011 316

**Summary of variation:** To update first aid instructions

**Date of variation:** 30 October 2020

Product registration no.: 61403

**Label approval no.:** 124257/61403

Application no.: 127044

Product name: Clompoze 80 Tablets

Active constituent/s: 80 mg/tb clomipramine hydrochloride equivalent to 72 mg clomipramine

Applicant name: Dechra Veterinary Products (Australia) Pty Ltd

**Applicant ACN:** 614 716 700

**Summary of variation:** To vary the dosing instructions and claim

Date of variation: 30 October 2020

Product registration no.: 86509

Label approval no.: 86509/127044

#### **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.: 123572

Active constituent/s: Pyroxasulfone

Applicant name: Max (Rudong) Chemicals Co Ltd

Applicant ACN: N/A

Summary of use: For use in agricultural chemical products

Date of approval: 26 October 2020

Approval no.: 89095

Application no.: 125080
Active constituent/s: Ivermectin

Applicant name: The Hunter River Company Pty Ltd

**Applicant ACN:** 133 798 615

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

Date of approval: 27 October 2020

Approval no.: 89500

Application no.: 124822
Active constituent/s: Trifloxystrobin

Applicant name: Zhejiang Zhongshan Chemical Industry Group Co Ltd

Applicant ACN: N/A

Summary of use: For use in agricultural chemical products

Date of approval: 28 October 2020

Approval no.: 89424

Application no.: 124791

Active constituent/s: Lambda-cyhalothrin

Applicant name: Jiangsu ChunJiangRunTian Agrochemical Co Ltd

Applicant ACN: N/A

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

Date of approval: 29 October 2020

Approval no.: 89420

Application no.: 123127
Active constituent/s: Pyraclostrobin

Applicant name: Sabero Australia Pty Ltd

**Applicant ACN:** 087 313 059

Summary of use: For use in agricultural chemical products

Date of approval: 29 October 2020

Approval no.: 89000

Active constituent/s: Zinc phosphide

Applicant name: Animal Control Technologies (Australia) Pty Ltd

**Applicant ACN:** 137 868 449

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

Date of approval: 30 October 2020

Approval no.: 90282

Application no.: 125312
Active constituent/s: Sulfadoxine

Applicant name: Randlab Australia Pty Ltd

**Applicant ACN:** 114 948 837

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

Date of approval: 2 November 2020

Approval no.: 89577

Application no.: 125771
Active constituent/s: Meloxicam

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 2 November 2020

Approval no.: 89680

Application no.: 124839

Active constituent/s: Paraquat dichloride manufacturing concentrate
Applicant name: Hebei Shanli Chemical Company Limited

Applicant ACN: N/A

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

Date of approval: 4 November 2020

Approval no.: 89426

Application no.: 125888

Active constituent/s: Miconazole nitrate
Applicant name: Avet Health Pty Ltd

**Applicant ACN:** 616 838 101

Summary of use: For use in veterinary chemical products

Date of approval: 4 November 2020

Approval no.: 89719

#### 2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.: 125362

Active constituent/s: Terbinafine hydrochloride
Applicant name: Elanco Australasia Pty Ltd

**Applicant ACN:** 076 745 198

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

Date of variation: 3 November 2020

Approval no.: 87388

#### Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019. The MRL Standard lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The MRL Standard also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the MRL Standard and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 9) 2020

The amendments will be incorporated into the compilation of the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019.

The MRL Standard is accessible via the Federal Register of Legislation website.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2401

Email: enquiries@apvma.gov.au

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

In the previous notice on page 17 of APVMA Gazette No. 23, the APVMA gazetted amendments which it has approved to vary maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's MRL Standard.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 9) 2020) to MRLs into Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

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

A Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) will be made.

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.

#### PROPOSED VARIATION TO SCHEDULE 20 IN THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

(17 November 2020)

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunsetting.

#### To commence: on gazettal of variation

#### [1] The table to section S20 – 3 in Schedule 20 is varied by

#### [1.1] inserting in alphabetical order

#### Agvet chemical: tiafenacil

Permitted residue – commodities of plant origin: tiafenacil

Permitted residue – sum of tiafenacil and 3-(2-(2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-2,3-dihydropyrimidin-1(6H)-yl) phenylthio)propanamido)propanoic acid (M-01), expressed as tiafenacil

Cereal grains \*0.01 Cotton seed \*0.01 Edible offal (mammalian) \*0.02 \*0.02 Eggs Meat (mammalian) \*0.02 Milks \*0.02 Poultry meat \*0.02 Poultry, edible offal of \*0.02 Pulses \*0.01

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

\*0.01

#### Agvet chemical: acequinocyl

Rape seed (canola)

Permitted residue – sum of acequinocyl and its metabolite 2-dodecyl-3-hydroxy-1,4-naphthoquinone, expressed as acequinocyl

Cherries 0.5

#### Agvet chemical: fludioxonil

Permitted residue – commodities of animal origin: sum of fludioxonil and oxidisable metabolites, expressed as fludioxonil

•	
Bayberries	T2
Blackberries	5
Blueberries	Т3
Boysenberry	5
Cloudberry	T2
Currants, black, red, white	2
Dewberries (including boysenberry and loganberry) [except boysenberry]	T2
Raspberries, red, black	5

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

Agvet chemical: acequinocyl	
Permitted residue – sum of acequinocyl and its	

metabolite 2-dodecyl-3-hydroxy-1,4naphthoquinone, expressed as acequinocyl

	-
Apricots, dried	1
Edible offal (mammalian)	*0.02
Meat (mammalian) (in the fat)	*0.02
Milks	*0.02
Peach, dried	1
Pome fruits	0.7
Prunes	1
Stone fruits	0.7

#### Agvet chemical: azoxystrobin

Permitted residue - azoxystrobin

remilled residue – azoxysirobin	
Bayberries	T5
Bayberry, red	T5

#### Agvet chemical: fludioxonil

Permitted residue – commodities of animal origin: sum of fludioxonil and oxidisable metabolites, expressed as fludioxonil

Berries and other small fruits [except	5
grapes]	
Dried grapes (currants, raisins and	5
sultanas)	

# Agvet chemical: forchlorfenuron Permitted residue – forchlorfenuron Apple \*0.01 Cherries \*0.01

#### Agvet chemical: propachlor

Permitted residue – sum of propachlor and metabolites hydrolysable to N-isopropylaniline, expressed as propachlor

All other foods except animal food	0.05
commodities	
Garlic	2.5

Agvet chemical: pydiflumetofen	
Permitted residue – pydiflumetofen	
Berries and other small fruits [except grapes; strawberry]	3
Strawberry	2

Agvet chemical: ractopamine	
Permitted residue – ractopamine	
Turkey kidney	0.3
Turkey liver	0.3
Turkey meat	0.02
Turkey fat/skin	0.05

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

Agvet chemical: captan	
Permitted residue – captan	
Lettuce, leaf	T15

#### Agvet chemical: fludioxonil

Permitted residue – commodities of animal origin: sum of fludioxonil and oxidisable metabolites, expressed as fludioxonil

Leafy vegetables	15
------------------	----

Agvet chemical: pydiflumetofen	
Permitted residue – pydiflumetofen	
All other foods except animal food commodities	0.05
Brassica leafy vegetables	15
Dried grapes (currants, raisins and sultanas)	5
Grapes	2

#### **INVITATION FOR SUBMISSIONS**

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code. Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

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

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

#### DEADLINE FOR PUBLIC SUBMISSIONS: 6 PM (AEST) 15 DECEMBER 2020

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

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

**Please note**: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the <u>public consultation coversheet</u>).

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

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

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2401

Email: enquiries@apvma.gov.au

#### Variations to Schedule 20 of the Australia New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA MRL Standard and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Schedule 20 – Maximum Residue Limits of the Australia New Zealand Food Standards Code. This notice pertains to proposals (No. 6) gazetted on 11 August 2020 (No. APVMA 16).

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 8, 2020) 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 <u>Legislation website</u>.

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.

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

A copy of these variations have been given to FSANZ.

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

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

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

**Phone:** +61 2 6770 2383

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 8, 2020

I, Jason Lutze, 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 Tenth day of November 2020

#### 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 8, 2020 (Amendment Instrument).

#### 2 Commencement

In accordance with subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this instrument commences on the day it is published in the Gazette.

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia Agricultural and Veterinary Chemicals Gazette.

#### 3 Object

The object of this instrument is for the APVMA to make variations to Schedule 20–Maximum residue limits in the Australia New Zealand Food Standards Code to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

#### 4 Interpretation

In this instrument: –

**APVMA** means the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and

**Principal Instrument** means Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standard Code as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the Code published in Gazette No. P 27 on 27 August 1987 together with any amendments of the standards in that Code. Schedule 20 was published in the Food Standards Gazette FSC 96 on Thursday 10 April 2015 and was registered as a legislative instrument on 1 April 2015 (F2015L00468).

## Part 2 Variations to Schedule 20 – Maximum Residue Limits

#### 5 Variations to Schedule 20

The Schedule to this instrument sets out the variations made to the Principal Instrument by this instrument.

#### **Schedule**

#### Variations to Schedule 20 - Maximum residue limits

- [1] The table to section S20 3 in Schedule 20 is varied by
- [1.1] omitting the chemical residue definition for isofetamid and substituting the following

Permitted residue – commodities of plant origin: isofetamid

Permitted residue – commodities of animal origin: sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3methylthiophene-2- carboxamido) propanoyl]phenoxy]propanoic acid (PPA), expressed as isofetamid

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

Agvet chemical: bifenthrin	
Permitted residue – bifenthrin	
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T1

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

# Agvet chemical: bifenazate Permitted residue – sum of bifenazate and bifenazate diazene (diazenecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl-3-yl] 1-methylethyl ester), expressed as bifenazate All other foods except animal food commodities Avocado T2 Agvet chemical: bifenthrin

Agvet chemical: bifenthrin	
Permitted residue – bifenthrin	
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas [except cabbages, head]	0.5
Cabbages, head	T0.5

Agvet chemical: isofetamid	
Permitted residue – isofetamid	
Berries and other small fruits [except grapes]	5
Poultry eggs	*0.02
Edible offal (mammalian)	*0.02
Meat (mammalian) (in the fat)	*0.02
Milks	*0.02
Milk fats	*0.02
Poultry, edible offal of	*0.02
Poultry meat (in the fat)	*0.02

Agvet chemical: metalaxyl	
Permitted residue – metalaxyl	
Parsley	T0.3

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

Agvet chemical: abamectin	
Permitted residue – avermectin B1a	
Adzuki bean (dry)	*0.002
Avocado	0.05
Blackberries	0.1
Blueberries	*0.02
Bulb vegetables	0.05
Common bean (dry) (navy bean)	*0.002
Cucumber	0.05
Custard apple	*0.01
Fruiting vegetables, other than cucurbits [except mushrooms, sweet corn (cornon-the-cob)]	0.1
Litchi	0.05
Mung bean (dry)	*0.002
Mushrooms	0.05
Papaya (pawpaw)	0.1
Passionfruit	0.2
Peas	0.5
Raspberries, red, black	0.1
Root and tuber vegetables	*0.01
Squash, summer	0.05
Sweet corn (corn-on-the-cob)	0.05
Associate and all hitesathain	
Agvet chemical: bifenthrin	
Permitted residue – bifenthrin	
Leafy vegetables [except chervil; mizuna; rucola (rocket)]	*0.01
Agvet chemical: bupirimate	
Permitted residue – bupirimate	
Egg plant	1
Agvet chemical: carfentrazone-ethyl	
Permitted residue – carfentrazone-ethyl	
Berries and other small fruits [except grapes]	*0.05
A 201 101 101 101 101	
Agvet chemical: clofentezine	
Permitted residue – clofentezine	
Almonds	0.5
Tomato	0.5

Agvet chemical: cyprodinil	
Permitted residue – cyprodinil	
Bulb vegetables [except fennel, bulb; onion, bulb]	3
Chives	3
Agvet chemical: fludioxonil	
Permitted residue – commodities of animal of Sum of fludioxonil and oxidisable metabolite expressed as fludioxonil	
Permitted residue – commodities of plant or Fludioxonil	igin:
Bulb vegetables [except fennel, bulb; onion, bulb]	3
Chestnuts	1
Chives	3
Pineapple	5
Agvet chemical: metsulfuron-methyl	
Permitted residue – metsulfuron-methyl	
Mung bean (dry)	0.2
Agvet chemical: phosphorous acid	
Permitted residue – phosphorous acid	
Basil	T300
Coriander (leaves, roots, stems)	T300
Fennel, leaf	T300
Parsley	T300
Agvet chemical: tolclofos-methyl	
Permitted residue – tolclofos-methyl	*0.04
Lettuce, head Lettuce, leaf	*0.01 *0.01
Lettuce, leai	0.01
Agvet chemical: triadimenol	
Permitted residue – triadimenol	
Anise myrtle leaves (dried)	0.05
Lemon myrtle leaves (dried)	0.05
Parsnip	0.2
Radish	0.2
Riberry	0.3
Swede	0.2 0.2
Turnip, garden	0.2