

## Commonwealth of Australia

## Gazette

No. APVMA 16, Tuesday, 8 August 2017

Published by The Australian Pesticides and Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS



### **Australian Government**

## **Australian Pesticides and Veterinary Medicines Authority**

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

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#### **GENERAL INFORMATION**

The APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

#### **DISTRIBUTION AND SUBSCRIPTION**

The APVMA Gazette is published in electronic format only and is available from the APVMA website,

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

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

#### **APVMA CONTACTS**

For enquiries regarding the publishing and distribution of the APVMA Gazette:

Telephone: +61 2 6210 4812

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

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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.: 110301

Product name: Spalding Propyzamide 500 SC Herbicide

Active constituent/s: 500 g/L propyzamide
Applicant name: Spalding Holdings Pty. Ltd

**Applicant ACN:** 010 155 852

Summary of use: For selective control of certain grasses and broad leaf weeds in lettuce, sports turf,

home lawns and legumes, seed crops and pastures in various agricultural situations

Date of registration:19 July 2017Product registration no.:84394

**Label approval no.:** 84394/110301

Application no.: 110209

Product name: Rid Australia Terminator Fast Knockdown Flying Insect Killer Kills Flying Insects Fast

Active constituent/s: 1.19 g/kg bioallethrin, 1.5 g/kg d-phenothrin, 3.82 g/kg tetramethrin

Applicant name: Aaron Laboratories Proprietary Limited

**Applicant ACN:** 004 856 848

Summary of use: For killing and protection against insects

Date of registration: 20 July 2017
Product registration no.: 84368

**Label approval no.:** 84368/110209

Application no.: 108377

Product name: Weed Force Weed Sweep General Purpose Herbicide

Active constituent/s: 200 g/L glufosinate-ammonium

Applicant name: Weed Force Pty Ltd

**Applicant ACN:** 602 207 152

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

non-agricultural situations

Date of registration:20 July 2017Product registration no.:83481

**Label approval no.:** 83481/108377

Product name: PyFlush Insect Spray

Active constituent/s: 50 g/kg piperonyl butoxide, 10 g/kg pyrethrins Applicant name: Sherwood Chemicals Australasia Pty Ltd

**Applicant ACN:** 136 993 630

Summary of use: For the control of a range of insect pests in agricultural buildings, domestic and public

service areas

Date of registration: 20 July 2017 Product registration no.: 82718 Label approval no.: 82718/106529

Application no.: 110924

Product name: Farmalinx Fighter Insecticide Active constituent/s: 250 g/L lambda-cyhalothrin

Applicant name: Farmalinx Pty Ltd **Applicant ACN:** 134 353 245

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

Date of registration: 21 July 2017 Product registration no.: 84606

Label approval no.: 84606/110924

Application no.: 109452

Product name: Community Co Swat Fast Knock Down Multi Insect Killer

Active constituent/s: 0.9 g/kg d-allethrin 20:80, 0.9 g/kg d-phenothin, 4.05 g/kg tetramethrin 20:80

Applicant name: Aaron Laboratories Proprietary Limited

**Applicant ACN:** 004 856 848

Summary of use: For protection against ants, cockroaches, flies, mosquitoes, moths, silverfish, spiders

and wasps

Date of registration: 21 July 2017 Product registration no.: 83986

Label approval no.: 83986/109452

109862 Application no.:

Product name: Dairy Power Flexi-Klenz Acid Detergent Sanitiser

Active constituent/s: 149 g/L phosphoric acid, 126 g/L sulphuric acid, 23 g/L sulphamic acid

Applicant name: **Ecolab Pty Limited Applicant ACN:** 000 449 990

Summary of use: For cleaning and sanitising high velocity dairy milking plants and storage equipment

Date of registration: 21 July 2017 Product registration no.: 84187

Label approval no.: 84187/109862

109653 Application no.:

Agroshine Alpha-Cyp 250SC Insecticide Product name:

Active constituent/s: 250 g/L alpha-cypermethrin Applicant name: Agroshine Australia Pty Ltd

**Applicant ACN:** 105 873 023

Summary of use: For the control of certain insect pests, including redlegged earth mite on certain field

crops and pastures and certain insect pests on fruit and vegetable crops

Date of registration: 21 July 2017 Product registration no.: 84079 84079/109653

Label approval no.:

Product name: Community Co Shoo Tropical Personal Insect Repellent

Active constituent/s: 190 g/kg diethyltolumide, 43.5 g/kg di-n-propyl isocinchomeronate, 10 g/kg n-octyl

bicycloheptene dicarmoximide

Applicant name: Aaron Laboratories Proprietary Limited

**Applicant ACN:** 004 856 848

Summary of use: For protection against leeches, flies, mosquitoes, ticks and other biting insects

Date of registration:21 July 2017Product registration no.:83985

**Label approval no.:** 83985/109451

Application no.: 108667

Product name: Platinum 360 Herbicide
Active constituent/s: 360 g/L clethodim

Applicant name: Adama Australia Pty Limited

**Applicant ACN:** 050 328 973

Summary of use: For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas,

cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, lettuce, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans

Date of registration:24 July 2017Product registration no.:83590Label approval no.:83590/108667

Application no.: 108925

Product name:

Active constituent/s:

Applicant name:

Revere 500 Herbicide

500 g/L propyzamide

Adama Australia Pty Limited

**Applicant ACN:** 050 328 973

Summary of use: For use on lettuce, lucerne, clover and medics and various turf and lawns for the

control of weeds

Date of registration:24 July 2017Product registration no.:83749Label approval no.:83749/108925

Application no.: 109647

Product name: Agristrobin 250SC Fungicide

Active constituent/s: 250 g/L azoxystrobin
Applicant name: Agritrading Pty Limited

Applicant ACN: 134 291 295

Summary of use: For the control of disease of grapes, potatoes, tomatoes, cucurbits, avocados,

mangoes, passionfruit and poppies

Date of registration: 26 July 2017
Product registration no.: 84076

Label approval no.: 84076/109647

Product name: Sharda s-Metolachlor 960 Herbicide

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

Applicant name: Sharda Cropchem Espana S.L

Applicant ACN: N/A

Summary of use: For the control of annual grasses and broadleaf weeds in various crops, pastures and

plantation situations

Date of registration:26 July 2017Product registration no.:84141

**Label approval no.:** 84141/109779

Application no.: 109571

Product name: Spraysure Sweep 450 Herbicide

Active constituent/s: 450 g/L glyphosate (present as the monoethanolamine salt)

Applicant name: Spraysure Pty Ltd
Applicant ACN: 616 617 951

Summary of use: For the control of weeds and plants in various situations including tree and vine crops,

pastures, sown crops and fallows

Date of registration:26 July 2017Product registration no.:84046Label approval no.:84046/109571

Application no.: 110079

Product name: Hovex Ant Spider & Cockroach Killer

Active constituent/s: 0.5 g/L bifenthrin
Applicant name: Pascoe's Pty Ltd
Applicant ACN: 055 220 463

**Summary of use:** For the control of insects around the home and garden

Date of registration:26 July 2017Product registration no.:84307Label approval no.:84307/110079

Application no.: 109881

Product name: Spalding Clopyralid 300 Herbicide

Active constituent/s: 300 g/L clopyralid present as the triisopropanolamine salt

Applicant name: Spalding Holdings Pty. Ltd

**Applicant ACN:** 010 155 852

Summary of use: For the control of broadleaf weeds in wheat, oats, triticale, canola, pastures, fallow

land, forests and industrial situations

Date of registration:26 July 2017Product registration no.:84204Label approval no.:84204/109881

Application no.: 109975

Product name: Raystar Azoxystrobin 250SC Fungicide

Active constituent/s: 250 g/L azoxystrobin

Applicant name: Raystar Cropprotection Pty Ltd

**Applicant ACN:** 610 946 784

**Summary of use:** For the control of diseases of grapes, potatoes, tomatoes, cucurbits, avocados,

mangoes, passionfruit and poppies in various agricultural situations

Date of registration:26 July 2017Product registration no.:84248

**Label approval no.:** 84248/109975

Product name: Rot Rid Fungicide

Active constituent/s: 200 g/L phosphorous acid present as mono-di-potassium phosphite

Applicant name: Amgrow Pty Ltd Applicant ACN: 100 684 786

Summary of use: For the control of phytophthora root rot, collar rot and crown rot in young, small and

transplanted citrus and ornamentals

Date of registration:26 July 2017Product registration no.:84182Label approval no.:84182/109853

Application no.: 109699

Product name: Conquest Thoram 600 SC Fungicide

Active constituent/s: 600 g/L thiram

Applicant name: Conquest Crop Protection Pty Ltd

Applicant ACN: 098 814 932

Summary of use For use as a seed treatment to control various fungal diseases of seeds and as a

drench to control fungal diseases of turf

Date of registration:27 July 2017Product registration no.:84097

**Label approval no.:** 84097/109699

Application no.: 110076

Product name: Surefire Trident 250 EC Fungicide

Active constituent/s: 250 g/L triadimenol
Applicant name: PCT Holdings Pty Ltd

**Applicant ACN:** 099 023 962

Summary of use: For the control of certain fungal diseases in various fruit, vegetable and sugarcane

crops

Date of registration: 27 July 2017
Product registration no.: 84304

**Label approval no.:** 84304/110076

Application no.: 109989

Product name: Raystar Oxyfluorfen 240 EC Herbicide

Active constituent/s: 240 g/L oxyfluorfen

Applicant name: Raystar Cropprotection Pty Ltd

**Applicant ACN:** 610 946 784

Summary of use: For the selective control of certain broadleaf and grass weeds in various agricultural

situations

Date of registration:27 July 2017Product registration no.:84250Label approval no.:84250/109989

Application no.: 104501

Product name:

Active constituent/s:

Applicant name:

Suspend Flexx Insecticide
25 g/L deltamethrin

Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of use: For the control of a wide range of insect pests in domestic, commercial, industrial and

rural premises and in public places

Date of registration: 31 July 2017
Product registration no.: 81960

**Label approval no.:** 81960/104501

Product name: Fumithor Delta Insecticide Smoke Generator

Active constituent/s: 20 g/kg deltamethrin

Applicant name: Ensystex Australasia Pty Ltd

**Applicant ACN:** 102 221 965

Summary of use: For control of a range of insect pests in commercial, industrial, domestic and

agricultural buildings including glass houses

Date of registration:31 July 2017Product registration no.:70128Label approval no.:70128/62571

#### 2. VARIATIONS OF REGISTRATION

Application no.: 107342

Product name: Ecopar Herbicide
Active constituent/s: 20 g/L pyraflufen-ethyl

Applicant name: Sipcam Pacific Australia Pty Ltd

**Applicant ACN:** 073 176 888

**Summary of variation:** To extend the use to faba beans, vetch and field peas

Date of variation:18 July 2017Product registration no.:60493

**Label approval no.:** 60493/107342

Application no.: 108373

Product name: Sumi-Alpha Ready to Use Home Garden Insecticide

Active constituent/s: 1 g/L esfenvalerate

Applicant name: Sumitomo Chemical Australia Pty Limited

Applicant ACN: 081 096 255

Summary of variation: To extend use to ticks (paralysis ticks and brown dog ticks) and application via hose-on

applicator at the hose-on rate

Date of variation: 18 July 2017
Product registration no.: 61384

**Label approval no.:** 61384/108373

Application no: 106741

Product name:

Active constituent/s:

Applicant name:

Nail 600EC Herbicide
600 g/L carfentrazone-ethyl
Nufarm Australia Limited

**Applicant ACN:** 004 377 780

Summary of variation: To amend signal heading and change grazing withholding period to 'not required when

used as directed for all situations except for cotton/cotton trash'

Date of variation:19 July 2017Product registration no.:69772

Label approval no.: 69772/106741

Product name: GP Flupropanate Granular Herbicide

Active constituent/s: 86.9 g/kg flupropanate present as the sodium salt

Applicant name: Granular Products Pty Ltd

**Applicant ACN:** 110 555 952

**Summary of variation:**To extend the use for control of serrated tussock, parramatta grass and giant rats tails

grass in pasture and non-crop situations, a state extension to all states for some weeds in pastures and non-crop situations and urban open space, woodlands, roadsides and non-crop situations and amend the critical comments to offer a wider spray window. Also for use in commercial forestry in Queensland for serrated tussock and *sporobolus* 

sp

Date of variation: 24 July 2017
Product registration no.: 61689

**Label approval no.:** 61689/101309

Application no.: 109006

Product name: Triclops Herbicide

Active constituent/s: 600 g/L triclopyr present as the butoxyethyl ester

Applicant name: Crop Culture Pty Ltd

**Applicant ACN:** 142 860 473

**Summary of variation:** To extend uses and to include a pack size range

Date of variation:26 July 2017Product registration no.:67456

**Label approval no.:** 67456/109006

Application no.: 107530

Product name: Gala Growth Regulator
Active constituent/s: 100 g/L gibberellic acid

Applicant name: Victorian Chemical Company Proprietary Limited

**Applicant ACN:** 004 188 863

**Summary of variation:** To extend the use to cherries

Date of variation: 28 July 2017
Product registration no.: 53353

**Label approval no.:** 53353/107530

#### 3. VARIATION OF LABEL APPROVAL

Application no.: 110304

Product name: Brunnings Tomato Insect & Fungus Spray

Active constituent/s: 0.015 g/L abamectin, 0.1 g/L thiamethoxam, 0.167 g/L difenoconazole

Applicant name: Syngenta Australia Pty Ltd

Applicant ACN: 002 933 717

Summary of variation: To approve a new label for the product 'BRUNNINGS TOMATO INSECT & FUNGUS

SPRAY' with the label name 'GARDENLINE TOMATO INSECT AND FUNGUS SPRAY'

Date of variation:21 July 2017Product registration no.:70237

**Label approval no.:** 70237/110304

Product name: Richgro Garden Products Permethrin Ant Killer For Indoor And Outdoor Use

Active constituent/s: 10 g/kg permethrin (25:75::CIS:TRANS)

Applicant name: A. Richards Pty Ltd
Applicant ACN: 008 734 852

Summary of variation: To approve a new label for the product 'RICHGRO GARDEN PRODUCTS

PERMETHRIN ANT KILLER FOR INDOOR AND OUTDOOR USE' with the label name

'GREEN GRUB ANT KILLER FOR INDOOR AND OUTDOOR USE'

Date of variation: 21 July 2017

Product registration no.: 55426

**Label approval no.:** 55426/110085

Application no.: 107875

Product name: Wildebeest 700 Herbicide

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

Applicant name: Crop Culture Pty Ltd

**Applicant ACN:** 142 860 473

**Summary of variation:** To include application by helicopter

Date of variation: 25 July 2017
Product registration no.: 68797

**Label approval no.:** 68797/107875

Application no.: 109827

Product name: Hy-Clor Liquid Chlorine

Active constituent/s: 125 g/L available chlorine (CI) present as sodium hypochlorite

Applicant name: Hy-Clor (Australia) Pty Ltd

**Applicant ACN:** 000 655 381

Summary of variation: To approve a new label for the product 'HY-CLOR LIQUID CHLORINE' with the label

name 'TPM LIQUID CHLORINE'

Date of variation:25 July 2017Product registration no.:66166

**Label approval no.:** 66166/109827

#### **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.: 103201

Product name: Neove Imidacloprid Pour-On Lousicide For Sheep

Active constituent/s: 35 g/L imidacloprid

Applicant name: Neove Pharma Australia Pty Limited

Applicant ACN: 140 367 442

Summary of use: For use in the control of body lice (bovicola ovis) on sheep

Date of registration:20 July 2017Product registration no.:81485

Label approval no.: 81485/103201

Application no.: 110148

Product name: 4 Season Protect

Active constituent/s: 100 g/kg alcohol ethoxylate
Applicant name: 4 Season Company Pty Ltd

**Applicant ACN:** 075 508 664

**Summary of use:** For use in the aid of bloat control in cattle

Date of registration:20 July 2017Product registration no.:84338Label approval no.:84338/110148

Application no.: 107324

Product name: Exilice Pour-On Lousicide For Sheep

Active constituent/s: 35 g/L imidacloprid

Applicant name: Abbey Laboratories Pty Ltd

**Applicant ACN:** 156 000 430

Summary of use: For use in the control of body lice (bovicola ovis) on sheep

Date of registration:25 July 2017Product registration no.:83017

**Label approval no.:** 83017/107324

Application no.: 110473

Product name: Pole-Axe Sheep Drench

Active constituent/s: 800 g/kg naphthalophos (an anticholinesterase compound)

Applicant name: The Hunter River Company Pty Limited

**Applicant ACN:** 133 798 615

Summary of use: For control of organophosphate sensitive gastrointestinal roundworms in sheep and

lambs

Date of registration:26 July 2017Product registration no.:84466Label approval no.:84466/110473

#### **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.: 108875
Active constituent/s: Boscalid

Applicant name: UPL Australia Limited

**Applicant ACN:** 066 391 384

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

Date of approval: 20 July 2017 Approval no.: 83713

Application no.: 108282
Active constituent/s: Prochloraz

Applicant name: FMC Australasia Pty Ltd

Applicant ACN: 095 326 891

Summary of use: For use in agricultural chemical products

**Date of approval:** 25 July 2017 **Approval no.:** 83439

#### **New Agricultural Active Constituent Cedarwood Oil**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, Cedarwood Oil, for use in personal insect repellent products.

#### PARTICULARS OF THE ACTIVE CONSTITUENT

Common name: Cedarwood Oil

**Botanical name:** Essential oil of the wood of *Juniperus* spp., particularly *J. virginiana*, *J. ashei*, or *J.* 

deppeana, or, less commonly, Cedrus spp., particularly C. deodara or C. atlantica

**Chemical composition:** Depending on the species of tree, and as a result of natural variability between

sources, Cedarwood Oil contains a mixture of sesquiterpene compounds such as

cedrol, alpha- and beta-cedrene, and thujopsene in varying proportions

**CAS number:** 8000-27-9

Minimum purity: Must be of a suitable standard for use in cosmetic and/or personal care preparations

Mode of action: Insect repellent

#### SUMMARY OF THE APVMA'S EVALUATION OF CEDARWOOD OIL ACTIVE CONSTITUENT

Cedarwood Oil is an essential oil extracted (usually by steam distillation) from the wood of trees commonly known as cedars, from the genus *Juniperus* (particularly *J. virginiana, J. ashei,* or *J. deppeana*) or, less commonly, the genus *Cedrus* (particularly *C. deodara* or *C. atlantica*). It has applications as a fragrance in aromatherapy oils, personal care products such as liquid hand soaps and colognes, and as an ingredient in polishes for wooden furniture and floors.

The APVMA has considered the toxicological aspects of Cedarwood Oil and has concluded that there are no objections on toxicological grounds to the approval of this active constituent. Given that the associated products are for use as personal insect repellents, i.e. food uses are not proposed, neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) have been established. Cedarwood oil has low acute oral and dermal toxicity and is listed as an active constituent permitted for use in minimum risk pesticides by the United States Environmental Protection Agency (EPA). It is not scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard).

The APVMA is satisfied that the proposed importation and use of Cedarwood Oil would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

#### **MAKING A SUBMISSION**

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Cedarwood Oil should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

When making a submission please include a:

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

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

Written submissions should be addressed to:

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

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

Email: enquiries@apvma.gov.au

### Nature's Botanical Crème Personal Insect Repellent containing Rosemary Oil and Cedarwood Oil

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing the new active constituent Cedarwood Oil. The product is Nature's Botanical Crème Personal Insect Repellent.

#### PARTICULARS OF THE APPLICATION

Proposed product name(s): Nature's Botanical Crème Personal Insect Repellent

Applicant company: National Machinery Traders (NSW) Pty Ltd

Name of active constituent: Rosemary Oil and Cedarwood Oil

Signal heading: Not required

Summary of proposed use: Personal insect repellent to repel mosquitoes, flies and biting midges

Pack sizes: 50 g to 500 g

Withholding period: N/A

SUMMARY OF THE APVMA'S EVALUATION OF NATURE'S BOTANICAL CRÈME PERSONAL INSECT REPELLENT 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 Nature's Botanical Crème Personal Insect Repellent containing the active constituents Rosemary Oil and Cedarwood Oil is not likely to be harmful to human beings if used according to the product label directions.

Rosemary Oil and Cedarwood oil are used in aromatherapy, cosmetics, complimentary medicines and as food flavouring agents. Rosemary oil and Cedar wood oil are listed as active constituents permitted for use in minimum risk pesticides by the United States Environmental Protection Agency (EPA) (US-EPA <a href="https://www.regulations.gov/">www.regulations.gov/</a>).

The product is estimated to have low oral and dermal toxicity, low inhalational toxicity, is not estimated to be a skin irritant or sensitiser, although is expected to have potential for slight eye irritancy. Given that the product is for use as a personal insect repellent, i.e. food uses are not proposed, neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) have been established. The APVMA considers there are no toxicological concerns with the product when used according to instructions.

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

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The results from several Australian trials support the label claims that Nature's Botanical Crème Personal Insect Repellent is effective as a personal insect repellent against the pest species flies, mosquitoes and biting midges. The product was trialled under high challenge conditions and demonstrated good repellence of pest species at up to 4 hours after treatment.

#### **MAKING A SUBMISSION**

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Nature's Botanical Crème Personal Insect Repellent 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 or efficacy criteria have been met. Submissions should state the grounds on which they are based.

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

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

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

KINGSTON ACT 2604 **Phone:** +61 2 6210 4701 **Fax:** +61 2 6210 4721

Email: enquiries@apvma.gov.au

#### Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves Maximum Residue Limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *Agricultural and Veterinary Chemicals Code Instrument No. 4* (MRL Standard) 2012. The MRL Standard lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The MRL Standard also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

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

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

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard)* Amendment Instrument 2017 (No. 8).

The amendments will be incorporated into the compilation of the <u>Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012.</u>

The MRL Standard is accessible via the Federal Register of Legislation website <a href="www.legislation.gov.au">www.legislation.gov.au</a> or the links above.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
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#### Proposal to Amend Schedule 20 in the Australia New Zealand Food Standards Code

In the previous notice on page 18 of APVMA Gazette No. 16, 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 Instrument No. 4 (MRL Standard)* Amendment Instrument 2017 (No. 8)) 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.

FSANZ will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

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

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

## PROPOSED VARIATION TO SCHEDULE 20 IN THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (8 August 2017)

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

#### To commence: on gazettal of variation

- [1] The table to section S20–3 in Schedule 20 is varied by
- [1.1] omitting from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Cloquintocet-m	nexyl
Permitted residue: Sum of cloquintocet mexyl and 5- chloro-8-quinolinoxyacetic acid, expressed as cloquintocet mexyl	
Barley	*0.1
Rye	*0.1
Triticale	*0.1
Wheat	*0.1
Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Cereal grains	0.2

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

Agvet chemical: Cloquintocet-mexyl	
Permitted residue: Sum of cloquinto chloro-8-quinolinoxyacetic acid, expr cloquintocet mexyl	,
Cereal grains	*0.1
Agvet chemical: Diquat	
Permitted residue: Diquat cation	
Quinoa	T5
Agvet chemical: Fludioxonil	
Permitted residue—commodities of animal origin: Sum of fludioxonil and oxidisable metabolites, expressed as fludioxonil	
Permitted residue—commodities of p Fludioxonil	olant origin:
Pineapple	T20

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Barley	1
Cereal grains [except barley and oats]	0.2
Oats	1

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

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Soya bean (dry)	0.1

#### **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) 5 September 2017

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

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

For further information please contact:

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#### 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. 5) gazetted on 16 May 2017 (No. APVMA 10).

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 16, 2017) 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 at <a href="https://www.legislation.gov.au">www.legislation.gov.au</a>

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:

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#### **Australian Government**

### Australian Pesticides and Veterinary Medicines Authority

# Australia New Zealand Food Standards Code — Schedule 20 — Maximum residue limits Variation Instrument No. APVMA 8, 2017

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 Fourth day of August 2017

#### 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, 2017.* 

#### 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 16 of 8 August 2017.

#### 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 from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Bixafen

Permitted residue—commodities of plant origin:

Bixafen

Permitted residue—commodities of animal origin: Sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen

\*0.01 Rape seed

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

Agvet chemical: Bixafen

Permitted residue—commodities of plant origin:

Permitted residue—commodities of animal origin: Sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen

All other foods	0.03
Cereal grains [except barley; wheat]	*0.01
Milk fats	0.5
Oilseed	*0.01

Agvet chemical: Clopyralid Permitted residue: Clopyralid

All other foods except animal food

commodities

0.1

0.02

Agvet chemical: Clothianidin

Permitted residue: Clothianidin

All other foods except animal food

commodities

Mango T0.05

Agvet chemical: Flumioxazin	
Permitted residue: Flumioxazin	
Avocado	*0.02
Blueberries	*0.02
Citrus fruits	*0.05
Olives	*0.02
Pome fruits	*0.02
Pomegranate	*0.02
Stone fruits	*0.02
Tree nuts	*0.02
Agvet chemical: Imazamox	
Permitted residue: Imazamox	
Sorghum	*0.02
Agvet chemical: Imazapyr	
Permitted residue: Imazapyr	
Sorghum	0.02

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

#### Agvet chemical: Bixafen

Poppy Seed

Permitted residue—commodities of plant origin: Bixafen

Permitted residue—commodities of animal origin: Sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen

Barley	T0.02
Edible offal (mammalian)	0.7
Meat (mammalian) (in the fat)	0.2
Milks	0.05
Pulses	*0.01
Wheat	T0.02

Agvet chemical: Buprofezin	
Permitted residue: Buprofezin	
Tomato	T1
Agvet chemical: Clopyralid	
Permitted residue: Clopyralid	

T1