

# Commonwealth of Australia

# Gazette

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Published by The Australian Pesticides and Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS



# **Australian Government**

# **Australian Pesticides and Veterinary Medicines Authority**

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

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#### **GENERAL INFORMATION**

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

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

# **DISTRIBUTION AND SUBSCRIPTION**

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

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

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# **Agricultural Chemical Products and Approved Labels**

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

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

Application no.: 48927

Product name: Specticle Herbicide
Active constituent/s: 200 g/L indaziflam

Applicant name: Bayer CropScience Pty Ltd

**Applicant ACN:** 000 226 022

Summary of use For the pre-emergent control of summer grass, crowsfoot grass and winter

grass in turf on golf course fairways

Date of registration/approval: 2 March 2016

Product registration no.: 64673 Label approval no.: 64673/48927

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

Application no.: 60431

Product name: Family Protection Aerogard Extreme Protection 40% Deet 8 Hours Protection Effective In

Areas Of Intense Insect Activity Insect Repellent

Active constituent/s: 40 g/kg n-octyl bicycloheptene dicarboximide, 400 g/kg diethyltoluamide

Applicant name: Reckitt Benckiser (Australia) Pty Limited

Applicant ACN: 003 274 655

Summary of use For use as a personal insect repellent

Date of registration/approval: 29 February 2016

Product registration no.: 69293

Label approval no.: 69293/60431

Application no.: 101357

Product name: Storm Soft Bait Rodenticide

Active constituent/s: 0.05 g/kg flocoumafen

Applicant name: BASF Australia Ltd

Applicant ACN: 008 437 867

Summary of use For the control of rats and mice in and around industrial, commercial, agricultural and

domestic buildings, also controls rats and mice resistant to warfarin

Date of registration/approval: 1 March 2016

Product registration no.: 80663

**Label approval no.:** 80663/101357

Application no.: 103647

Product name: Eureka! Glyphosate 540 SL Herbicide

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

Applicant name: Eureka! Agresearch Pty Ltd

**Applicant ACN:** 086 194 738

Summary of use For the non-selective control of many annual and perennial weeds

Date of registration/approval:2 March 2016Product registration no.:81684

Label approval no.: 81684/103647

Product name: I-MOX 700 WG Herbicide
Active constituent/s: 700 g/kg imazamox

Applicant name: Shandong Rainbow International Co., Ltd

Applicant ACN: N/A

Summary of use For the post-emergence control of certain annual grass and broadleaf weeds in field

peas, legume-based pastures, lucerne, peanuts and soybeans

Date of registration/approval: 2 March 2016

Product registration no.: 81174

Label approval no.: 81174/102487

Application no.: 104862

Product name: Relyon Garner 750WG Herbicide

Active constituent/s: 750 g/kg chlorsulfuron
Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of use For the control of annual ryegrass and certain broadleaf weeds in wheat, barley, oats, cereal

rye and triticale 2 March 2016

Product registration no.: 82041

Date of registration/approval:

Label approval no.: 82041/104862

Application no.: 62951

Product name: Peroxypure395 Chlorine Free Pool Sanitiser

Active constituent/s: 395 g/L hydrogen peroxide

Applicant name: Waterco Limited
Applicant ACN: 002 070 733

Summary of use For control of bacteria in private (domestic) spas and pools

Date of registration/approval: 3 March 2016

Product registration no.: 69474

Label approval no.: 69474/62951

Application no.: 101690

Product name: Biforce Low-Odour 200EC Insecticide

Active constituent/s: 200 g/L bifenthrin

Applicant name: Sherwood Chemicals Public Company Limited

Applicant ACN: N/A

Summary of use For the control of a range of urban pests

Date of registration/approval: 3 March 2016

Product registration no.: 80803

**Label approval no.:** 80803/101690

Application no.: 104140

Product name: Relyon Insight 750 SG Herbicide

Active constituent/s: 750 g/kg clopyralid present as the potassium salt

Applicant name: Ruralco Holdings Limited

**Applicant ACN:** 009 660 879

Summary of use For the control of a wide range of broadleaf weeds in wheat, barley, oats, triticale,

canola, pastures and fallow land

Date of registration/approval: 3 March 2016

Product registration no.: 81837

**Label approval no.:** 81837/104140

Product name: Eurochem 6-BA Plant Growth Regulator

Active constituent/s: 20 g/L 6-benzyladenine

Applicant name: Ronic International Pty Limited

Applicant ACN: 101 193 131

Summary of use For the use of reducing fruit set, increasing fruit size and improving firmness of

harvested apples

Date of registration/approval: 4 March 2016

Product registration no.: 81342

Label approval no.: 81342/102857

Application no.: 104834

Product name: Tapout 240 Herbicide
Active constituent/s: 240 g/L clethodim
Applicant name: Crop Culture Pty Ltd
Applicant ACN: 142 860 473

**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/approval: 4 March 2016

Product registration no.: 82035

Label approval no.: 82035/104834

Application no.: 104051

Product name: Relyon Triflon 480EC Herbicide

Active constituent/s: 480 g/L trifluralin

Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

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

agricultural crops

Date of registration/approval: 7 March 2016

Product registration no.: 81784

Label approval no.: 81784/104051

Application no.: 104451

**Product name:** Weed Force Evict 450 Herbicide

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

Applicant name: Weed Force Pty Ltd

**Applicant ACN:** 602 207 152

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

Date of registration/approval:7 March 2016Product registration no.:81935

Label approval no.: 81935/104451

Application no.: 104990

Product name: O-MAT 290 SL Insecticide

Active constituent/s: 290 g/L omethoate (an anticholinesterase compound)

Applicant name: Arysta Lifescience Australia Pty Ltd

**Applicant ACN:** 005 225 507

Summary of use For the control of redlegged earth mite, blue oat mite and lucerne flea on

pastures, cereals, oilseed and legume crops, and bluegreen aphid and cowpea

aphid on pasture legumes, lucerne, faba beans and vetch

Date of registration/approval: 7 March 2016

Product registration no.: 8209

**Label approval no.:** 82095/104990

Product name: Propeller 250 Fungicide
Active constituent/s: 250 g/L propiconazole
Applicant name: Crop Culture Pty Ltd

**Applicant ACN:** 142 860 473

Summary of use For the control of certain fungal diseases of bananas, oats, peanuts, perennial

ryegrass, pineapples, stone fruit, sugarcane, wheat and other crops. For the control of dollar spot in bent and Queensland blue couch and spring dead spot

in couch

Date of registration/approval: 8 March 2016

Product registration no.: 82044

Label approval no.: 82044/104867

Application no.: 104887

Product name: Kelpie DFF + Brom MX Herbicide

Active constituent/s: 250 g/L bromoxynil present as the octanoate, 25 g/L diflufenican

**Applicant name:** Sinochem International Australia Pty Ltd

**Applicant ACN:** 160 164 616

Summary of use For the control of certain broadleaf weeds in winter cereals and pastures

Date of registration/approval: 8 March 2016
Product registration no.: 82057

Label approval no.: 82057/104887

Application no.: 104830

Product name:Tebby 430 FungicideActive constituent/s:430 g/L tebuconazoleApplicant name:Crop Culture Pty Ltd

Applicant ACN: 142 860 473

Summary of use For the control of leaf spot and leaf speckle on bananas; rust, leaf spot and net

blotch of peanuts; foliar diseases on cereal crops; and other diseases on beans, lettuce, peas, onions, pawpaw, pyrethrum and ryegrass and fescue seed crops

Date of registration/approval: 8 March 2016

Product registration no.: 82030

Label approval no.: 82030/104830

Application no.: 63370

**Product name:** eChem Clopyralid 300 Herbicide

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

Applicant name: eChem (Aust) Pty Limited

Applicant ACN: 089 133 095

Summary of use For the control of a wide range of broadleaf weeds in wheat, barley,triticale, oats,

pastures, canola, fallow land, forests and industrial situations

Date of registration/approval: 8 March 2016

Product registration no.: 70397

Label approval no.: 70397/63370

Application no.: 104890

Product name: Kelpie DFF + MCPA MX Herbicide

Active constituent/s: 250 g/L MCPA present as the ethyl hexyl ester, 25 g/L diflufenican

Applicant name: Sinochem International Australia Pty Ltd

**Applicant ACN:** 160 164 616

Summary of use For the control of certain broadleaf weeds in winter cereals and clover

Date of registration/approval:9 March 2016Product registration no.:82058

**Label approval no.:** 82058/104890

Apparent Fluroxypyr 400 Herbicide Product name:

Active constituent/s: 400 g/L fluroxypyr present as the methyl heptyl ester

Applicant name: Apparent Pty. Ltd Applicant ACN: 143 724 136

For the control of a wide range of broadleaf weeds in fallow, lucerne, maize, Summary of use

millets, pastures, poppies, sorghum, sugarcane, sweet corn and winter cereals. Also for the control of woody weeds in agricultural non-crop areas, commercial

and industrial areas, forests, pastures and rights-of-way

Date of registration/approval: 9 March 2016

Product registration no.: 81917

Label approval no .: 81917/104411

Application no.: 104065

Product name: Relyon Oxon 240EC Herbicide

Active constituent/s: 240 g/L oxyfluorfen Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of use For the selective control of certain broadleaf and grass weeds

Date of registration/approval: 9 March 2016 Product registration no.: 81796

Label approval no.: 81796/104065

Application no.: 104774

AC Capsize 500 SC Fungicide Product name:

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

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

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

vegetables

Date of registration/approval: 9 March 2016

Product registration no.: 81995

Label approval no.: 81995/104774

104457 Application no.:

Product name: Relyon Rialto 750WG Herbicide

Active constituent/s: 750 g/kg triasulfuron Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

For pre-plant control of annual ryegrass, paradoxa grass and certain broadleaf weeds Summary of use

in wheat and for post-emergent control of wild radish in wheat, oats and barley

Date of registration/approval: 9 March 2016

Product registration no.: 81938

81938/104457 Label approval no.:

104510 Application no.:

Product name: AC Rampant Selective Herbicide

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

Applicant name: Axichem Pty Ltd Applicant ACN: 131 628 594

For the control of broadleaf weeds prior to sowing crops and pastures in Summary of use

conservation tillage situations and for selective weed control in crops

Date of registration/approval: 10 March 2016

Product registration no.: 81968

81968/104510 Label approval no.:

Product name: OzCrop Isoxaflutole 750 WG Herbicide

Active constituent/s: 750 g/kg isoxaflutole
Applicant name: OzCrop Pty. Ltd
Applicant ACN: 160 656 431

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

sugarcane and chickpeas

Date of registration/approval: 10 March 2016

Product registration no.: 81887

**Label approval no.:** 81887/104347

Application no.: 104037

Product name:

Active constituent/s:

Applicant name:

Ronaldo 240 Herbicide
240 g/L oxyfluorfen
Crop Culture Pty Ltd

**Applicant ACN:** 142 860 473

Summary of use For the selective control of certain broadleaf and grass weeds

Date of registration/approval: 11 March 2016

Product registration no.: 81777

Label approval no.: 81777/104037

Application no.: 101091

Product name: Propermide 900 WG Herbicide

Active constituent/s: 900 g/kg propyzamide

Applicant name: Agro-Alliance (Australia) Pty Ltd

**Applicant ACN:** 130 864 603

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

home lawns and legume seed crops and pastures

**Date of registration/approval:** 11 March 2016

Product registration no.: 80551

**Label approval no.:** 80551/101091

Application no.: 104831

**Product name:** Mongrel 750 Herbicide

Active constituent/s: 750 g/kg clopyralid present as the potassium salt

Applicant name: Crop Culture Pty Ltd

**Applicant ACN:** 142 860 473

Summary of use For the control of a wide range of broadleaf weeds in wheat, barley, oats,

triticale, canola, pastures and fallow land

Date of registration/approval: 11 March 2016

Product registration no.: 82031

**Label approval no.:** 82031/104831

Application no.: 104923

Product name: Relyon Zulfa 800wg Fungicide

Active constituent/s: 800 g/kg sulfur (S) present as elemental sulfur

Applicant name: Ruralco Holdings Limited

**Applicant ACN:** 009 660 879

Summary of use For the control of powdery mildew, rust and mites in pome and stone fruit, citrus,

grapevines, kiwifruit, strawberries and some vegetables

Date of registration/approval: 11 March 2016

Product registration no.: 82072

**Label approval no.:** 82072/104923

Product name: Relyon Triamate 500EC Herbicide

Active constituent/s: 500 g/L tri-allate

**Applicant name:** Ruralco Holdings Limited

**Applicant ACN:** 009 660 879

For the control of wild oats in wheat, triticale, chickpeas, barley, peas, linseed, Summary of use

lupins, canola (rapeseed), faba beans and safflower

Date of registration/approval: 15 March 2016

Product registration no.: 81798

Label approval no.: 81798/104067

104874 Application no.:

Product name: Agro-Essence Sulfosulfuron 750WG Herbicide

Active constituent/s: 750 g/kg sulfosulfuron

Applicant name: Agro-Alliance (Australia) Pty Ltd

**Applicant ACN:** 130 864 603

Summary of use For the control of certain weeds in wheat and triticale

Date of registration/approval: 15 March 2016

Product registration no.: 82051

82051/104874 Label approval no.:

#### 3. **VARIATIONS OF REGISTRATION**

Application no.: 105555

Product name: Unistar Selective Herbicide Active constituent/s: 750 g/kg triasulfuron **Applicant name: UPL** Australia Limited

**Applicant ACN:** 066 391 384

To change the distinguishing product name and the name that appears on the label from 'UNI-STAR SELECTIVE HERBICIDE' to 'UNISTAR Summary of variation:

SELECTIVE HERBICIDE'

Date of variation: 2 February 2016

Product no.: 62782

Label approval no.: 62782/105555

Application no: 105551 Product name: Nemasol

Active constituent/s: 423 g/L metham present as sodium salt Applicant name: Eastman Chemical Australia Pty Ltd

**Applicant ACN:** 077 977 649

To change the name that appears on the label from 'TAMINCO Summary of variation:

METHAM SODIUM 510 SOIL FUMIGANT' to 'NEMASOL'

Date of variation: 3 February 2016

Product registration no.: 67922

Label approval no.: 67922/105551

Product name: Apparent Weedfree RTU Herbicide

Active constituent/s: 7.2 g/L glyphosate present as the isopropylamine salt

Applicant name: Apparent Pty. Ltd Applicant ACN: 143 724 136

Summary of variation:

To change the distinguishing product name and the name that appears on the label from

'APPARENT KNOCK-OUT RTU HERBICIDE' to 'APPARENT WEEDFREE RTU HERBICIDE'

**Date of variation:** 5 February 2016

 Product no.:
 80396

 Label approval no.:
 80396/105582

Application no: 105682

Product name: Relyon Oxon 240 Herbicide

Active constituent/s: 240 g/L oxyfluorfen
Applicant name: Profeng Australia Pty Ltd

**Applicant ACN:** 156 055 533

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

'YGEL OXYFLUORFEN HERBICIDE' to 'RELYON OXON 240 HERBICIDE'

**Date of variation:** 16 February 2016

Product registration no.: 64219

**Label approval no.:** 64219/105682

Application no: 101154

Product name: Fipforce Aqua Termiticide & Insecticide

Active constituent/s: 100 g/L fipronil

Applicant name: Sherwood Chemicals Public Company Limited

Applicant ACN: N/A

Summary of variation: To extend the use of the product to include pre-construction, reticulation systems, nests in

poles and trees and wall cavity treatment

Date of variation: 2 March 2016 Product registration no.: 63789

Label approval no.: 63789/101154

Application no: 101039

Product name: Custodia Fungicide

Active constituent/s: 200 g/L tebuconazole, 120 g/L azoxystrobin

Applicant name: Adama Australia Pty Limited

**Applicant ACN:** 050 328 973

Summary of variation: For the extension of use to include control of rust, shot hole and brown rot of almonds and to

vary the current use pattern for control of septoria tritici blotch (STB) in wheat

Date of variation:3 March 2016Product registration no.:66541

**Label approval no.:** 66541/101039

Application no: 104924

Product name:

Active constituent/s:

Applicant name:

Black Flag Odourless Fly & Mosquito Killer

1.1 g/kg esbiothrin, 0.5 g/kg permethrin

Reckitt Benckiser (Australia) Pty Limited

**Applicant ACN:** 003 274 655

**Summary of variation:**To add additional pack sizes

Date of variation: 3 March 2016
Product registration no.: 67835

**Label approval no.:** 67835/104924

Product name:Monaco HerbicideActive constituent/s:750 g/kg sulfosulfuronApplicant name:Crop Culture Pty Ltd

**Applicant ACN:** 142 860 473

**Summary of variation:** To alter the approved pack size

**Date of variation:** 9 March 2016

Product registration no.: 68230

**Label approval no.:** 68230/104946

Application no: 104897

Product name: Tri-Form 35 Soil Fumigant

Active constituent/s: 630 g/kg (844 g/L) 1,3-dichloropropene, 345 g/kg (465 g/L) chloropicrin

Applicant name: Trical Australia Pty Ltd

**Applicant ACN:** 600 066 966

Summary of variation: To amend the pack size

**Date of variation:** 09 March 2016

Product registration no.: 64245

**Label approval no.:** 64245/104897

Application no: 100190

Product name: Yates Confidor Lawn & Garden Insecticide

Active constituent/s: 15 g/L imidacloprid

Applicant name: Bayer Cropscience Pty Ltd

**Applicant ACN:** 000 226 022

**Summary of variation:** To add pack sizes and extend uses

**Date of variation:** 10 March 2016

Product registration no.: 60571

**Label approval no.:** 60571/100190

Application no: 104776

Product name: Yates Lawnweedkiller Bindii & Clover Concentrate

Active constituent/s: 25 g/L dicamba present as the dimethylamine salt, 150 g/L MCPA present as the

dimethylamine salt

Applicant name: Duluxgroup (Australia) Pty Ltd

**Applicant ACN:** 000 049 427

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

'YATES BINDII & CLOVER WEEDER' to 'YATES LAWNWEEDKILLER BINDII & CLOVER

CONCENTRATE' and to add a range of pack sizes

Date of variation: 10 March 2016

Product registration no.: 58022

Label approval no.: 58022/104776

Application no: 104898

Product name: Tri-Form Soil Fumigant

Active constituent/s: 970 g/kg (1174 g/L) 1,3-dichloropropene

Applicant name: Trical Australia Pty Ltd

**Applicant ACN:** 600 066 966

Summary of variation: To amend the pack sizes

Date of variation: 10 March 2016

Product registration no.: 64246

**Label approval no.:** 64246/104898

Product name: Ceasefire 2G Granular Insecticide

Active constituent/s: 2 g/kg bifenthrin

Applicant name: Turf Culture Pty Ltd

Applicant ACN: 117 986 615

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

'TURF CULTURE CEASEFIRE 2G GRANULAR INSECTICIDE' to 'CEASEFIRE 2G

GRANULAR INSECTICIDE'

Date of variation: 11 March 2016

Product registration no.: 61005

**Label approval no.:** 61005/104757

Application no: 104761

Product name: Trinex 120 ME Growth Regulator

Active constituent/s: 120 g/L trinexapac-ethyl
Applicant name: Turf Culture Pty Ltd
Applicant ACN: 117 986 615

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

'TURF CULTURE TRINEX 120 ME GROWTH REGULATOR' to 'TRINEX 120 ME GROWTH

REGULATOR'

**Date of variation:** 11 March 2016

Product registration no.: 64368

**Label approval no.:** 64368/104761

Application no: 104931

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

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

bicycloheptene dicarboximide

Applicant name: Reckitt Benckiser (Australia) Pty Limited

**Applicant ACN:** 003 274 655

Summary of variation: To add additional pack sizes

**Date of variation:** 15 March 2016

Product registration no.: 67874

**Label approval no.:** 67874/104931

Application no: 104930

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

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

3.18 g/kg n-octyl bicycloheptene dicarboximide

Applicant name: Reckitt Benckiser (Australia) Pty Limited

**Applicant ACN:** 003 274 655

Summary of variation: To add additional pack sizes

**Date of variation:** 15 March 2016

Product registration no.: 53238

**Label approval no.:** 53238/104930

# **Veterinary Chemical Products and Approved Labels**

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

#### 1. VARIATIONS OF REGISTRATION

Application no: 105546

Product name: Troy Entera Allwormer Tablets For Small Dogs

Active constituent/s: Each tablet contains: 75 mg febantel, 15 mg praziquantel, 14.9 mg pyrantel as the embonate

Applicant name: Troy Laboratories Pty Ltd

Applicant ACN: 000 283 769

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

VANGARD ALLWORMER TABLETS FOR SMALL DOGS' to 'TROY ENTERA ALLWORMER

TABLETS FOR SMALL DOGS'

**Date of variation:** 1 February 2016

Product registration no.: 67312

Label approval no.: 67312/105546

Application no: 105548

Product name: Troy Entera Allwormer Tablets For Medium Dogs

Active constituent/s: Each tablet contains: 250 mg febantel, 50 mg praziquantel, 49.8 mg pyrantel (as the embonate)

Applicant name: Troy Laboratories Pty Ltd

Applicant ACN: 000 283 769

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

VANGARD ALLWORMER TABLETS FOR MEDIUM DOGS' to 'TROY ENTERA ALLWORMER

TABLETS FOR MEDIUM DOGS'

**Date of variation:** 1 February 2016

Product registration no.: 67313

Label approval no.: 67313/105548

# **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.

Note: The APVMA is currently assigning separate approval numbers for vet actives which means some vet actives listed in this gazette will have an approval date that occurred in the past. For more information.

#### 1. ACTIVE CONSITUTENT

Application no.: 2455

Active constituent/s: Sodium Hyaluronate
Applicant name: Merial Australia Pty Ltd

**Applicant ACN:** 071 187 285

Summary of use: For use in veterinary chemical products

Date of approval: 24 March 1995

Approval no.: 82357

Application no.: 4199

Active constituent/s: Triclabendazole

Applicant name: Elanco Australasia Pty Ltd

**Applicant ACN:** 076 745 198

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

Date of approval: 6 April 1995 Approval no.: 82176

Application no.: 3872

Active constituent/s: Salinomycin Sodium
Applicant name: Huvepharma EOOD

Applicant ACN: N/A

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

Date of approval: 19 April 1996 Approval no.: 82327

Application no.: 6121
Active constituent/s: Ketoprofen

Applicant name: Merial Australia Pty Ltd

**Applicant ACN:** 071 187 285

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

Date of approval: 24 October 1996

Approval no.: 82360

Application no.: 26597

Active constituent/s: Oxytetracycline Hydrochloride
Applicant name: Phibro Animal Health Pty Limited

Applicant ACN: 093 869 991

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

**Date of approval:** 16 April 1997 **Approval no.:** 82410

Active constituent/s: Nandrolone Decanoate

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

Summary of use: For use in veterinary chemical products

Date of approval: 28 April 1998

Approval no.: 82157

Application no.: 26510

Active constituent/s: Morantel Citrate

Applicant name: Phibro Animal Health Pty Limited

Applicant ACN: 093 869 991

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

Date of approval: 29 April 1998

Approval no.: 82421

Application no.: 17358

Active constituent/s: Testosterone

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

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

Date of approval: 19 July 1999 Approval no.: 82155

Application no.: 17987

Active constituent/s: Testosterone Propionate

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

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

Date of approval: 21 December 1999

Approval no.: 82154

Application no.: 17987

Active constituent/s: Testosterone Cypionate

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

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

Date of approval: 21 December 1999

Approval no.: 82153

Application no.: 11019
Active constituent/s: Inositol

Applicant name: Ceva Animal Health Pty Ltd

Applicant ACN: 002 692 426

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

Date of approval: 26 April 2000 Approval no.: 82318

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

**Applicant ACN:** 156 476 425

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

Date of approval: 25 July 2000 Approval no.: 81641

Application no.: 21919

Active constituent/s: Flavophospholipol
Applicant name: Huvepharma EOOD

Applicant ACN: N/A

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

Date of approval: 13 March 2001

Approval no.: 82328

Application no.: 26401

Active constituent/s: Monensin Sodium

Applicant name: Phibro Animal Health Pty Limited

Applicant ACN: 093 869 991

Summary of use: For use in veterinary chemical products

Date of approval: 26 November 2002

Approval no.: 82398

Application no.: 29139
Active constituent/s: Nicarbazin

Applicant name: Phibro Animal Health Pty Limited

**Applicant ACN:** 093 869 991

Summary of use: For use in veterinary chemical products

Date of approval:8 April 2003Approval no.:82391

Application no.: 30915
Active constituent/s: Carprofen

Applicant name: Apex Laboratories Pty Ltd

**Applicant ACN:** 000 397 240

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

Date of approval: 11 September 2003

Approval no.: 82092

Application no.: 31476

Active constituent/s: Clindamycin Hydrochloride Chanelle Animal Health Ltd

Applicant ACN: N/A

Summary of use: For use in veterinary chemical products

Date of approval: 4 March 2004 Approval no.: 82458 Application no.: 33441
Active constituent/s: Dinitolmide

Applicant name: Phibro Animal Health Pty Limited

**Applicant ACN:** 093 869 991

Summary of use: For use in veterinary chemical products

Date of approval: 27 September 2004

Approval no.: 82372

Application no.: 33163

Active constituent/s: Zinc Bacitracin

Applicant name: Phibro Animal Health Pty Limited

Applicant ACN: 093 869 991

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

Date of approval: 23 March 2005

Approval no.: 82385

Application no.: 35625

Active constituent/s: Methandriol Dipropionate

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

Summary of use: For use in veterinary chemical products

Date of approval: 12 April 2005 Approval no.: 82139

Application no.: 36829

Active constituent/s: Boldenone Undecylenate

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

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

Date of approval: 4 July 2006 Approval no.: 82135

Application no.: 35928
Active constituent/s: Omeprazole

Applicant name: Ceva Animal Health Pty Ltd

**Applicant ACN:** 002 692 426

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

Date of approval: 22 February 2007

Approval no.: 82185

Application no.: 42063

Active constituent/s: Oxantel Embonate

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

Summary of use: For use in veterinary chemical products

Date of approval: 30 July 2007 Approval no.: 82045

Active constituent/s: Pyrantel Embonate

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

Summary of use: For use in veterinary chemical products

Date of approval: 30 July 2007 Approval no.: 82048

Application no.: 40472

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

Applicant ACN: 002 692 426

Summary of use: For use in veterinary chemical products

**Date of approval:** 19 February 2008

Approval no.: 82187

Application no.: 36334
Active constituent/s: Praziquantel

Applicant name: Chanelle Animal Health Ltd

Applicant ACN: N/A

Summary of use: For use in veterinary chemical products

Date of approval: 31 March 2008

Approval no.: 82471

Application no.: 36334

Active constituent/s: Fenbendazole

Applicant name: Chanelle Animal Health Ltd

Applicant ACN: N/A

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

Date of approval: 31 March 2008

Approval no.: 82473

Application no.: 41964
Active constituent/s: Tilmicosin

Applicant name: Huvepharma EOOD

Applicant ACN: N/A

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

Date of approval: 1 July 2008 pproval no.: 82339

Application no.: 42674

Active constituent/s: Monensin Sodium
Applicant name: Huvepharma EOOD

Applicant ACN: N/A

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

Date of approval: 3 October 2008

Active constituent/s: Salinomycin Sodium

Applicant name: Phibro Animal Health Pty Limited

Applicant ACN: 093 869 991

Summary of use: For use in veterinary chemical products

Date of approval: 6 February 2009

Approval no.: 82370

Application no.: 41838

Active constituent/s: Tylosin Phosphate
Applicant name: Huvepharma EOOD

Applicant ACN: N/A

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

Date of approval: 2 October 2009

Approval no.: 82342

Application no.: 49225
Active constituent/s: Dinitolmide

Applicant name: Nutriment Health Pty Ltd

**Applicant ACN:** 628 638 300

Summary of use: For use in veterinary chemical products

Date of approval: 8 November 2010

Approval no.: 82436

Application no.: 48712

Active constituent/s: Glucosamine Hydrochloride

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

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

Date of approval: 24 November 2010

Approval no.: 82107

Application no.: 49987
Active constituent/s: Nicarbazin

Applicant name: Nutriment Health Pty Ltd

Applicant ACN: 628 638 300

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

Date of approval: 3 December 2010

Approval no.: 82388

Application no.: 48753
Active constituent/s: Moxidectin

Applicant name: Merial Australia Pty Ltd

**Applicant ACN:** 071 187 285

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

Date of approval: 10 February 2011

Application no.: 53352
Active constituent/s: Ivermectin

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 008 423 018

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

Date of approval: 21 July 2011 Approval no.: 82361

Application no.: 53352
Active constituent/s: Praziquantel

Applicant name: RWR Veterinary Products Pty Ltd

**Applicant ACN:** 088 423 018

Summary of use: For use in veterinary chemical products

Date of approval: 21 July 2011 Approval no.: 82362

Application no.: 51351

Active constituent/s: Flavophospholipol
Applicant name: Nutriment Health Pty Ltd

**Applicant ACN:** 628 638 300

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

Date of approval: 25 July 2011 Approval no.: 82433

Application no.: 57612

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

**Applicant ACN:** 628 638 300

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

Date of approval: 26 August 2012

Approval no.: 82427

Application no.: 46158
Active constituent/s: Meloxicam

Applicant name: Chanelle Animal Health Ltd

Applicant ACN: N/A

Summary of use: For use in veterinary chemical products

Date of approval: 28 May 2013
Approval no.: 82470

Application no.: 63230

Active constituent/s: Bacitracin Zinc

Applicant name: Nutriment Health Pty Ltd

Applicant ACN: 628 638 300

Summary of use: For use in veterinary chemical products

Date of approval: 2 June 2015 Approval no.: 82424

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

**Applicant ACN:** 628 638 300

Summary of use: For use in veterinary chemical products

Date of approval: 8 July 2015 Approval no.: 82431

Application no.: 101895
Active constituent/s: Praziquantel

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

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

Date of approval: 27 November 2015

Approval no.: 80904

Application no.: 102411
Active constituent/s: Abamectin

Applicant name: Zoetis Australia Pty Ltd

**Applicant ACN:** 156 476 425

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

Date of approval: 16 December 2015

Approval no.: 81143

Application no.: 101377
Active constituent/s: Ivermectin

Applicant name: Exelpet Products A Div Of Mars Australia Pty Ltd

**Applicant ACN:** 008 454 313

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

Date of approval: 20 January 2016

Approval no.: 82319

Application no.: 24620

Active constituent/s: Clostridium Perfringens Type D Toxoid (Inactivated)

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of use: For use in veterinary chemical products

Date of approval: 21 January 2016

Approval no.: 82177

Application no.: 24620

Active constituent/s: Clostridium Tetani Toxoid (Inactivated)

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

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

Date of approval: 21 January 2016

Active constituent/s: Corynebacterium Pseudotuberculosis (Inactivated)

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

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

Date of approval: 21 January 2016

Approval no.: 82179

Application no.: 102688
Active constituent/s: Moxidectin

Applicant name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

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

Date of approval: 3 February 2016

Approval no.: 81254

#### 2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.: 103526

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

**Applicant ACN:** 156 476 425

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

Date of variation: 31 July 2015

Approval no.: 81641

Application no.: 101660

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

**Applicant ACN:** 156 476 425

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

Date of variation: 13 January 2016

Approval no.: 81897

Application no.: 104265
Active constituent/s: Omeprazole

Applicant name: Merial Australia Pty Ltd

**Applicant ACN:** 071 187 285

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

Date of variation: 18 January 2016

Approval no.: 55318

Application no.: 104256
Active constituent/s: Spiramycin

Applicant name: Merial Australia Pty Ltd

**Applicant ACN:** 071 187 285

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

**Date of variation:** 16 February 2016

Application no.: 105359
Active constituent/s: Eprinomectin

Applicant name: Merial Australia Pty Ltd

**Applicant ACN:** 071 187 285

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

**Date of variation:** 18 February 2016

Approval no.: 55471

Application no.: 103127
Active constituent/s: Metribuzin

Applicant name: Bayer Cropscience Pty Ltd

**Applicant ACN:** 000 226 022

Summary of use: For use in agricultural chemical products

Date of approval: 23 February 2016

Approval no.: 81441

Application no.: 103317
Active constituent/s: Isoxaflutole

Applicant name: Adama Australia Pty. Limited

**Applicant ACN:** 050 328 973

Summary of use: For use in agricultural chemical products

Date of approval: 3 March 2016

Approval no.: 81538

Application no.: 103070
Active constituent/s: Fluioxonil

Applicant name: UPL Australia Limited

**Applicant ACN:** 066 391 384

Summary of use: For use in agricultural chemical products

Date of approval: 4 March 2016

Approval no.: 81424

Application no.: 103440
Active constituent/s: Hexazinone

Applicant name: Sanonda (Australia) Pty Ltd

**Applicant ACN:** 059 813 973

Summary of use: For use in agricultural chemical products

Date of approval: 8 March 2016

Approval no.: 81602

Application no.: 103060

Active constituent/s: Clodinafop-propargyl
Applicant name: Agrogill Chemicals Pty Ltd

**Applicant ACN:** 094 672 107

Summary of use: For use in agricultural chemical products

Date of approval: 9 March 2016

Application no.: 102763
Active constituent/s: Prosulfocarb

Applicant name: TGAC Australia Pty. Ltd

**Applicant ACN:** 134 570 700

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

Date of approval: 15 March 2016

### APVMA review of maldison—suspension of product and associated labels

This notice is issued under s.45A(1)(b) of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (the Agvet Code) and provides notice that the Australian Pesticides and Veterinary Medicines Authority (APVMA) has suspended the registration of product 33018 Nufarm Maldison 500 Insecticide (product 33018) and all associated labels as specified in Table 1 below.

The suspension will be in effect from 15 March 2016 until 1 March 2017.

The suspension will include a phase-out period from 15 March 2016 until 1 March 2017 under the conditions of a deemed permit under s.45B of the Agvet Code, allowing possession, custody, supply and use of the product according to label directions. The deemed permit does not allow manufacture or import of the product. The APVMA declares that after 1 March 2017, s.45B(1) of the the Agvet Code ceases to apply in respect of product 33018 and the permit will not be in force.

Table 1—Details of product registration and label approvals subject to suspension

Product number	Product name	Holder	Label approval(s)
33018	Nufarm Maldison 500 Insecticide	Nufarm Australia Limited	0100, 0103, 0207, 0402, 0901

#### **REASONS FOR THE SUSPENSION**

The APVMA review of maldison commenced in 2003 due to human health concerns including the potential formation of toxic impurities during storage. As part of the review, the APVMA conducted a chemical stability assessment of product 33018 and determined that the concentration of the toxic impurity, isomalathion, exceeded the safe limit after extended storage, based on Food and Agricultural Organisation of the United Nations (FAO) specifications for maldison (2013). Consequently, it appears to the APVMA that the product does not meet the *safety criteria as defined under s5A of the Agvet Code* (the safety criteria) as it may:

- be an undue hazard to the safety of people exposed to it during its handling
- have an effect that is harmful to human beings.

Under s.41(1)(b) of the Agvet Code, the APVMA may suspend the registration of a chemical product if it appears to the APVMA that the product may not meet the safety criteria. The APVMA may also suspend the approval of a label under s.44(2) of the Agvet Code if the APVMA suspends the registration of the inter-related chemical product.

Consequently, the APVMA has suspended the registration of product 33018, based on s.41(1)(b) of the Agvet Code, for the reasons outlined above. The APVMA has also suspended all associated label approvals under s.44(2) of the Agvet Code.

# INSTRUCTIONS FOR DEALING WITH THE SUSPENDED PRODUCT

The following instructions apply to people dealing with product 33018 during the period of suspension from 15 March 2016 until 1 March 2017:

- possession, custody, supply and use of product 33018 in accordance with label directions is permitted
- manufacture or import of product 33018 is not permitted.

#### **WARNING**

From 15 March 2016 until 1 March 2017, under s.45C(2) of the Agvet Code, a person may only possess, have custody of or otherwise deal with product 33018 in accordance with the instructions contained in this notice. Failure to comply with the instructions contained in this notice is an offence which attracts a fine of 300 penalty units<sup>1</sup> as specified under s.45C(5) of the Agvet Code.

The APVMA may undertake further regulatory actions for product 33018 during the suspension period which may impact the suspension conditions.

#### **APVMA CONTACT**

### For further information please contact:

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

Phone: +61 2 6210 4749 Fax: +61 2 6210 4776

Email: <a href="mailto:chemicalreview@apvma.gov.au">chemicalreview@apvma.gov.au</a>

1 A penalty unit is defined by the Crimes Act 1914 to mean \$180.

# This content is subject to an erratum to be published in Gazette No. 7, 5 April 2016. The correct title is 'New active constituent—bixafen'

### New veterinary active constituent—bixafen

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, bixafen for use as a fungicide in agricultural products.

Common Name Bixafen

IUPAC Name: N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methyl-1H-

pyrazole-4-carboxamide

Chemical Abstracts Name: N-(3',4'-dichloro-5-fluoro[1,1'-biphenyl]-2-yl)-3-(difluoromethyl)-1-methyl-

1H-pyrazole-4-carboxamide

CAS Number: 581809-46-3

Molecular Formula: C<sub>18</sub>H<sub>12</sub>Cl<sub>2</sub>F<sub>3</sub>N<sub>3</sub>O

Molecular Weight: 414.21

Structure:

Chemical Family: Anilide fungicide and pyrazole fungicide

Mode of Action: Inhibition of mitochondrial function by disrupting complex II (succinate

dehydrogenase) in the respiratory electron transport chain

# SUMMARY OF THE APVMA'S EVALUATION OF BIXAFEN ACTIVE CONSTITUENT

The Scientific Assessment and Chemical Review Program of the APVMA has evaluated the chemistry aspects of bixafen active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The Office of Chemical Safety has considered the toxicological aspects of bixafen, and advised that there are no objections on toxicological grounds to the approval of the active constituent bixafen. An Acceptable Daily Intake (ADI) of 0.02 mg/kg bw/d and an Acute Reference Dose (ARfD) of 0.2 mg/kg bw have been set. On 27 November 2015, the Delegate to the Secretary of the Department of Health published a final scheduling decision to create a new Schedule 5 entry for bixafen in the Standard for the Uniform Scheduling of Medicines and Poisons, with no exemption cut-off, and an implementation date of 1 February 2016.

The APVMA accepts the findings and recommendations of its adviser on these criteria.

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

#### **MAKING A SUBMISSION**

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of bixafen should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. These grounds include chemistry and manufacture, and toxicity. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

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

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

Written submissions on the APVMA's proposal to grant approval for bixafen that relate to the grounds for approval should be addressed in writing to:

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

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

Email: enquiries@apvma.gov.au

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

This content is subject to an erratum to be published in Gazette No. 7, 5 April 2016.

The correct applicant name is Bayer CropScience Pty Ltd. Product use information has been corrected to remove application on barley, oats, triticale and wheat and minor typographical errors have been corrected.

# New agricultural chemical products bixafen in aviator xpro foliar fungicde

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Sumitomo Chemical Australia Pty Ltd for registration of a new product containing the new active bixafen and the existing active constituent prothioconazole. The product Aviator Xpro Foliar Fungicide is for use on canola.

#### PARTICULARS OF THE APPLICATION

Proposed Product Name(s): AVIATOR XPRO FOLIAR FUNGICIDE

Applicant Company:

Name of Active Constituent: Bixafen

Signal Heading:

Summary of Proposed Use: For the control of black leg (Leptosphaeria maculans)) in canola

Pack Sizes: 10 L, 15 L, 10 L, 20 L, 100 L, 110 L and 1000 L

Withholding Period: Harvest: Not required when used as directed

Grazing: Livestock Not Producing Milk for Human Consumption: Do not

graze or cut for stock food for 4 weeks after application.

<u>Livestock Producing milk for Human Consumption</u>: Do not graze livestock producing milk for human consumption on treated crops.

SUMMARY OF THE APVMA'S EVALUATION OF AVIATOR XPRO FOLIAR FUNGICIDE IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

(i) The APVMA is satisfied that the proposed use of AVIATOR XPRO FOLIAR FUNGICIDE would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Department of Health and Ageing has conducted a risk assessment on the product and concluded that it can be used safely.

Aviator Xpro Foliar Fungicide is intended only for professional use, and farmers and their employees will be the main users of the product. The product will be applied by various ground boom or aerial applications. Workers may be exposed to the product when opening containers, mixing/loading, application, cleaning up spills, maintaining equipment and entering treated crops. The main routes of exposure to the product spray will be dermal and inhalation, with possible ocular exposure.

In the absence of exposure data for bixafen and for the proposed aerial mode of application for prothioconazole, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide was used to estimate exposure. The database was also used to verify the calculated exposure of workers to prothioconazole via ground boom application from submitted exposure studies.

Estimated exposures to the product when preparing and using the spray by ground boom or aerial application were at acceptable levels when wearing personal protective equipment (PPE). Based on the risk assessment, First Aid Instructions, Safety Directions and Re-entry statements have been recommended for the product label.

Based on the risk assessment, First Aid Instructions, Safety Directions and Re-entry statements have been recommended for the product label.

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of Aviator Xpro Foliar Fungicide when used in accordance with the label directions.

(ii) The APVMA is satisfied that the proposed use of AVIATOR XPRO FOLIAR will not be an undue hazard to the safety of people using anything containing its residues.

The product will be used as a foliar spray canola. The APVMA Residues and Trade Section has evaluated the residues aspects of the proposed product and has recommended amendments to the APVMA MRL Standard for bixafen and for inclusion in the Food Standards Code. Dietary intake modelling has shown the expected chronic and acute dietary exposures to bixafen are both below the relevant health standards. Recommendations in regard to the withholding period and protection statements for livestock have been included on the label.

The APVMA is satisfied that the proposed use of AVIATOR XPRO FOLIAR FUNGICIDE containing the active constituents bixafen and prothioconazole is not likely to be harmful to human beings if used according to the product label.

Bixafen is a carboxamide fungicide belonging to the sub-class of the pyrazole-carboxamides, a succinate dehydrogenase inhibitor of fungal pathogens. The proposed use of a new emulsifiable concentrate product, Aviator Xpro Foliar Fungicide, containing bixafen at 75 g/L and prothioconazole at 150 g/L, is for the control and/or suppression of foliar diseases in barley, oats, triticale, wheat and canola. Aviator Xpro Foliar Fungicide will be available in pack sizes between 10 and 1000 L.

In toxicokinetics studies in rats, bixafen was absorbed rapidly and overall oral absorption was high. After absorption, bixafen was widely distributed and detected, at low concentrations, in most examined tissues. Elimination of absorbed bixafen was rapid, with the majority of the administered radioactivity eliminated in faeces within the first 24 hours. Bixafen was highly metabolised with only approximately 9 % was excreted in the unchanged form.

Based on the findings of the acute toxicological studies evaluated, bixafen has low acute oral, dermal and inhalational toxicity in rats. Bixafen is not a skin or eye irritant in rabbits. No determination on whether bixafen is a skin sensitiser could be made, as a guideline-compliant skin sensitisation study was not provided.

Bixafen was generally well tolerated across the species tested in repeat-dose toxicity studies, with decreases in body weight and body weight gain identified along with increases in liver weights, with associated histopathological changes, as the main treatment-related effects. Carcinogenicity studies indicated that bixafen was not carcinogenic in mice or rats. Bixafen was negative in *in vitro* and *in vivo* mutagenicity and/or genotoxicity studies.

Bixafen was not a reproductive or developmental toxicant, as measured reproductive and developmental indices, including malformation/variation frequencies, were only seen at doses that showed significant maternal toxicity. Across acute and subchronic studies, bixafen was not a neurotoxicant.

Based on the findings of the acute toxicological studies evaluated, the product Aviator Xpro Foliar Fungicide has low acute oral and dermal toxicity in rats and has low estimated inhalational toxicity. Aviator Xpro Foliar Fungicide was a severe eye and a slight skin irritant in rabbits, and was not a skin sensitiser in mice (LLNA method).

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of Aviator Xpro Foliar Fungicide when used in accordance with the label directions.

(iii) The APVMA is satisfied that the proposed use of AVIATOR XPRO FOLIAR FUNGICIDE containing the active constituents bifaxen and prothioconazole is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

Data provided in support of the proposed use have been assessed and it is concluded that the risks to the environment from this use are acceptable provided that the draft label is updated to meet current spray drift requirements.

Bixafen is stable to hydrolysis and photolytic degradation. It is persistent in the terrestrial environment with field half-lives potentially exceeding 1000 days. However, it is not expected to be mobile in soil. When released to water, bixafen may be expected to partition to the sediments where again, it is likely to be very persistent. Bixafen is not likely to bio-accumulate.

Bixafen is practically non-toxic to birds based on acute and dietary exposure. No effects on avian reproduction are expected based on application rates and uses assessed. It was found to be very highly toxic to fish and moderately toxic to aquatic invertebrates based on both acute and chronic exposure.

Bixafen was very highly toxic to two of four standard algal test species and was at worst highly toxic to the standard floating aquatic macropyte, *Lemna gibba*.

Bixafen generally did not exhibit toxicity towards terrestrial invertebrates or soil microorganisms at levels expected through the proposed use pattern. Tier 1 testing using the formulated end-use product showed some terrestrial plants were potentially based on growth measurements, but mortality was not observed at use rates higher than those currently proposed.

In spite of conservative modelling, the risk assessment determined that the chemical is unlikely to pose an environmental risk under the proposed use pattern, provided the draft label is updated to meet current requirements, and appropriate down-wind spray drift buffer zones are implemented for the protection of sensitive aquatic and terrestrial areas.

The APVMA has considered these findings accepts these conclusions.

(iv) The APVMA is considering whether the proposed use of AVIATOR XPRO FOLAIR FUNGICDE would not adversely affect trade between Australia and places outside Australia.

Export of treated produce containing finite (measurable) residues of bixafen and prothioconazole may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

No changes to established prothioconazole MRLs for rape seed and animal commodities are proposed and therefore the proposed use of prothioconazole is unlikely to increase the risk to international trade.

The proposed residue definition for bixafen is the same as that established by Codex, the EU and New Zealand. International MRLs have not been established for bixafen by Codex, the USA, Korea and Taiwan.

An MRL for canola is proposed at the LOQ (\*0.01 mg/kg) and therefore the export of treated canola is unlikely to result in an undue risk to international trade.

Bixafen MRLs for meat [mammalian] [in the fat] and edible offal (Mammalian) at 0.1 and 0.3 mg/kg respectively are required for the proposed use on canola. The proposed Export Slaughter Interval of 7 days should adequately prevent residues above the LOQ of 0.02 mg/kg in animal commodities destined for export.

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

'EXPORT OF TREATED PRODUCE: Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with Aviator Xpro. If you are growing produce for export, please check with Bayer CropScience for the latest information on MRLs and import tolerances before using Aviator Xpro', and, 'EXPORT SLAUGHTER INTERVAL (ESI—7 DAYS: Livestock not producing milk for human consumption that have been grazing on treated crops should be placed on clean feed for 7 days prior to slaughter').

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

(v) 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.

#### **FURTHER INFORMATION**

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, or by contacting the APVMA via the details listed below.

### **MAKING A SUBMISSION**

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of AVIATOR XPRO FOLIAR FUNGICIDE should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds include occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

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 a:

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

All personal and *confidential commercial information (CCI)*<sup>3</sup> material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Case Management and Evaluation
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

**Phone:** +61 2 6210 4700 **Fax:** +61 2 6210 4776

Email: enquiries@apvma.gov.au

<sup>3</sup> A full definition of 'confidential commercial information' is contained in the <u>Agvet Code</u>.

# Final pesticide and veterinary medicines product sales 2014–15 financial year

This notice provides the collated final product sales information provided to the APVMA for the 2014–15 financial year.

# AGRICULTURAL (PESTICIDES) PRODUCT SALES FOR THE 2014–15 FINANCIAL YEAR

AGRICULTURAL PRODUCT TYPES	NO OF PRODUCTS	TOTAL \$
ADJUVANTS/SURFACTANTS	424	80,014,340.00
ANTIFOULING—BOAT	48	17,227,430.00
DAIRY CLEANSER	133	12,573,155.00
DISINFECTANT/SANITISER	104	10,193,093.00
FUNGICIDE	959	206,610,557.00
GROWTH PROMOTERS/REGULATORS	243	30,144,204.00
HERBICIDE	3119	1,545,493,477.00
HOUSEHOLD INSECTICIDE	588	141,589,433.00
INSECTICIDE	1514	332,456,018.00
MISC(E.G: SEED SAFENERS, MARKERS ETC)	51	4,888,882.00
MITICIDE	128	20,860,763.00
MIXED FUNCTION PESTICIDE	219	71,744,276.00
MOLLUSCICIDE	53	15,569,949.00
NEMATICIDE	18	3,904,630.00
POOL PRODUCTS/ALGICIDE	757	63,705,670.00
REPELLENTDOGS/BIRDS ETC	18	1,224,072.00
SEED TREATMENTS	64	8,130,289.00
VERTEBRATE POISON	217	18,471,093.00
WOOD PRESERVATIVE	16	2,870,360.00
GRAND TOTAL	8673	2,587,671,691.00

# VETERINARY MEDICINES PRODUCT SALES FOR THE 2014–15 FINANCIAL YEAR

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL \$
ALIMENTARY SYSTEM	ANTI BLOAT	17	1,791,473.00
ALIMENTARY SYSTEM	ANTIDIARRHOEALS AND SCOUR TREATMENTS	17	1,409,472.00
ALIMENTARY SYSTEM	LAXATIVES, PURGATIVES & LUBICANTS, ANTISPASMODICS	14	2,290,657.00
ANAESTHETICS/ANALGESICS	ANAESTHETICS—LOCAL AND GENERAL	51	11,577,854.00
ANAESTHETICS/ANALGESICS	ANALGESICS	19	4,887,581.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—INTRAMAMMARY	28	11,217,459.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—ORAL	200	25,995,462.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—PARENTERAL	79	28,038,113.00
ANTIBIOTIC & RELATED	OTHER ANTI-INFECTIVE AGENTS	46	1,682,589.00
ANTIBIOTIC & RELATED	SULFONAMIDES	40	2,922,236.00
ANTIDOTES	ANTIDOTES	16	1,302,556.00
CARDIOVASCULAR SYSTEM	CARDIAC REACTANTS, CLOTTING AGENTS	43	7,345,104.00
CENTRAL NERVOUS SYSTEM	HYPNOTICS, TRANQUILIZERS, EMETICS, ANTIEMETICS	43	4,645,783.00
DERMATOLOGICAL PREPS.	ANTIBIOTICS, ANTIFUNGALS, CORTICOSTEROID COMBINATIONS	30	2,572,941.00
DERMATOLOGICAL PREPS.	ANTISEPTICS (DERMATOLOGICAL AND GENERAL)	139	24,210,888.00
DERMATOLOGICAL PREPS.	NONSTEROIDAL ANTIPRURITICS, KERATOLYICS	36	5,556,013.00
EAR,NOSE,THROAT PREPS.	AURAL	27	6,434,754.00
ENDOCRINE SYSTEM	ANABOLIC STEROIDS	21	174,256.00
ENDOCRINE SYSTEM	CORTICOSTEROIDS AND ADRENAL COMPOUNDS	32	3,272,236.00
ENDOCRINE SYSTEM	SEX HORMONES	56	9,233,990.00
ENDOCRINE SYSTEM	TROPIC HORMONES (PITUITARY) & INSULIN PREPARATIONS	37	6,309,977.00
GENITOURINARY SYSTEM	DIURETICS, ACIDIFIERS, ALKANISERS	27	1,612,727.00
GENITOURINARY SYSTEM	UTERINE OR VAGINAL ACTING AGENTS	7	1,070,336.00
IMMUNOTHERAPY	ANTISERA, ANTIVENIM	9	2,647,060.00

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL \$
IMMUNOTHERAPY	IMMUNOMODIFYING AGENTS	11	2,523,090.00
IMMUNOTHERAPY	INJECTABLE VACCINES	177	134,775,418.00
IMMUNOTHERAPY	NASAL, ORAL, OPTHALMIC VACCINES	34	26,856,036.00
MISC	MISC	92	21,672,580.00
MUSCULOSKELETAL SYSTEM	ANTI-INFLAMMATORY AGENTS	236	30,667,346.00
MUSCULOSKELETAL SYSTEM	COUNTER-IRRITANTS, RUBEFACIENTS, POULTICES	16	2,712,813.00
NUTRITION & METABOLISM	ANTIBIOTIC AND ANTI-INFECTIVE SUPPLEMENTS	47	4,086,166.00
NUTRITION & METABOLISM	DIETARY/THERAPEUTIC PET FOODS	147	51,606,194.00
NUTRITION & METABOLISM	DIGESTIVE ENZYME SUPPLEMENTS	78	14,670,986.00
NUTRITION & METABOLISM	ELECTROLYTES	71	4,864,031.00
NUTRITION & METABOLISM	GROWTH PROMOTANTS	66	22,823,595.00
NUTRITION & METABOLISM	IRON AND HAEMOPOIETIC AGENTS	24	1,391,344.00
NUTRITION & METABOLISM	PROBIOTIC AND PREBIOTIC	25	1,790,699.00
NUTRITION & METABOLISM	TONICS, STIMULANTS	13	365,076.00
NUTRITION & METABOLISM	VITAMIN, MINERAL, & NUTRITIONAL SUPPLEMENTS	226	31,044,170.00
OPHTHALMIC PREPARATIONS	OPHTHALMIC PREPARATIONS	21	2,247,854.00
PARASITICIDES	BIRDS—EXTERNAL	12	335,106.00
PARASITICIDES	BIRDS—INTERNAL	30	2,736,734.00
PARASITICIDES	LARGE & SMALL ANIMALS— EXTERNAL	18	2,062,593.00
PARASITICIDES	LARGE ANIMALS—EXTERNAL	193	68,050,511.00
PARASITICIDES	LARGE ANIMALS—INTERNAL	285	55,081,482.00
PARASITICIDES	LARGE ANIMALS—INTERNAL & EXTERNAL	96	54,881,156.00
PARASITICIDES	SMALL ANIMALS—EXTERNAL	227	108,580,997.00
PARASITICIDES	SMALL ANIMALS—INTERNAL	263	81,753,386.00
PARASITICIDES	SMALL ANIMALS INTERNAL AND EXTERNAL	39	57,785,403.00
RESPIRATORY SYSTEM	EXPECTORANTS, MUCOLYTICS, DECONGESTANTS, BRONCHODILATORS, RESP STIMULANTS	20	1,297,823.00
GRAND TOTAL		3501	954,864,106.00

# **APVMA CONTACT**

For further information please contact:

Finance

Corporate Services
Australian Pesticides and Veterinary Medicines Authority
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KINGSTON ACT 2604

Phone: +61 2 6210 4808Fax: +61 2 6210 4874Email: finance@apvma.gov.au