

Commonwealth of Australia

Gazette

No. APVMA 25, Tuesday, 13 December 2016

Published by The Australian Pesticides and Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS



Australian Government

Australian Pesticides and Veterinary Medicines Authority

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

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GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

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

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

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

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

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Erratum Notice

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, APVMA 24, Tuesday, 29 November 2016.

In the notice, Sero-X Insecticide containing Clitoria ternatea extract, the signal heading was listed incorrectly.

The correct entry for Sero-X Insecticide containing Clitoria ternatea extract is on page 18 of this gazette.

Agricultural Chemical Products and Approved Labels

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

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.: 107595

Product name: Am-troll 250 Herbicide

Active constituent/s: 250 g/L amitrole, 220 g/L ammonium thiocyanate

Applicant name: Crop Culture Pty Ltd

Applicant ACN: 142 860 473

Summary of use For the control of weeds in orchards, vineyards, irrigation ditches and drains, roadsides, wheat

and barley, and for general industrial situations

Date of registration: 18 November 2016

Product registration no.: 83128

Label approval no.: 83128/107595

Application no.: 107564

Product name: CGS Prep 900 Growth Regulator

Active constituent/s: 900 g/L ethephon (an anticholinesterase compound)

Applicant name: Cotton Growers Services Pty Ltd

Applicant ACN: 001 723 048

Summary of use For accelerated boll opening and pre-conditioning before defoliation of cotton

Date of registration: 18 November 2016

Product registration no.: 83118

Label approval no.: 83118/107564

Application no.: 107629

Product name: Relyon Mueso 720 Fungicide

Active constituent/s: 720 g/L chlorothalonil
Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

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

onions, peaches, peanuts, pulses, plums, potatoes, tomatoes and vegetables

Date of registration: 22 November 2016

Product registration no.: 83144

Label approval no.: 83144/107629

Application no.: 107614

Product name: Relyon Prosumi 500SC Fungicide

Active constituent/s: 500 g/L procymidone
Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of use For the control of certain fungal diseases on various crops

Date of registration: 22 November 2016

Product registration no.: 83139

Label approval no.: 83139/107614

Product name: GP FluPro 745 SL Herbicide

Active constituent/s: 745 g/L flupropanate present as the sodium salt

Applicant name: Granular Products Pty Ltd

Applicant ACN: 110 555 952

Summary of use For use as a component of integrated management of serrated tussock, giant parramatta grass,

giant rat's tail grass, chilean needle grass, african lovegrass and certain grasses

Date of registration: 23 November 2016

Product registration no.: 83153

Label approval no.: 83153/107643

Application no.: 107631

Product name: Relyon Mueso 900WG Fungicide

Active constituent/s: 900 g/kg chlorothalonil Ruralco Holdings Limited Applicant name:

Applicant ACN: 009 660 879

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

grapes, onions, peaches, peanuts, pulses, plums, potatoes, tomatoes and vegetables

23 November 2016 Date of registration:

Product registration no.: 83145

83145/107631 Label approval no.:

Application no.: 104167

Product name: Farmalinx Zombie Fungicide

Active constituent/s: 200 g/L tebuconazole, 100 g/L trifloxystrobin

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

For control of fungal diseases in recreational turf Summary of use

Date of registration: 24 November 2016

Product registration no.: 81858

Label approval no.: 81858/104167

107096 Application no.:

Product name: Relyon Aspire 400WG Herbicide

Active constituent/s: 400 g/kg tralkoxydim Applicant name: Ruralco Holdings Limited

009 660 879 **Applicant ACN:**

Summary of use For the control of wild oats and annual ryegrass and suppression of annual phalaris in wheat,

barley, rye and triticale

Date of registration: 24 November 2016

Product registration no.: 82910

82910/107096 Label approval no.:

106648 Application no.:

Product name: Metsa 600 Herbicide

Active constituent/s: 600 g/kg metsulfuron-methyl Applicant name: FDC Eco Solutions Pty Ltd

Applicant ACN: 608 235 187

Summary of use For the control of brush and broadleaf weeds in rights of way, native pastures, commercial and

industrial areas and for the control of certain broadleaf weeds in winter cereal crops

Date of registration: 24 November 2016

Product registration no.: 82750

Label approval no.: 82750/106648

Product name: Rid Away Herbicide

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

Applicant name: Shandong Rainbow International Co., Ltd

Applicant ACN: N/A

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

Date of registration: 28 November 2016

Product registration no.: 83008

Label approval no.: 83008/107299

Application no.: 107686

Product name: Relyon Stark 440EC Herbicide

Active constituent/s: 440 g/L pendimethalin
Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of use For the control of wireweed, annual grasses and certain broadleaf weeds in various crops

Date of registration: 28 November 2016

Product registration no.: 83181

Label approval no.: 83181/107686

Application no.: 105293

Product name: Genfarm Triclopyr 755EC Herbicide

Active constituent/s: 755 g/L triclopyr present as the butoxyethyl ester

Applicant name: Landmark Operations Limited

Applicant ACN: 008 743 217

Summary of use For control of a range of woody weeds and melons in various situations

Date of registration: 29 November 2016

Product registration no.: 82254

Label approval no.: 82254/105293

Application no.: 107678

Product name: Barmac Metalaxyl 250 Systemic Fungicide

Active constituent/s: 250 g/L metalaxyl
Applicant name: Amgrow Pty Ltd
Applicant ACN: 100 684 786

Summary of use For control of phytophthora heart rot and root rot of pineapples

Date of registration: 29 November 2016

Product registration no.: 83174

Label approval no.: 83174/107678

Application no.: 107672

Product name: Barmac Fipronil 200 SC Insecticide

Active constituent/s: 200 g/L fipronil
Applicant name: Amgrow Pty Ltd
Applicant ACN: 100 684 786

Summary of use For the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger,

wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane and swede

Date of registration: 29 November 2016

Product registration no.: 83168

Label approval no.: 83168/107672

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Product name: Relyon Adopt Spray Oil

Active constituent/s: 582 g/L paraffinic oil, 240 g/L alkoxylated alcohol non-ionic surfactants

Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of use For use in improving the spreading and wetting of herbicides, insecticides and defoliants

on plant surfaces

Date of registration: 29 November 2016

Product registration no.: 82841

Label approval no.: 82841/106916

Application no.: 107697

Product name: Spalding Billabong Spray Oil

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

Applicant name: Spalding Holdings Pty. Ltd

Applicant ACN: 010 155 852

Summary of use For use as a biodegradable penetrator adjuvant to enhance the effectiveness of certain

herbicides

Date of registration: 1 December 2016

Product registration no.: 83186

Label approval no.: 83186/107697

Application no.: 107676

Product name: Barmac Picloram/Triclopyr Herbicide

Active constituent/s: 100 g/L picloram present as the hexyloxypropylamine salt, 300 g/L triclopyr present as the

butoxyethyl ester

Applicant name: Amgrow pty ltd Applicant ACN: 100 684 786

Summary of use For control of a range of environmental and noxious woody and herbaceous weeds

Date of registration: 1 December 2016

Product registration no.: 83172

Label approval no.: 83172/107676

Application no.: 105057

Product name: Titan Flamprop 90 Herbicide
Active constituent/s: 90 g/L flamprop-m-methyl

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

Summary of useFor the control of wild oats (black oats) by post-emergence treatment in wheat and triticale and

selective spray topping of wild oats in wheat only

Date of registration/approval: 1 December 2016

Product registration no.: 82126

Label approval no.: 82126/105057

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Product name: Relyon Splice 700WG Herbicide

Active constituent/s: 700 g/kg imazethapyr
Applicant name: Ruralco Holdings Limited

Applicant ACN: 009 660 879

Summary of use For the pre- or post-emergence control of certain weeds in centrosema, chickpeas, faba

beans, field peas, lucerne, mung beans, peanuts, serradella, soybeans and subterranean

clover

Date of registration: 1 December 2016

Product registration no.: 82942 Label approval no.: 82942/107177

Application no.: 102599

Product name:

Active constituent/s:

Applicant name:

AC Feud 800 WG Herbicide
800 g/kg flumetsulam
Axichem Pty Ltd

Applicant ACN: 131 628 594

Summary of use For the control of post-emergence and salvage control of certain broad leaf weeds in winter cereals

(including those undersown with clover, lucerne or medics); clover, fenugreek, lathyrus, lucerne, medic, serradella and vetch (popany only) seed crops and pastures; chickpeas, field peas, lentils, maize, peanuts; and for the pre-emergence control of certain broadleaf weeds in maize and

soybeans

Date of registration: 1 December 2016

Product registration no.: 81255

Label approval no.: 81255/102599

Application no.: 107438

Product name: Eureka! Dimethomorph Fungicide WP

Active constituent/s: 500 g/kg dimethomorph
Applicant name: Eureka! Agresearch Pty Ltd

Applicant ACN: 086 194 738

Summary of use For the control of various diseases of cucurbits, grapevines, head lettuce, onions, oilseed poppies

and potatoes, when mixed with mancozeb or metiram 700 g/kg dry flowable fungicide spray,

protectant fungicides

Date of registration: 1 December 2016

Product registration no.: 83072

Label approval no.: 83072/107438

Application no.: 107093

Product name: Spalding Climax 400 Herbicide

Active constituent/s: 300 g/L triclopyr present as the butoxyethyl ester,100 g/L picloram present as

hexyloxypropylamine salt

Applicant name: Spalding Holdings Pty Ltd

Applicant ACN: 010 155 852

Summary of use For the control of a range of environmental and noxious woody and herbaceous weeds

Date of registration: 6 December 2016

Product registration no.: 82908

Label approval no.: 82908/107093

2. VARIATIONS OF REGISTRATION

Application no: 108196

Product name: Monza Herbicide

Active constituent/s: 750 g/kg sulfosulfuron

Applicant name: Sumitomo Chemical Australia Pty Limited

Applicant ACN: 081 096 255

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

HERBICIDE BY MONSANTO' to 'MONZA HERBICIDE'

Date of variation: 12 October 2016

Product registration no.: 49993

Label approval no.: 49993/108196

Application no: 108494

Product name: Garden Essentials Weed Kill 360 Concentrate

Active constituent/s: 360 g/L glyphosate present as the isopropylamine salt

Applicant name: Australian Prime Fibre Pty Ltd

Applicant ACN: 092 742 991

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

'ACCENSI GLYPHOSATE 360 BIAQUATIC WEED KILLER' to 'GARDEN ESSENTIALS WEED

KILL 360 CONCENTRATE'

Date of variation: 2 November 2016

Product registration no.: 65078

Label approval no.: 65078/108494

Application no: 106998

Product name: Melpat Hydrocop WG Fungicide/Bactericide

Active constituent/s: 500 g/kg copper (CU) present as cupric hydroxide

Applicant name: Melpat International Pty Ltd

Applicant ACN: 066 067 507

Summary of variation:

To remove restriction preventing application after shuck fall and to increase maximum number of

applications to 4 in almonds

Date of variation: 17 November 2016

Product registration no.: 62910 Label approval no.: 62910/106998

Application no: 107380

Product name: Agroreg Atrazine 500 SC Herbicide

Active constituent/s: 500 g/L atrazine
Applicant name: Ozcrop Pty Ltd
Applicant ACN: 160 656 431

Summary of variation: To change product name from 'AGROREG ATRAZINE 500 SC HERBICIDE' to 'OZCROP

ATRAZINE 500 SC HERBICIDE' and add new pack sizes

Date of variation: 17 November 2016

Product registration no: 59849

Label approval no: 59849/107380

Product name: Apparent Gibberellic Acid Plant Growth Regulator

Active constituent/s: 200 g/kg gibberellic acid
Applicant name: Apparent Pty. Ltd.

Applicant ACN: 143 724 136

Summary of variation: To extend the product to stimulate the production of winter dormant grass for high intensity grazing

Date of variation: 23 November 2016

Product registration no.: 81255

Label approval no.: 81255/107682

Application no: 106871

Product name: Campbell Cheers 720 Weathershield Fungicide

Active constituent/s: 720 g/L chlorothalonil

Applicant name: Colin Campbell (Chemicals) Pty Ltd

Applicant ACN: 000 045 590

Summary of variation: To extend the use for the control of downy mildew (peronospora viciae), ascochyta rot disease

complex (ascochyta pisi, mycosphaerella pinodes and phoma pinodella) in processing peas, ascochyta blight (ascochyta rabeie) in chickpeas and ascochyta blight (ascochyta lentis), grey mould

(botrytis cinerea) in lentils

Date of variation: 29 November 2016

Product registration no.: 63122

Label approval no.: 63122/106871

3. LABEL APPROVAL

Application no: 107532

Product name: Brunnings Fast Action Weed Kill Ready To Use

Active constituent/s: 7.2 g/L glyphosate present as the isopropylamine salt, 0.16 g/L butafenacil

Applicant name: Syngenta Australia Pty Ltd

Applicant ACN: 002 933 717

Summary of variation: To approve a new label for the product with the name 'GARDENLINE WEED KILL FAST

ACTION READY TO USE'

Date of variation: 28 November 2016

Product registration no.: 70038

Label approval no.: 70038/107532

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 NEW ACTIVE CONSTITUENTS

Application no.: 51387

Product name: Maprelin

 Active constituent/s:
 75 μg/mL peforelin

 Applicant name:
 Veyx-Pharma GmbH

Applicant ACN: N/A

Summary of use For induction of the oestrous cycle in sows after weaning and induction of oestrus in sexually

mature gilts following therapy to inhibit the oestrous cycle with progestagens

Date of registration: 23 November 2016

Product registration no.: 65595 Label approval no.: 65595/51387

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.: 61136

Product name: Pastoral Ag Moxidectin Pour-On for Cattle

Active constituent/s: 5 g/L moxidectin
Applicant name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574

Summary of use For the treatment and control of moxidectin-sensitive internal and external parasites of cattle, and

for the treatment and control of lungworm and gastrointestinal roundworms of red deer

Date of registration: 16 November 2016

Product registration no.: 69563 Label approval no.: 69563/61136

Application no.: 61138

Product name:

Pastoral Ag Moxidectin Oral Drench for Sheet With Selenium

Active constituent/s:

5 g/L moxidectin; 0.5 mg/mL selenium as sodium selenate

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

Summary of use For the treatment and control of moxidectin sensitive gastrointestinal parasites (including

benzimidazole and/or levamisole resistant strains), lungworm and itchmite of sheep. As an aid in

control of selenium responsive conditions

Date of registration: 16 November 2016

Product registration no.: 69565 Label approval no.: 69565/61138

No. APVMA 25, Tuesday, 13 December 2016

Product name: Apramax Apramycin Soluble Powder

Active constituent/s: 595 mg/g apramycin (as Apramycin sulphate)

Applicant name: Abbey Laboratories Pty Ltd

Applicant ACN: 156 000 430

Summary of use For the treatment of infections caused by bacteria sensitive to Apramycin in pigs, calves and

broilers

Date of registration: 23 November 2016

Product registration no.: 81028

Label approval no.: 81028/102185

Application no.: 60314

Product name: Rheumocam 2.5 mg Chewable Tablets for Dogs

Active constituent/s: Each tablet contains 2.5 mg meloxicam

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 156 476 425

Summary of use For the alleviation of inflammation and pain in acute and chronic musculoskeletal disorders dogs

Date of registration: 6 December 2016

Product registration no.: 69231 Label approval no.: 69231/60314

Application no.: 60307

Product name: Rheumocam 1 mg Chewable Tablets for Dogs

Active constituent/s: Each tablet contains 1 mg meloxicam

Applicant name: Zoetis Australia Pty Ltd

Applicant ACN: 156 476 425

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

in dogs

Date of registration: 6 December 2016

Product registration no.: 69229 Label approval no.: 69229/60307

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 CONSITUTENT

Application no.: 106281
Active constituent/s: Indaziflam

Applicant name: Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of use: For use in agricultural chemical products

Date of approval: 30 November 2016

Approval no.: 82627

Application no.: 106015

Active constituent/s: Clethodim manufacturing concentrate

Applicant name: Jiangsu Sevencontinent Green Chemicals Co. Ltd

Applicant ACN: N/A

Summary of use: For use in agricultural chemical products

Date of approval: 1 December 2016

Approval no.: 82538

Licensing of Veterinary Chemical Manufacturers

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

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

1. NEW LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code]

V.I.P. PETFOODS (AUST.)

PTY. LTD.

ACN: 069 880 164

6-10 Blaxland Avenue

THOMASTOWN VIC 3074

LICENCE NO: 4098

Product Types:*

• Category 4: Therapeutic pet foods

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, sachet packaging, pellet extrusion, microbiological reduction treatment (heat) analysis and testing (physical), storage and release for supply.

Licence Issued: 1 November 2016

ANIMAL PHARMA PTY LTD

ACN: 150 842 596

60 Pile Road

SOMERSBY NSW 2250

LICENCE NO: 2243

Product Types:*

• Category 2: Palatable ingestible chews

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, filling, packaging, labelling, blister and sachet packaging, tableting, analysis and testing (physical), storage and release for

supply.

Licence Issued: 22 November 2016

^{*} Category 1: Immunobiologicals and sterile veterinary preparations

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

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer

2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code

QEA AUSTRALIA PTY LIMITED LICENCE NO: 6116

Unit 4/127 Magower Road • Category 6: Single step manufacture

GIRRAWEEN NSW 2145 Step(s) of Manufacture: Quality assurance (QA) of raw materials, repackaging,

relabelling, secondary/supplementary labelling, storage and release for supply.

Amended Licence Issued: 17 November 2016

MARS AUSTRALIA PTY LTD LICENCE NO: 2106
TRADING AS MARS PETCARE

AUSTRALIA

Petcare Place • Category 2: Palatable ingestible chews

WODONGA VIC 3690 Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation

including blending, filling, packaging, labelling, strip, blister or sachet packaging, microbiological reduction treatment (heat), analysis and testing (physical and

chemical), storage and release for supply.

Amended Licence Issued: 18 November 2016

3. LICENCE CANCELLATIONS

The APVMA has cancelled the following licences under subsection 127(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

ZAMIRA LIFE SCIENCES PTY LICENCE NO: 6184

LTD

ACN: 130 641 502 **Date Cancelled:** 8 November 2016

Level 1, Suite 4

321 Whitehorse Road NUNAWADING VIC 3131

4. LICENCE SUSPENSIONS

The APVMA has suspended the following licences under subsection 127(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

* Category 1: Immunobiologicals and sterile veterinary preparations

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

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer

5. REVOCATION OF LICENCE CANCELLATION

The APVMA has revoked the cancellation of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Section
Legal and Compliance Program
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* Category 1: Immunobiologicals and sterile veterinary preparations

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

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer

Cancellation of Label Approval at the Request of the Holder

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

| Product label no. | Product name | Label Approval Number | Approval holder | Date of effect |
|-------------------|-------------------------------|--------------------------|--------------------------------------|------------------|
| 33051 | Folimat Garden Insecticide | 33051/01 | Arysta LifeScience North America LLC | 25 November 2016 |

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

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 25 November 2016 at wholesale and retail level, until 25 November 2017.

After 25 November 2017 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product bearing the cancelled label.

USE

A person may continue to use the product bearing the cancelled label according to its label instructions until 25 November 2017.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing the cancelled label in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product bearing the cancelled label after the approval has been cancelled until 25 November 2017.

The supply and use of the product bearing the cancelled label must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product bearing the cancelled label in the table in a manner that contravenes the above instructions.

APVMA CONTACT

For any enquiries or further information about this matter, please contact:

Chemical Review

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

SYMONSTON ACT 2609

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Email: chemicalreview@apvma.gov.au

Sero-X Insecticide Containing Clitoria Ternatea Extract

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing the new active constituent *Clitoria ternatea* extract. The product is Sero-X Insecticide.

PARTICULARS OF THE APPLICATION

Proposed product name(s): Sero-X Insectide

Applicant company: Innovate Ag Pty Limited

Name of active constituent: Clitoria ternatea extract

Signal heading: Unscheduled (Appendix B entry)

Summary of proposed use: For the control or suppression of green mirid, silverleaf whitefly

(biotype B) and heliothis in cotton.

Pack sizes: 1 L – 1000 L

Withholding period: Harvest: not required when used as directed

SUMMARY OF THE APVMA'S EVALUATION OF SERO-X INSECTICIDE 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 Sero-X Insecticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The then Office of Chemical Safety (OCS) in the Department of Health conducted a risk assessment on the product and concluded that there should be no adverse effects on human health from the use of Sero-X Insecticide when used in accordance with the label directions. OCS has recommended first aid and safety directions which have been incorporated into the label particulars.

Clitoria ternatea extract is included in Appendix B, Part 3 of the SUSMP as an agricultural substance considered not to require control by scheduling due to its low toxicity.

(ii) The APVMA is satisfied that the proposed use of Sero-X Insecticide will not be an undue hazard to the safety of people using anything containing its residues.

An ADI for *Clitoria ternatea* extract is not considered necessary as no effects were observed in a 90 day oral toxicity study in rats at the NOEL of 1000 mg/kg bw/d.

- (iii) The APVMA is satisfied that the proposed use of Sero-X Insecticide containing the active constituent *Clitoria ternatea* extract is not likely to be harmful to human beings if used according to the product label directions.
- (iv) The APVMA is satisfied that the proposed use of Sero-X Insecticide 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.

Environmental risks posed by the use of this product are acceptable to terrestrial vertebrates and invertebrates, soil organisms and terrestrial plants, as no adverse effects are expected. In a worst-case scenario of direct overspray, risk was shown to the aquatic environment. However, with a downwind no-spray zone of 5 m to aquatic and wetland areas, this risk was considered acceptable.

The APVMA has considered these findings and accepts these conclusions.

- 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 Sero-X Insecticide adequately demonstrate that if used according to the product label directions, the product is effective for its proposed use for the control or suppression of green mirid, silverleaf whitefly (Biotype B) and heliothis in cotton.
- 3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (ii) The APVMA is satisfied that the proposed use of Sero-X Insecticide would not adversely affect trade between Australia and overseas markets.

Clitoria ternatea extract is a biological extract manufactured from Clitoria ternatea plant material. The residues relating to the proposed use of Clitoria ternatea extract in Sero-X Insecticide will not occur in foods and animal feeds above background levels of similar compounds naturally present in the environment. The extract components are the same or closely similar to those found in food. The trade risk associated with the proposed use of Clitoria ternatea extract on cotton is considered to be low and not undue.

It is recommended that a Table 5 entry be established for the use of *Clitoria ternatea* extract on food and non-food producing crops, as *Clitoria ternatea* extract is indistinguishable from natural food components and is of no toxicological significance.

No. APVMA 25, Tuesday, 13 December 2016 Agricultural and Veterinary Chemicals Code Act 1994

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

WITHHOLDING PERIODS:

Harvest: Not required when used as directed

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.

FURTHER INFORMATION

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

below.

MAKING A SUBMISSION

In accordance with section13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Sero-X Insecticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

Submissions must be received by the APVMA by 5pm, 27 December, 2016 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

New Agricultural Active Constituent Metazachlor

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

Common Name Metazachlor

IUPAC Name: 2-chloro-N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)acetamide

Chemical Abstracts Name: 2-chloro-N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl) acetamide

CAS Number: 67129-08-2

Molecular Formula: C₁₄H₁₆CIN₃O

Molecular Weight: 277.8

Structure:

CH₃

Chemical Family: Chloracetamide

Mode of Action: Herbicide inhibiting cell division and germination

SUMMARY OF THE APVMA'S EVALUATION OF METAZACHLOR ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of metazachlor active constituent (spectroscopic data, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for metazachlor active constituent:

| Constituent | Specification | Level |
|-------------|---------------|-------------------------------------|
| Metazachlor | metazachlor | 950 g/kg minimum (dry weight basis) |

Impurities of toxicological significance are not expected to occur in metazachlor as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of metazachlor, and concluded that there are no toxicological concerns to the approval of this active constituent. An ADI for metazachlor was established at 0.2 mg/kg bw/d. An ARfD for metazachlor was considered to be unnecessary.

The scheduling delegate of the Secretary to the Department of Health determined on 27 October 2016 that a new Schedule 5 entry without cut-offs for metazachlor would be created in the SUSMP (Poisons Standard), with an implementation date of 1 February 2017.

The APVMA is satisfied that the proposed importation and use of metazachlor 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 section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of metazachlor should be granted. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

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

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

Email: enquiries@apvma.gov.au

New Agricultural Active Constituent Metazachlor

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

New Chemical Product Butisan Herbicide Containing the New Active Constituent Metazachlor

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

PARTICULARS OF THE APPLICATION

Proposed product name(s): Butisan Herbicide

Applicant company: BASF Australia Ltd

Name of active constituent: Metazachlor

Signal heading: Schedule 5

Summary of proposed use: For the pre-emergent control of annual ryegrass, wild oats and wirewood

in canola

Pack sizes: 1 L, 3 L, 5 L, 10 L and 110 L

Withholding period: HARVEST: Not required when used as directed

GRAZING: Do not graze or cut for stockfood for 12 weeks after

application

SUMMARY OF THE APVMA'S EVALUATION OF BUTISAN HERBICIDE 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 Agyet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of Butisan Herbicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - (ii) The APVMA is satisfied that the proposed use of Butisan Herbicide will not be an undue hazard to the safety of people using anything containing its residues.
 - (iii) The APVMA is satisfied that the proposed use of Butisan Herbicide containing the active constituent metazachlor is not likely to be harmful to human beings if used according to the product label directions.
 - (iv) The APVMA is satisfied that the proposed use of the new products Butisan Herbicide containing the active constituent metazachlor, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.
- 2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (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.

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

FURTHER INFORMATION

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

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 Butisan Herbicide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

When making a submission please include:

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

All personal and confidential commercial information (CCI) 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

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