



**Commonwealth
of Australia**

Gazette

No. APVMA 17, Tuesday, 22 August 2017

Published by The Australian Pesticides and Veterinary Medicines Authority

**AGRICULTURAL AND
VETERINARY CHEMICALS**



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

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

© Commonwealth of Australia 2017

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority. Requests and inquiries concerning reproduction and rights should be addressed to:

Director, Public Affairs and Communications
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Email: communications@apvma.gov.au

Website: www.apvma.gov.au.

GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

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

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

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

APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4812

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

CONTENTS

Agricultural Chemical Products and Approved Labels.....	4
Veterinary Chemical Products and Approved Labels.....	13
Approved Active Constituents.....	14
New Agricultural Active Constituent <i>Aureobasidium pullulans</i> strain DSM 14940.....	16
New Agricultural Active Constituent <i>Aureobasidium pullulans</i> strain DSM 14941.....	18
Botector Fungicide Containing the New Active Constituent <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941).....	20
Licensing of Veterinary Chemical Manufacturers.....	22
Cancellation of Label Approvals at the Request of the Holder.....	25

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.:	106642
Product name:	Greenzone Termite and Insect Repellent Barrier
Active constituent/s:	2 g/kg bifenthrin
Applicant name:	Termite Solutions Victoria Pty Ltd
Applicant ACN:	112 311 289
Summary of use:	For the protection of buildings and structures against subterranean termites
Date of registration:	4 July 2017
Product registration no.:	82746
Label approval no.:	82746/106642

Application no.:	109566
Product name:	Spraysure Clearup 360 Herbicide
Active constituent/s:	360 g/L glyphosate present as the monoethanolamine salt
Applicant name:	Spraysure Pty Ltd
Applicant ACN:	616 617 951
Summary of use:	For the control of annual and perennial woody weeds and grasses in various agricultural situations
Date of registration:	31 July 2017
Product registration no.:	84044
Label approval no.:	84044/109566

Application no.:	109861
Product name:	Surefire Decimate Selective Herbicide
Active constituent/s:	250 g/L bromoxynil present as the octanoate, 25 g/L diflufenican
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For control of certain broadleaf weeds in winter cereals and pastures
Date of registration:	1 August 2017
Product registration no.:	84186
Label approval no.:	84186/109861

Application no.:	107162
Product name:	Fuhua Glyphosate 540 K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Sichuan Leshan Fuhua Tongda Agro-Chemical Tech. Co. Ltd
Applicant ACN:	N/A
Summary of use:	For the control of many annual and perennial weeds
Date of registration:	2 August 2017
Product registration no.:	82938
Label approval no.:	82938/107162

Application no.:	108927
Product name:	Mitre 18 Insecticide
Active constituent/s:	18 g/L abamectin
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use on cotton, soybeans, tomatoes, apples, pears, citrus fruit, capsicums, strawberries and various ornamental plants and turfs for the control of pests
Date of registration:	2 August 2017
Product registration no.:	83751
Label approval no.:	83751/108927
Application no.:	107070
Product name:	Genfarm Sulfometuron 750 WG Herbicide
Active constituent/s:	750 g/kg sulfometuron-methyl
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the control of certain annual and perennial grasses and broadleaf weeds in commercial and industrial areas
Date of registration:	2 August 2017
Product registration no.:	82892
Label approval no.:	82892/107070
Application no.:	109223
Product name:	First Force Fly And Mosquito Coils
Active constituent/s:	4 g/kg d-allethrin, 0.5 g/kg citronella oil
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	To repel flies and mosquitoes around the home and garden
Date of registration:	3 August 2017
Product registration no.:	83909
Label approval no.:	83909/109223
Application no.:	109922
Product name:	Surefire Procon 250 EC Fungicide
Active constituent/s:	250 g/L propiconazole
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of fungal diseases in bananas, peanuts, pineapples, stone fruit, sugarcane, wheat and other crops
Date of registration:	3 August 2017
Product registration no.:	84232
Label approval no.:	84232/109922
Application no.:	109527
Product name:	Apparent Carbendazim 500 SC Fungicide
Active constituent/s:	500 g/L carbendazim
Applicant name:	Apparent Pty. Ltd.
Applicant ACN:	143 724 136
Summary of use:	For the control of fungal disease on macadamia nuts, chickpeas, faba beans, lentils and vetch
Date of registration:	3 August 2017
Product registration no.:	84027
Label approval no.:	84027/109527

Application no.:	110110
Product name:	Surefire Tusk Fungicide
Active constituent/s:	430 g/L tebuconazole
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of leaf spot and leaf speckle on bananas; rust, leaf spot and net blotch on peanuts; foliar diseases on cereal crops; and other diseases on beans, lettuce, peas, onions, pawpaw, pyrethrum and ryegrass and fescue seed crops in various agricultural situations
Date of registration:	3 August 2017
Product registration no.:	84325
Label approval no.:	84325/110110
Application no.:	109537
Product name:	AAttach Spray Adjuvant
Active constituent/s:	582 g/L paraffinic oil, 120 g/L nonyl phenol ethoxylate, 120 g/L alcohol ethoxylate
Applicant name:	Australian Adjuvants Pty Ltd
Applicant ACN:	614 361 705
Summary of use:	For use in improving the spreading and wetting of herbicides, insecticides and defoliant on plant surfaces
Date of registration:	3 August 2017
Product registration no.:	84033
Label approval no.:	84033/109537
Application no.:	110935
Product name:	Rid Australia Rid Insect Repellent Tropical Strength Roll-On 6 Hours Mosquito Protection Neutral Scent Protection Against Mosquitoes That May Carry Ross River Virus And Dengue
Active constituent/s:	40 g/L n-octyl bicycloheptene dicarboximide, 20 g/L di-n-propyl isocinchomeronate, 191 g/L n,n-diethyl-m-toluamide
Applicant name:	Cavalieri Investing Pty Ltd
Applicant ACN:	162 722 625
Summary of use:	For protection against mosquitoes that may carry ross river virus and dengue
Date of registration:	3 August 2017
Product registration no.:	84614
Label approval no.:	84614/110935
Application no.:	107696
Product name:	Accensi Paraquat 300 Herbicide
Active constituent/s:	300 g/L paraquat present as paraquat dichloride
Applicant name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of use:	For the control of a wide range of grasses and broadleaf weeds
Date of registration:	7 August 2017
Product registration no.:	83185
Label approval no.:	83185/107696

Application no.:	109786
Product name:	Sharda Glyphosate 540 Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Sharda Cropchem Espana S.L
Applicant ACN:	N/A
Summary of use:	For the control of annual and perennial weeds
Date of registration:	8 August 2017
Product registration no.:	84145
Label approval no.:	84145/109786
Application no.:	110149
Product name:	Sharda Abamectin 18 Insecticide
Active constituent/s:	18 g/L abamectin
Applicant name:	Sharda Cropchem Espana S.L
Applicant ACN:	N/A
Summary of use:	For the control of pest mites and native budworm on cotton and for the control of pest mites on pears, apples, capsicums, tomatoes, strawberries and ornamentals
Date of registration:	8 August 2017
Product registration no.:	84339
Label approval no.:	84339/110149
Application no.:	109917
Product name:	Smart Silver 800 Herbicide
Active constituent/s:	800 g/L prosulfocarb
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use:	For the control of annual ryegrass (<i>lolium rigidum</i>) in barley and wheat
Date of registration:	9 August 2017
Product registration no.:	109917
Label approval no.:	84227/109917
Application no.:	109616
Product name:	Agriclopid 600FS Insecticide
Active constituent/s:	600 g/L imidacloprid
Applicant name:	Agri trading Pty Limited
Applicant ACN:	134 291 295
Summary of use:	For the control of insect pests in crops and the control of barley yellow dwarf virus in cereal crops in various agricultural situations
Date of registration:	9 August 2017
Product registration no.:	109616
Label approval no.:	84066/109616
Application no.:	109759
Product name:	Bishield 200SC Termiticide & Insecticide
Active constituent/s:	200 g/L bifenthrin
Applicant name:	Agroshine Australia Pty Ltd
Applicant ACN:	105 873 023
Summary of use:	For pre-construction and post-construction management of subterranean termites and for the control of a range of other urban pests both indoors and outdoors
Date of registration:	9 August 2017
Product registration no.:	84132
Label approval no.:	84132/109759

Application no.:	105848
Product name:	Echem Indox 150 Insecticide
Active constituent/s:	150 g/L indoxacarb
Applicant name:	Echem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of use:	For the control of various species of insect pests in azuki beans, chickpeas, cotton, faba beans, mungbeans and soybeans
Date of registration:	10 August 2017
Product registration no.:	82478
Label approval no.:	82478/105848

Application no.:	104462
Product name:	ProHex Plant Growth Regulator
Active constituent/s:	100 g/kg prohexadione calcium
Applicant name:	TGAC Australia Pty. Ltd.
Applicant ACN:	134 570 700
Summary of use:	For the reduction of shoot growth in apples
Date of registration:	10 August 2017
Product registration no.:	81941
Label approval no.:	81941/104462

Application no.:	110042
Product name:	Arysta Lifescience Chlorothalonil 720 Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Arysta Lifescience Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of use:	For the control of fungal diseases on a variety of crops and situations
Date of registration:	11 August 2017
Product registration no.:	84284
Label approval no.:	84284/110042

Application no.:	109043
Product name:	Pool Pro Granular Blackspot Remover
Active constituent/s:	900 g/kg chlorine (Cl) present as trichloroisocyanuric acid
Applicant name:	The Pops Group Pty Ltd
Applicant ACN:	095 828 461
Summary of use:	To control blackspot in pebblecrete, white plaster and tiled pools
Date of registration:	11 August 2017
Product registration no.:	83831
Label approval no.:	83831/109043

Application no.:	109798
Product name:	Hovex Mosquito Candle
Active constituent/s:	21.1 g/kg piperonyl butoxide, 6 g/kg bioallethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For use to repel and reduce the annoyance of mosquitoes around the home and garden
Date of registration:	11 August 2017
Product registration no.:	84153
Label approval no.:	84153/109798

2. VARIATIONS OF REGISTRATION

Application no.:	109239
Product name:	Azoxy 95 Fungicide
Active constituent/s:	95 g/L azoxystrobin
Applicant name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of variation:	To include the control of spring dead spot and alter the pack sizes
Date of variation:	31 July 2017
Product registration no.:	65575
Label approval no.:	65575/109239

Application no.:	107253
Product name:	Ultraforce Cockroach Bait
Active constituent/s:	0.5 g/kg fipronil
Applicant name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of variation:	To approve a new label and add new pack sizes
Date of variation:	2 August 2017
Product registration no.:	70090
Label approval no.:	70090/107253

Application no.:	107763
Product name:	Accensi Simazine 500 Flowable Herbicide
Active constituent/s:	500 g/L simazine
Applicant name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of variation:	To add additional pack sizes and different packaging material
Date of variation:	3 August 2017
Product registration no.:	64211
Label approval no.:	64211/107763

Application no.:	107687
Product name:	Specticle Herbicide
Active constituent/s:	200 g/L indaziflam
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To amend the use from 'turf on golf fairways' to 'turf.'
Date of variation:	4 August 2017
Product registration no.:	64673
Label approval no.:	64673/107687

Application no.:	109674
Product name:	Apparent Shout 720 Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of variation:	To include additional uses on the label to include control of ascochyta blight and grey mould diseases in chickpeas and lentils
Date of variation:	7 August 2017
Product registration no.:	81801
Label approval no.:	81801/109674

Application no.:	105621
Product name:	Foragemax Herbicide
Active constituent/s:	50 g/L aminopyralid present as triisopropanolamine salt, 100 g/L halauxifen-methy
Applicant name:	Dow Agrosiences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To amend the poison scheduling
Date of variation:	8 August 2017
Product registration no.:	68249
Label approval no.:	68249/105621

Application no.:	109080
Product name:	Atlas 3 in 1 Garden Indoor & Outdoor Surface Spray
Active constituent/s:	1 g/L esfenvalerate
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of variation:	To add a new claim of 12 month protection for cockroaches and ants
Date of variation:	8 August 2017
Product registration no.:	81709
Label approval no.:	81709/109080

Application no.:	105292
Product name:	Dupont Exirel Insecticide
Active constituent/s:	100 g/L cyantraniliprole
Applicant name:	Du Pont (Australia) Pty Ltd
Applicant ACN:	000 716 469
Summary of variation:	To add control of kelly's citrus thrip and light brown apple moth and suppression of fuller's rose weevil, in citrus
Date of variation:	11 August 2017
Product registration no.:	64103
Label approval no.:	64103/105292

3. RESTRICTED PRODUCT VARIATION

Application no.:	109316
Product name:	Titan Bifenthrin 100 Termiticide & Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To vary the application rate for control of ants, cockroaches, mosquitoes, fleas, flies, ticks in external areas and surrounds of domestic, commercial, public and industrial buildings and structures
Date of variation:	8 August 2017
Product registration no.:	57837
Label approval no.:	57837/109316

4. VARIATION OF LABEL APPROVAL

Application no.:	109670
Product name:	Fallowboss Tordon Herbicide
Active constituent/s:	300 g/L 2,4-D present as the triisopropanolamine salt, 75 g/L picloram present as the triisopropanolamine salt, 7.5 g/L aminopyralid present as the triisopropanolamine salt
Applicant name:	Dow Agrosiences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To change the application rates in the directions for use table
Date of variation:	4 August 2017
Product registration no.:	69106
Label approval no.:	69106/109670

Application no.:	109415
Product name:	Nufarm Kyte 700 WG Herbicide
Active constituent/s:	700 g/kg imazethapyr
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To update names of products in the direction for use table
Date of variation:	7 August 2017
Product registration no.:	69128
Label approval no.:	69128/109415

Application no.:	108970
Product name:	Nufarm Broadsword Herbicide
Active constituent/s:	800 g/kg flumetsulam
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To update adjuvant and companion products
Date of variation:	8 August 2017
Product registration no.:	67509
Label approval no.:	67509/108970

Application no.:	109531
Product name:	Titan Metribuzin 750 WG Herbicide
Active constituent/s:	750 g/kg metribuzin
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To update environmental protection statement for sugarcane use pattern
Date of variation:	8 August 2017
Product registration no.:	62150
Label approval no.:	62150/109531

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.

5. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	58382
Product name:	Eon Broad Spectrum Pour On For Beef And Dairy Cattle
Active constituent/s:	5 mg/mL eprinomectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use:	For use in the treatment and control of eprinomectin sensitive gastrointestinal roundworms in beef and dairy cattle
Date of registration:	21 July 2017
Product registration no.:	68450
Label approval no.:	68450/58382
Application no.:	107825
Product name:	Tridectin 3-Way Oral Drench For Sheep
Active constituent/s:	1 g/L moxidectin, 40 g/L levamisole hydrochloride, 25 g/L albendazole
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in the treatment and control of gastrointestinal parasites in sheep
Date of registration:	11 August 2017
Product registration no.:	83241
Label approval no.:	83241/107825

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.

6. ACTIVE CONSTITUENT

Application no.:	108617
Active constituent/s:	Terbutylazine
Applicant name:	Zhejiang Zhongshan Chemical Industry Group Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	2 August 2017
Approval no.:	83559

Application no.:	104088
Active constituent/s:	Prosulfocarb
Applicant name:	Agroserve Pty Ltd
Applicant ACN:	163 422 464
Summary of use:	For use in agricultural chemical products
Date of approval:	4 August 2017
Approval no.:	81808

Application no.:	110851
Active constituent/s:	Prochloraz-manganese chloride
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of use:	For use in agricultural chemical products
Date of approval:	7 August 2017
Approval no.:	84576

Application no.:	108301
Active constituent/s:	Imiprothrin manufacturing concentrate
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For use in agriculture chemical products
Date of approval:	8 August 2017
Approval no.:	83451

Application no.:	106737
Active constituent/s:	Flumioxazin
Applicant name:	Foison Scitech Co., Limited
Applicant ACN:	N/A
Summary of use:	For use in agriculture chemical products
Date of approval:	10 August 2017
Approval no.:	82780

Application no.:	109095
Active constituent/s:	Trifloxystrobin
Applicant name:	Yancheng Huihuang Chemical Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	8 August 2017
Approval no.:	83861

Application no.:	109038
Active constituent/s:	2,4-D
Applicant name:	Thai Harvest Limited
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	10 August 2017
Approval no.:	83830

New Agricultural Active Constituent *Aureobasidium pullulans* strain DSM 14940

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, the microbial fungus *Aureobasidium pullulans* strain DSM 14940, for use as a biological fungicide that protects grapes from infections with grey mould (*Botrytis cinerea*).

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	Aureobasidium pullulans strain DSM 14940
Species Name:	Aureobasidium pullulans (var. pullulans)
Strain:	DSM 14940
CAS Number:	67891-88-7
Genus:	Aureobasidium
Family:	Dothioraceae
Order:	Dothideales
Class:	Euascomyces
Phylum:	Ascomycota
Kingdom:	Fungi
Brief description:	Strain A. pullulans DSM 14940 was isolated in 1989 at the University of Konstanz from an apple plantation. A. pullulans is a globally ubiquitous saprophytic yeast-like fungus

SUMMARY OF THE APVMA'S EVALUATION OF AUREOBASIDIUM PULLULANS STRAIN DSM 14940 ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of *Aureobasidium pullulans* strain DSM 14940 active constituent (identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

Impurities of toxicological significance are not expected to occur in *Aureobasidium pullulans* strain DSM 14940 as a result of the raw materials and the fermentation process used.

Aureobasidium pullulans strain DSM 14940 is a ubiquitous microorganism normally present on fruit and vegetables. The microorganisms are not infective or pathogenic and were not toxic at limit doses in acute toxicity tests, consequently the establishment of an Acceptable Daily Intake (ADI), or of an Acute Reference Dose (ARfD), is not required.

The APVMA has considered the toxicological aspects of *Aureobasidium pullulans* strain DSM 14940, and concluded that there are no toxicological concerns relating to the approval of this active constituent.

The Scheduling Delegate has made a final decision to list *Aureobasidium pullulans* strain DSM 14940 in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with an implementation date on 1 October 2017.

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 *Aureobasidium pullulans* strain DSM 14940 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 a:

- 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) 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 *Aureobasidium pullulans* strain DSM 14941

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, the microbial fungus *Aureobasidium pullulans* strain DSM 14941, for use as a biological fungicide that protects grapes from infections with grey mould (*Botrytis cinerea*).

Common Name:	<i>Aureobasidium pullulans</i> strain DSM 14941
Species Name:	<i>Aureobasidium pullulans</i> (var. <i>pullulans</i>)
Strain Name:	DSM 14941
CAS Number:	67891-88-7
Genus:	<i>Aureobasidium</i>
Family:	<i>Dothioraceae</i>
Order:	<i>Dothideales</i>
Class:	<i>Euascomyces</i>
Phylum:	<i>Ascomycota</i>
Kingdom:	<i>Fungi</i>
Brief description:	Strain <i>A. pullulans</i> DSM 14941 was isolated in 1989 at the University of Konstanz from an apple plantation. <i>A. pullulans</i> is a globally ubiquitous saprophytic yeast-like fungus

SUMMARY OF THE APVMA'S EVALUATION OF AUREOBASIDIUM PULLULANS STRAIN DSM 14941 ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of *Aureobasidium pullulans* strain DSM 14941 active constituent (identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

Impurities of toxicological significance are not expected to occur in *Aureobasidium pullulans* strain DSM 14941 as a result of the raw materials and the fermentation process used.

Aureobasidium pullulans strain DSM 14941 is a ubiquitous microorganism normally present on fruit and vegetables. The microorganisms are not infective or pathogenic and were not toxic at limit doses in acute toxicity tests, consequently the establishment of an Acceptable Daily Intake (ADI), or of an Acute Reference Dose (ARfD), is not required.

The APVMA has considered the toxicological aspects of *Aureobasidium pullulans* strain DSM 14941, and concluded that there are no toxicological concerns relating to the approval of this active constituent.

The Scheduling Delegate has made a final decision to list *Aureobasidium pullulans* strain DSM 14941 in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with an implementation date on 1 October 2017.

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 *Aureobasidium pullulans* strain DSM 14941 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 a:

- 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) 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

Botector Fungicide Containing the New Active Constituent *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent *Aureobasidium pullulans*. The product is Botector Fungicide.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Botector Fungicide
Applicant company:	Nufarm Australia Limited
Name of active constituent:	5 x 10 ⁹ cfu/g (1.000 g/kg) of the new active constituent <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941)
Signal heading:	Not Required – Appendix B
Summary of proposed use:	For use as a preventative treatment in the control of botrytis bunch rot / grey mould (<i>Botrytis cinerea</i>) in grapes
Pack sizes:	400 g, 1.2 kg, 2 kg, 2.5 kg and 5 kg
Withholding period:	Not required when used as directed

SUMMARY OF THE APVMA'S EVALUATION OF BOTECTOR FUNGICIDE 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 Botector Fungicide 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 Botector Fungicide 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 Botector Fungicide containing the active constituents *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941) 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 product Botector Fungicide containing the active constituents *Aureobasidium pullulans* (strains DSM 14940 and DSM 14941), 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:
 - (i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

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 Botector Fungicide 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 'Public Consultation' page on the APVMA website, www.apvma.gov.au/consultation/public or by contacting the APVMA as indicated 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 Botector Fungicide 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
KINGSTON ACT 2604
Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

Licensing of Veterinary Chemical Manufacturers

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

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

1. NEW LICENCES

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

Nil

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]

VIRBAC (AUSTRALIA) PTY LTD

ACN: 003 268 871

361 Horsley Road

MILPERRA NSW 2214

LICENCE NO: 6137

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Storage and release for supply

Amended Licence Issued: 6 July 2017

NORTHERN SERUMS PTY LTD

ACN: 003 809 318

1/61 Centennial Circuit

BYRON BAY NSW 2481

LICENCE NO: 1108

Product Types: *

- *Category 1:* Immunobiologicals (tick antiserum)

Step(s) of Manufacture: Quality assurance (QA) of raw materials, management and immunisation of donor animals, serum collection, formulation including blending, aseptic filling, packaging, labelling, sterilisation (heat and filtration), microbiological reduction treatment (chemical and filtration), analysis and testing (physical), storage and release for supply.

Amended Licence Issued: 6 July 2017

* 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*

**MEDICAL DEVELOPMENTS
INTERNATIONAL LIMITED**

ACN: 106 340 667

Buildings 8 and 10

56 Smith Road

SPRINGVALE VIC 3171

LICENCE NO: 2196

Product Types:*

- *Category 2: Liquids (Methoxyflurane only)*

Step(s) of Manufacture: Quality assurance (QA) of raw materials, chemical synthesis, filling, packaging, labelling, secondary packaging, secondary/supplementary labelling, storage and release for supply.

Amended Licence Issued: 18 July 2017

3. LICENCE CANCELLATIONS

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

HPC HOLDINGS PTY LTD

ACN: 079 645 015

1 Braidwood Street

ENFIELD NSW 2066

LICENCE NO: 6205

Date Cancelled: 13 July 2017

ANIMAL PHARMA PTY LTD

ACN: 150 842 596

42-46 Somersby Falls Road

SOMERSBY NSW 2250

LICENCE NO: 2217

Date Cancelled: 18 July 2017

RABAR PTY LTD

ACN: 010 969 776

152 Enterprise Drive

BEAUDESERT QLD 4285

LICENCE NO: 4051

Date Cancelled: 21 July 2017

**AGRICON PTY LTD TRADING
AS AGRICON PRODUCTS**

ACN: 010 147 958

Lot 13, Enterprise Street

Industrial Estate

MARYBOROUGH QLD 4650

LICENCE NO: 4002

Date Cancelled: 31 July 2017

* 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*

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

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, Compliance and MQL
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Phone: +61 2 6210 4899
Fax: +61 2 6210 4813
Email: mls@apvma.gov.au

* 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 Approvals at the Request of the Holder

At the request of the holder, the APVMA has cancelled the following label approvals:

Product no.	Product name	Approval holder	Product label approvals	Date of effect
68251	PROLECTUS FUNGICIDE	SUMITOMO CHEMICAL AUSTRALIA PTY LIMITED	68251/57838 68251/110327	8 August 2017

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

SUPPLY

A person may supply or cause to be supplied product bearing the cancelled labels 68251/57838 and 68251/110327 manufactured prior to 8 August 2017 at wholesale and retail level, until 8 August 2018.

After 8 August 2018 it will be an offence against the Agvet Codes to have possession or custody of the product bearing labels 68251/57838 and 68251/110327 with the intention to supply, or to supply the product.

USE

A person may continue to use the product bearing the cancelled labels 68251/57838 and 68251/110327 according to those label instructions until 8 August 2018.

Any person who possesses, has custody of, uses, or otherwise deals with the product bearing the cancelled labels 68251/57838 and 68251/110327 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 labels until 8 August 2018.

The supply and use of the product bearing the cancelled label approvals 68251/57838 and 68251/110327 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 labels listed 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
Phone: +61 2 6210 4749
Fax: +61 2 6210 4773
Email: chemicalreview@apvma.gov.au