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Gazette

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**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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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.:	104388
Product name:	Insectigone Gold Insecticide
Active constituent/s:	25 g/L deltamethrin
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of a range of urban pests in domestic, commercial, industrial and public buildings; and for short term protection of timber and for treatment of cut flowers for export
Date of registration/approval:	2 June 2017
Product registration no.:	81903
Label approval no.:	81903/104388
Application no.:	108158
Product name:	Macspred Triclopyr 600 Herbicide
Active constituent/s:	600 g/L triclopyr present as the butoxyethyl ester
Applicant name:	Macspred Pty. Ltd
Applicant ACN:	011 029 495
Summary of use:	For the control of various woody and broadleaf weeds in a range of agricultural situations, commercial and industrial areas
Date of registration/approval:	7 June 2017
Product registration no.:	83384
Label approval no.:	83384/108158
Application no.:	109009
Product name:	Spalding Diflufenican 500 SC Selective Herbicide
Active constituent/s:	500 g/L diflufenican
Applicant name:	Spalding Holdings Pty. Ltd
Applicant ACN:	010 155 852
Summary of use:	For control of certain weeds in clover-based pasture, field peas, lentils, lupins and oilseed poppy
Date of registration/approval:	7 June 2017
Product registration no.:	83809
Label approval no.:	83809/109009
Application no.:	108891
Product name:	AC Longbow 250 CS Insecticide
Active constituent/s:	250 g/L lambda-cyhalothrin
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use:	To control certain insect pests in cotton, barley, wheat and various field crops
Date of registration/approval:	8 June 2017
Product registration no.:	83725
Label approval no.:	83725/108891

Application no.:	107449
Product name:	4Farmers Terbutylazine 750 WG Herbicide
Active constituent/s:	750 g/kg terbutylazine
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of use:	For the control of weeds in chickpeas, faba beans, field peas, lentils, lupins and triazine tolerant canola
Date of registration/approval:	9 June 2017
Product registration no.:	83079
Label approval no.:	83079/107449
Application no.:	109240
Product name:	Weed Force Thiss-Off Thistle & Broadleaf Herbicide
Active constituent/s:	750 g/L MCPA present as the dimethylamine salt
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of use:	For the control of broadleaf weeds in cereals, linseed, pastures, rice, sugar cane and turf
Date of registration/approval:	9 June 2017
Product registration no.:	83914
Label approval no.:	83914/109240
Application no.:	108598
Product name:	Chemforce Sulfosulfuron 750 WG Herbicide
Active constituent/s:	750 g/kg sulfosulfuron
Applicant name:	Chemforce 2010 Pty Ltd
Applicant ACN:	146 807 356
Summary of use:	For the control of certain weeds in wheat and triticale
Date of registration/approval:	9 June 2017
Product registration no.:	83550
Label approval no.:	83550/108598
Application no.:	108376
Product name:	Weed Force Grass Clear Grass Herbicide
Active constituent/s:	520 g/L haloxyfop present as the haloxyfop-r-methyl ester
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of use:	For the post-emergent control of a wide range of annual and perennial grass weeds in grain legume and oilseed crops, lucerne, medic and clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops
Date of registration/approval:	9 June 2017
Product registration no.:	83480
Label approval no.:	83480/108376
Application no.:	108906
Product name:	Raystar Glyphosate 360 IPA SL Herbicide
Active constituent/s:	360 g/L glyphosate present as the isopropylamine salt
Applicant name:	Raystar Cropprotection Pty Ltd
Applicant ACN:	610 946 784
Summary of use:	To control annual, aquatic and perennial weeds in a range of agricultural and non-agricultural situations
Date of registration/approval:	9 June 2017
Product registration no.:	83738
Label approval no.:	83738/108906

Application no.:	106507
Product name:	Kenso Agcare Fumiken Fumigation Tablet
Active constituent/s:	330 g/kg phosphine (PH ₃) present as aluminium phosphide
Applicant name:	Kenso Corporation (M) SDN. BHD
Applicant ACN:	N/A
Summary of use:	For the control of insect pests of stored products in certain situations and for control of rabbits in burrows
Date of registration/approval:	9 June 2017
Product registration no.:	82704
Label approval no.:	82704/106507
Application no.:	105409
Product name:	Richgro Lawn Feed & Weed For All Lawns Including Buffalo
Active constituent/s:	6 g/L bromoxynil present as the potassium salt, 6 g/L MCPA present as the potassium salt
Applicant name:	A. Richards Pty Ltd T/A Richgro Garden Products
Applicant ACN:	008 734 852
Summary of use:	For control of weeds in domestic lawns
Date of registration/approval:	9 June 2017
Product registration no.:	82309
Label approval no.:	82309/105409
Application no.:	109839
Product name:	Black Flag Baits Cockroach
Active constituent/s:	2.5 g/kg indoxacarb
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of use:	To control cockroaches in the household
Date of registration/approval:	9 June 2017
Product registration no.:	84172
Label approval no.:	84172/109839
Application no.:	104935
Product name:	Pascoe's Cockroach Gel
Active constituent/s:	21.5 g/kg imidacloprid
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For the control of cockroaches in commercial situations
Date of registration/approval:	9 June 2017
Product registration no.:	82077
Label approval no.:	82077/104935
Application no.:	108850
Product name:	Ozcrop Glyphosate 540 K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Ozcrop Pty. Ltd
Applicant ACN:	160 656 431
Summary of use:	For use as a non-selective herbicide for the control of annual and perennial weeds
Date of registration/approval:	13 June 2017
Product registration no.:	83692
Label approval no.:	83692/108850

Application no.:	108929
Product name:	Raystar Glufosinate-Ammonium 200 SL Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Raystar Cropprotection Pty Ltd
Applicant ACN:	610 946 784
Summary of use:	For the non-residual control of broadleaf and grass weeds in various agricultural, commercial and industrial situations
Date of registration/approval:	13 June 2017
Product registration no.:	83753
Label approval no.:	83753/108929
Application no.:	108792
Product name:	Rywett TX Nonionic Penetrating Surfactant
Active constituent/s:	1040 g/L octyl phenol ethoxylate
Applicant name:	Agspec Australia Pty Ltd
Applicant ACN:	109 573 953
Summary of use:	For use with glyphosate herbicides when treating annual ryegrass, silvergrass and perennial grasses
Date of registration/approval:	14 June 2017
Product registration no.:	83655
Label approval no.:	83655/108792
Application no.:	107327
Product name:	Rat X Non Toxic Rodenticide
Active constituent/s:	20 g/kg sodium chloride, 550 g/kg corn gluten meal
Applicant name:	Importing Innovation Australasia Pty Ltd
Applicant ACN:	608 326 138
Summary of use:	For control of rats and mice in domestic buildings and other indoor situations where alternative food sources can be removed such as warehouses and empty feed storage situations
Date of registration/approval:	14 June 2017
Product registration no.:	83020
Label approval no.:	83020/107327
Application no.:	109225
Product name:	First Force Home Protection Insect Spray
Active constituent/s:	1 g/L esfenvalerate
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For the control against flying and crawling insects around the home and in the garden
Date of registration/approval:	15 June 2017
Product registration no.:	83911
Label approval no.:	83911/109225
Application no.:	109717
Product name:	Triumph 240 Fungicide
Active constituent/s:	240 g/L metalaxyl-m
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For the control of pythium and seedling damping off in turf
Date of registration/approval:	15 June 2017
Product registration no.:	84103
Label approval no.:	84103/109717

Application no.:	108791
Product name:	Citowett Spreader Wetter
Active constituent/s:	1000 g/L ethoxylated octyl phenol (an alkylaryl polyglycol ether)
Applicant name:	Agspec Australia Pty Ltd
Applicant ACN:	109 573 953
Summary of use:	For use with vines, fruit, vegetables, ornamentals and herbicide sprays
Date of registration/approval:	15 June 2017
Product registration no.:	83654
Label approval no.:	83654/108791
Application no.:	107395
Product name:	Smart Gold Herbicide
Active constituent/s:	960 g/L s-metolachlor
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use:	For the control of annual grasses and broadleaf weeds in certain crops
Date of registration/approval:	15 June 2017
Product registration no.:	83056
Label approval no.:	83056/107395
Application no.:	109471
Product name:	Forward Chlorothalonil 720 Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Forward Australia Pty Ltd
Applicant ACN:	112 532 395
Summary of use:	For control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba bean, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and various other vegetables
Date of registration/approval:	15 June 2017
Product registration no.:	83992
Label approval no.:	83992/109471
Application no.:	109449
Product name:	Ozcrop Musta 450 Herbicide
Active constituent/s:	450 g/L glyphosate present as the isopropylamine salt
Applicant name:	Ozcrop Pty. Ltd
Applicant ACN:	160 656 431
Summary of use:	For control of annual and perennial weeds
Date of registration/approval:	15 June 2017
Product registration no.:	83983
Label approval no.:	83983/109449
Application no.:	108969
Product name:	Raystar Chlorsulfuron 750 WG Herbicide
Active constituent/s:	750 g/kg chlorsulfuron
Applicant name:	Raystar Crop Protection Pty Ltd
Applicant ACN:	610 946 784
Summary of use:	For control of annual (wimmera) ryegrass and broadleaf weeds in wheat, barley, oats, cereal rye and triticale crop situations
Date of registration/approval:	16 June 2017
Product registration no.:	83785
Label approval no.:	83785/108969

Application no.:	106915
Product name:	Amgrow Azoxystrobin 95 Fungicide
Active constituent/s:	95 g/L azoxystrobin
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use:	For the control of various diseases of turf
Date of registration/approval:	19 June 2017
Product registration no.:	82840
Label approval no.:	82840/106915
Application no.:	108999
Product name:	Sharda Bifenthrin 80 SC Insecticide
Active constituent/s:	80 g/L bifenthrin
Applicant name:	Sharda Cropchem Espana S.L
Applicant ACN:	N/A
Summary of use:	For the control of pests of turf and the control of a range of urban pests; spiders, ants, cockroaches, mosquitoes, fleas, flies and ticks; and for the management of subterranean termites in domestic, commercial, public and industrial building situations
Date of registration/approval:	19 June 2017
Product registration no.:	83805
Label approval no.:	83805/108999
Application no.:	109267
Product name:	BioAAid Winter Dormant Oil Insecticide
Active constituent/s:	859 g/L Petroleum Oil
Applicant name:	Australian Adjuvants Pty Ltd
Applicant ACN:	614 361 705
Summary of use:	For the control of scale insects and mites on pome and stone fruit trees and grapevines
Date of registration/approval:	21 June 2017
Product registration no.:	83934
Label approval no.:	83934/109267
Application no.:	109252
Product name:	BioAAid Summer Spray Oil Insecticide
Active constituent/s:	851 g/L Petroleum Oil
Applicant name:	Australian Adjuvants Pty Ltd
Applicant ACN:	614 361 705
Summary of use:	For the control of insects on citrus, stone and pome fruit trees, diseases on bananas and for use as a spreader
Date of registration/approval:	21 June 2017
Product registration no.:	83924
Label approval no.:	83924/109252

2. VARIATIONS OF REGISTRATION

Application no.:	110736
Product name:	Nufarm Amulet Cue-Lure Fruit Fly Stations
Active constituent/s:	3.4 g/kg fipronil, 94 g/kg 4-(p-acetoxyphenyl)-2-butanone
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CROP CARE AMULET CUE-LURE FRUIT FLY STATIONS' to 'NUFARM AMULET CUE-LURE FRUIT FLY STATIONS'
Date of variation:	8 May 2017
Product registration no.:	60664
Label approval no.:	60664/110736

Application no.:	110734
Product name:	Spark Herbicide
Active constituent/s:	240 g/L imazapic present as the ammonium salt
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CROP CARE SPARK HERBICIDE' to 'SPARK HERBICIDE'
Date of variation:	8 May 2017
Product registration no.:	67753
Label approval no.:	67753/110734

Application no.:	110737
Product name:	Dragon 700 WG Fungicide
Active constituent/s:	700 g/kg dithianon
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CROP CARE DRAGON 700 WG FUNGICIDE' to 'DRAGON 700 WG FUNGICIDE'
Date of variation:	8 May 2017
Product registration no.:	68856
Label approval no.:	68856/110737

Application no.:	110731
Product name:	Flex GT 250 Fungicide
Active constituent/s:	250 g/L iprodione
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 FLEX GT 250 FUNGICIDE' to 'FLEX GT 250 FUNGICIDE' and to add a pack size change (5 L – 20 L) and to include the withholding period for turf
Date of variation:	8 May 2017
Product registration no.:	65210
Label approval no.:	65210/110731

Application no.:	110733
Product name:	Slasher Organic Weedkiller
Active constituent/s:	525 g/L nonanoic acid
Applicant name:	Organic Crop Protectants Pty Ltd
Applicant ACN:	003 149 719
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'SLASHER WEEDKILLER' to 'SLASHER ORGANIC WEEDKILLER'
Date of variation:	8 May 2017
Product registration no.:	68118
Label approval no.:	68118/110733
Application no.:	108324
Product name:	Fumaphos Fumigation Tablets
Active constituent/s:	330 g/kg phosphine (PH ₃) present as aluminium phosphide
Applicant name:	National Fumigants Pty Ltd
Applicant ACN:	090 505 785
Summary of variation:	To extend the use to include the control of rabbits in burrows and make minor variations to label instructions
Date of variation:	2 June 2017
Product registration no.:	52020
Label approval no.:	52020/108324
Application no.:	109041
Product name:	Mortein Home Expert Cockroach Gel
Active constituent/s:	2.5 g/kg indoxacarb
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the product name from 'MORTEIN DO-IT-YOURSELF PROFESSIONAL COCKROACH GEL BAIT TRUSTED HOUSEHOLD PROTECTION' to 'MORTEIN HOME EXPERT COCKROACH GEL' and extend claim to include control of cockroaches and the eggs they carry in a single feed
Date of variation:	6 June 2017
Product registration no.:	62046
Label approval no.:	62046/109041
Application no.:	108485
Product name:	Leopard 200 Herbicide
Active constituent/s:	200 g/L quizalofop-p-ethyl
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To update grazing withholding period for sub-clover and harvest withholding period for cauliflower and minor label updates, change product name from 'LEOPARD 200 EC HERBICIDE' to 'LEOPARD 200 HERBICIDE'
Date of variation:	8 June 2017
Product registration no.:	68000
Label approval no.:	68000/108485

Application no.:	107630
Product name:	Luna Sensation Fungicide
Active constituent/s:	250 g/L fluopyram, 250 g/L trifloxystrobin
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To add a new pack size range and to reduce the withholding period for use in apples and pears
Date of variation:	15 June 2017
Product registration no.:	65560
Label approval no.:	65560/107630

3. LABEL APPROVAL

Application no.:	108411
Product name:	Callington Top of Descent Aircraft Insecticide
Active constituent/s:	20 g/kg d-phenothrin 20:80
Applicant name:	Callington Haven Pty Ltd
Applicant ACN:	000 632 404
Summary of variation:	To approve a new label for the product 'CALLINGTON TOP OF DESCENT AIRCRAFT INSECTICIDE' with the label name 'CALLINGTON AEROSAFE AIRCRAFT INSECTICIDE'
Date of variation:	13 June 2017
Product registration no.:	51084
Label approval no.:	51084/108411

Veterinary Chemical Products and Approved Labels

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

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	107326
Product name:	Meloxicam Horse Paste 30
Active constituent/s:	30 mg/mL meloxicam
Applicant name:	Kato Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of use:	For alleviation of inflammation and relief of pain in both acute and chronic musculoskeletal disorders in horses
Date of registration/approval:	7 June 2017
Product registration no.:	83019
Label approval no.:	83019/107326
Application no.:	59108
Product name:	Polygon Moxidectin Pour-On For Cattle And Red Deer
Active constituent/s:	5 g/L moxidectin
Applicant name:	Polygon (NZ) Limited
Applicant ACN:	N/A
Summary of use:	For use in 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/approval:	9 June 2017
Product registration no.:	68799
Label approval no.:	68799/59108

2. VARIATIONS OF REGISTRATION

Application no.:	109772
Product name:	Vetmedin 1.25 mg Capsules for Dogs
Active constituent/s:	Each capsule contains 1.25 mg pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To extend uses to dogs with preclinical myxomatous mitral valve disease
Date of variation:	21 June 2017
Product registration no.:	55523
Label approval no.:	55523/109772
Application no.:	109766
Product name:	Vetmedin 1.25 mg Chewable Tablets for Dogs
Active constituent/s:	Each tablet contains 1.25 mg pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To extend uses to dogs with preclinical myxomatous mitral valve disease
Date of variation:	21 June 2017
Product registration no.:	60800
Label approval no.:	60800/109766

Application no.:	109773
Product name:	Vetmedin 5 mg Capsules for Dogs
Active constituent/s:	Each capsule contains 5 mg pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To extend uses to dogs with preclinical myxomatous mitral valve disease
Date of variation:	21 June 2017
Product registration no.:	53562
Label approval no.:	53562/109773

Application no.:	109769
Product name:	Vetmedin 10 mg Chewable Tablets for Dogs
Active constituent/s:	Each tablet contains 10 mg pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To extend uses to dogs with preclinical myxomatous mitral valve disease
Date of variation:	21 June 2017
Product registration no.:	69391
Label approval no.:	69391/109769

Application no.:	109767
Product name:	Vetmedin 5 mg Chewable Tablets for Dog
Active constituent/s:	Each tablet contains 5 mg pimobendan.
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To extend uses to dogs with preclinical myxomatous mitral valve disease
Date of variation:	21 June 2017
Product registration no.:	60798
Label approval no.:	60798/109767

Application no.:	109758
Product name:	Vetmedin 2.5 mg Chewable for Dogs
Active constituent/s:	Each tablet contains 2.5 mg pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To extend uses to dogs with preclinical myxomatous mitral valve disease
Date of variation:	21 June 2017
Product registration no.:	60799
Label approval no.:	60799/109758

3. LABEL APPROVAL

Application no.:	109707
Product name:	Anihealth Egu Defend Paste
Active constituent/s:	370 mg/g omeprazole
Applicant name:	Cipla Ltd
Applicant ACN:	N/A
Summary of variation:	To add an additional label name 'EQUIPEP ULCER PASTE FOR HORSES' under product 'ANIHEALTH EGU DEFEND PASTE'
Date of variation:	9 June 2017
Product registration no.:	63080
Label approval no.:	63080/109707

Approved Active Constituents

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

1. ACTIVE CONSTITUENT

Application no.:	107879
Active constituent/s:	Bacillus thuringiensis subsp aizawai Strain ABTS-1857
Applicant name:	Valent Biosciences a Div of Sumitomo Chemical Australia
Applicant ACN:	081 096 255
Summary of use:	For use in agricultural chemical products
Date of approval:	13 June 2017
Approval no.:	83278

Revision of Existing APVMA Standard for Active Constituents—Dimethoate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has revised the standard for the active constituent dimethoate, following advice arising from the recently finalised reconsideration of dimethoate. These revisions are consistent with the Food and Agriculture Organisation (FAO) standard for dimethoate¹.

DESCRIPTION OF THE CHANGE TO THE APVMA STANDARD FOR DIMETHOATE ACTIVE CONSTITUENT

Change to sections:

Change to Section 1 (description) from:

- the material shall consist of dimethoate together with related manufacturing impurities and shall be in the form of white to greyish crystals, free from visible extraneous matter and added modifying agents

to:

- the material shall consist of dimethoate together with related manufacturing impurities and shall be a white solid, having a mercaptanic odour, free from visible extraneous matter and added modifying agents

Changes to Section 6 composition:

6.1 Active constituent: 950 g/kg minimum—no change

6.2 Change title from 'Toxicological impurity' to 'Impurities'

O,O,S-Trimethyl phosphorodithioate: 5 g/kg max—no change

ADD Omethoate (CAS No. 1113-02-6): 2 g/kg max

ADD Isodimethoate (CAS No. 3344-11-4): 3 g/kg max

ADD Water (CAS No. 7732-18-5): 2 g/kg max.

The inclusion of these impurities in the standard is consistent with the FAO standard for dimethoate available from the site listed in the footnote below.

¹ www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Specs/Dimethoate2012_2.pdf available from www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/en/

PARTICULARS OF THE ACTIVE CONSTITUENT:

Common Name:	Dimethoate
Chemical Name IUPAC:	O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate
CAS Registry Number:	60-51-5
Current APVMA Minimum:	950 g/kg minimum
Published Purity:	
Molecular Formula:	C ₅ H ₁₂ NO ₃ PS ₂
Molecular Weight:	229.3

THE REVISED STANDARD IS AS FOLLOWS:

- 1. Description:** The material shall consist of dimethoate together with related manufacturing impurities and shall be a white solid, having a mercaptanic odour, free from visible extraneous matter and added modifying agents.
- 2. Common name:** Dimethoate
- 3. Chemical name (IUPAC):** O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate
- 4. CAS number:** 60-51-5
- 5. Identity test:** Identity of the active constituent must be established by one or more of the following methods: spectroscopic tests (IR spectrum, NMR, mass spectra), Chromatography (HPLC or GC retention time with reference compound) or any other suitable test method.

6. Composition

- 6.1 Active constituent:** 950 g/kg minimum
- 6.2 Impurities:**

O,O,S-trimethyl phosphorodithioate:	5 g/kg max
Omethoate (CAS No. 1113-02-6):	2 g/kg max
Isodimethoate (CAS No. 3344-11-4):	3 g/kg max
Water (CAS No. 7732-18-5):	2 g/kg max

7. Analytical methods

The analytical method used for the determination of the active constituent and toxicological significant impurities must be validated in accordance with the APVMA guidelines for the validation of analytical methods.

The APVMA guidelines on validation of analytical methods state that 'Analytical methods described in CIPAC¹ handbooks and AOAC International² Manual, and in recognised pharmacopoeias [BP, BP (Vet), Ph Eur and USP] for a particular active constituent or formulation are regarded as validated and do not require revalidation. However, the suitability of these methods must be verified under actual conditions of use ie, the selectivity and accuracy of the method should be demonstrated for the published method when applied to the relevant sample matrix and laboratory conditions.'

When a CIPAC or AOAC International method is used for the assay of an active constituent in a bulk active constituent, there is no matrix. The registrants need to check the specificity of the method to ensure there is no interference from impurities or degradation products. However, determination of accuracy of the method is not required as there is no matrix effect. However, when a CIPAC or AOAC method is used for the assay of an active constituent in a formulated product, determination of both specificity and accuracy is required as the matrix is relevant in formulated products (formulated products have different composition and quantities of excipients).

Refer to [Guidelines for the Validation of Analytical Methods for Active Constituent, Agricultural And Veterinary Chemical Products](#).

Unless the scope of the collaborative method (CIPAC and AOAC) also includes toxicological significant impurities in the active constituent, validation data for impurities are required.

APVMA CONTACT

Any questions regarding this change can be sent by email to: chemicalreview@apvma.gov.au, or by mail to

Director Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2609

Phone: +61 2 6210 4947

Fax: +61 2 6210 4776

Email: chemicalreview@apvma.gov.au

¹ CIPAC: Collaborative International Pesticides Analytical Council.

² AOAC International: a non-profit scientific organisation which publishes chemical analytical methods and was formerly known as the Association of Official Analytical Chemists.

Problad Plus Fungicide Containing the New Active Constituent BLAD

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 Problad Plus Fungicide.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Problad Plus Fungicide
Applicant company:	CEV, S.A
Name of active constituent:	BLAD
Signal heading:	Not required—Appendix B
Summary of proposed use:	For suppression of brown rot and blossom blight (<i>Monilinia spp.</i>) in stone fruit
Pack sizes:	1—110 L
Withholding period:	Not required when used as directed

SUMMARY OF THE APVMA'S EVALUATION OF PROBLAD PLUS 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 Problad Plus 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 Problad Plus 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 Problad Plus Fungicide containing the active constituent BLAD, 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 Problad Plus Fungicide containing the active constituent BLAD, 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 Problad Plus 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, apvma.gov.au/news-and-publications/public-consultations 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 Problad Plus 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

New Agricultural Active Constituent BLAD (Banda De Lupinus Albus Doce) Manufacturing Concentrate

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

Common Name	BLAD manufacturing concentrate
Description	A 20 kDa polypeptide, containing 173 amino acids, sourced from the proteolysis of the seed protein β -conglutin sourced from germinated seeds of sweet lupins (<i>Lupinus albus</i>).
CAS Number:	1219521-95-5
Amino acid sequence:	Arg-Arg-Gln-Arg-Asn-Pro-Tyr-His-Phe-Ser-Ser-Gln-Arg-Phe-Gln-Thr-Leu-Tyr-Lys-Asn-Arg-Asn-Gly-Lys-Ile-Arg-Val-Leu-Glu-Arg-Phe-Asp-Gln-Arg-Thr-Asn-Arg-Leu-Glu-Asn-Leu-Gln-Asn-Tyr-Arg-Ile-Val-Glu-Phe-Gln-Ser-Lys-Pro-Asn-Thr-Leu-Ile-Leu-Pro-Lys-His-Ser-Asp-Ala-Asp-Tyr-Val-Leu-Val-Val-Leu-Asn-Gly-Arg-Ala-Thr-Ile-Thr-Ile-Val-Asn-Pro-Asp-Arg-Arg-Gln-Ala-Tyr-Asn-Leu-Glu-Tyr-Gly-Asp-Ala-Leu-Arg-Ile-Pro-Ala-Gly-Ser-Thr-Ser-Tyr-Ile-Leu-Asn-Pro-Asp-Asp-Asn-Gln-Lys-Leu-Arg-Val-Val-Lys-Leu-Ala-Ile-Pro-Ile-Asn-Asn-Pro-Gly-Tyr-Phe-Tyr-Asp-Phe-Tyr-Pro-Ser-Ser-Thr-Lys-Asp-Gln-Gln-Ser-Tyr-Phe-Ser-Gly-Phe-Ser-Arg-Asn-Thr-Leu-Glu-Ala-Thr-Phe-Asn-Thr-Arg-Tyr-Glu-Glu-Ile-Gln-Arg-Ile-Ile-Leu-Gly-Asn-Glu-Asp
Molecular formula:	C ₉₀₉ H ₁₄₁₄ N ₂₆₆ O ₂₇₁
Molecular weight:	20408.95 daltons
Chemical family:	Polypeptide
Mode of action:	Binds to glycoproteins and chitin on the cell membranes of targeted fungal cells, leading to blockage of cell pores

SUMMARY OF THE APVMA'S EVALUATION OF BLAD MANUFACTURING CONCENTRATE ACTIVE CONSTITUENT

The Scientific Assessment and Chemical Review Program of the APVMA has evaluated the chemistry aspects of BLAD manufacturing concentrate active constituent (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 BLAD manufacturing concentrate active constituent:

Active	Constituent	Level
BLAD manufacturing concentrate	BLAD polypeptide (Banda de lupinus albus doce, a 20 kDa polypeptide of β -conglutin, which is a seed storage protein found in germinated sweet lupin seeds)	200 g/kg minimum
	Lupanine	0.1 g/kg maximum

Other impurities of toxicological significance are not expected to occur in BLAD manufacturing concentrate as a result of the raw materials and the manufacturing process used.

The APVMA has considered the toxicological aspects of BLAD manufacturing concentrate, and concluded that there are no toxicological concerns from the approval of this active constituent. Neither an ADI nor an ARfD have been established for BLAD, due to the very low toxicity observed in the available acute toxicological studies.

BLAD has been included in Appendix B, Part 3 of the Standard for the Uniform Scheduling of Medicines and Poisons (substances considered not to require control by scheduling), as a result of its low toxicity.

The APVMA is satisfied that the proposed importation and use of BLAD manufacturing concentrate 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 BLAD manufacturing concentrate 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

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