Commonwealth of Australia

Gazette

No. APVMA 12, Tuesday, 18 June 2019

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.

ISSN 1837 - 7629

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GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

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

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

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

APVMA CONTACTS

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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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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. RESTRICTED PRODUCT

Application no.:	119042
Product name:	4farmers 1080 Liquid 30g/L
Active constituent/s:	30g/L sodium fluoroacetate (1080)
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of use:	For the preparation of 1080 baits to control feral pigs, foxes, rabbits and wild dogs
Date of registration:	6 June 2019
Product registration no.:	87712
Label approval no.:	87712/119042

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	114564
Product name:	Contact Organics FarmSafe Weed Terminator Concentrate Herbicide
Active constituent/s:	900 g/L acetic acid, 10 g/L hydrochloric acid
Applicant name:	Contact Organics Pty Ltd
Applicant ACN:	607 848 091
Summary of use:	For the control of weeds and grasses in horticulture, orchards, vineyards, paddocks and around buildings and other non-crop areas
Date of registration:	28 May 2019
Product registration no.:	86050
Label approval no.:	86050/114564

Application no.:	120022
Product name:	Hemani Dicamba 500 SL Herbicide
Active constituent/s:	500 g/L dicamba (present as the dimethylamine salt)
Applicant name:	Hemani Industries Limited
Applicant ACN:	N/A
Summary of use:	For the control of certain broadleaf weeds in winter cereals, pastures, conservation tillage, sugar cane, turf, rice, grain sorghum and non-crop areas
Date of registration:	29 May 2019
Product registration no.:	88003
Label approval no.:	88003/120022

Application no.:	119642
Product name:	Speedy Eco Spray Adjuvant
Active constituent/s:	704 g/L ethyl and methyl esters of fatty acids derived from refined canola oil
Applicant name:	Grow Choice Pty Limited
Applicant ACN:	161 264 884
Summary of use:	For use to enhance the penetrating properties of certain herbicides and pyrethroid insecticides
Date of registration:	29 May 2019
Product registration no.:	87873
Label approval no.:	87873/119642

Application no.:	119465
Product name:	Daredevil 520 Herbicide
Active constituent/s:	520g/L haloxyfop present as the haloxyfop-R-methyl ester
Applicant name:	Sunrise Crop Science Co Ltd
Applicant ACN:	N/A
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, and tropical fruit and nut crops
Date of registration:	30 May 2019
Product registration no.:	87810
Label approval no.:	87810/119465

Application no.:	119546
Product name:	Eureka! Triclopyr Picloram Herbicide
Active constituent/s:	300 g/L triclopyr present as the butoxyethyl ester, 100 g/L picloram present as hexyloxypropylamine salt
Applicant name:	Eureka! Agresearch Pty Ltd
Applicant ACN:	086 194 738
Summary of use:	For control of a range of environmental and noxious woody and herbaceous weeds
Date of registration:	30 May 2019
Product registration no.:	87845
Label approval no.:	87845/119546

Application no.:	115216
Product name:	Freehand Herbicide
Active constituent/s:	10 g/kg pendimethalin, 7.5 g/kg dimethenamid-p
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For use as a pre-emergence herbicide in ornamental production, landscape and grounds maintenance, and other specified non-crop areas including warm season turf
Date of registration:	30 May 2019
Product registration no.:	86278
Label approval no.:	86278/115216

Application no.:	119485
Product name:	Orosorb Spray Adjuvant AU
Active constituent/s:	190.8 g/L anionic surfactants, 81.5 g/L alcohol ethoxylate
Applicant name:	Oro Agri International Ltd
Applicant ACN:	N/A
Summary of use:	For use as a wetting agent with insecticides, miticides, fungicides, herbicides, plant growth regulators and nutrients
Date of registration:	30 May 2019
Product registration no.:	87823
Label approval no.:	87823/119485

Application no.:	116091
Product name:	Conquest Pinyon 100 EC Selective Herbicide
Active constituent/s:	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
Applicant name:	098 814 932
Applicant ACN:	For the control of key grass weeds and selective spray topping of wild oats in wheat and barley
Summary of use:	30 May 2019
Date of registration:	86583
Product registration no.:	86583/116091
Label approval no.:	

Application no.:	113872
Product name:	Merivon Fungicide
Active constituent/s:	250 g/L pyraclostrobin, 250 g/L fluxapyroxad
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For the control of certain foliar diseases in almonds, macadamias and cherries per the Directions For Use
Date of registration:	30 May 2019
Product registration no.:	85698
Label approval no.:	85698/113872

Application no.:	115120
Product name:	Metropol SC Agricultural Fungicide
Active constituent/s:	200 g/L azoxystrobin, 125 g/L flutriafol
Applicant name:	Hanseandina Australia Pty Ltd
Applicant ACN:	616 236 929
Summary of use:	For the control of certain fungal diseases in wheat and barley
Date of registration:	31 May 2019
Product registration no.:	86246
Label approval no.:	86246/115120

Application no.:	114391
Product name:	Conquest Azoxyguard Xtra Fungicide
Active constituent/s:	200 g/L azoxystrobin, 80 g/L cyproconazole
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use:	To control certain fungal diseases in barley
Date of registration:	31 May 2019
Product registration no.:	86032
Label approval no.:	86032/114391

Application no.:	115714
Product name:	Titan Propiconazole 625 EC Fungicide
Active constituent/s:	625 g/L propiconazole
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use:	For control of certain fungal diseases of wheat
Date of registration:	31 May 2019
Product registration no.:	86411
Label approval no.:	86411/115714

Application no.:	118949
Product name:	Axiom MZ WG Fungicide
Active constituent/s:	640 g/kg mancozeb, 40 g/kg metalaxyl-M
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For control of downy mildew and certain foliar diseases
Date of registration:	31 May 2019
Product registration no.:	87679
Label approval no.:	87679/118949

Application no.:	117720
Product name:	Spalding Tree & Blackberry Killer
Active constituent/s:	50 g/L triclopyr present as the butoxyethyl ester
Applicant name:	Spalding Holdings Pty Ltd
Applicant ACN:	010 155 852
Summary of use:	For the control of blackberry, lantana, groundsel, privet, wattles and other woody weeds in the home garden
Date of registration:	6 June 2019
Product registration no.:	87184
Label approval no.:	87184/117720

Application no.:	116206
Product name:	Sindoxa Ant Gel
Active constituent/s:	0.67 g/kg indoxacarb equivalent to 0.5 g/kg active S-isomer
Applicant name:	Sharda Cropchem Espana SL
Applicant ACN:	N/A
Summary of use:	For the control of ants
Date of registration:	6 June 2019
Product registration no.:	86615
Label approval no.:	86615/116206

Application no.:	119845
Product name:	Value Fly & Insect Spray Pine
Active constituent/s:	3.18 g/kg n-octyl bicycloheptene dicarboximide, 2.17 g/kg piperonyl butoxide, 1.08 g/kg tetramethrin 20:80, 0.25 g/kg phenothrin 20:80
Applicant name:	Drake Supermarkets Pty Ltd
Applicant ACN:	109 544 416
Summary of use:	For protection against flying and crawling insects
Date of registration:	6 June 2019
Product registration no.:	87939
Label approval no.:	87939/119845

Application no.:	119844
Product name:	Value Fly & Insect Spray Low Irritant
Active constituent/s:	1.08 g/kg tetramethrin 20:80, 0.25 g/kg d-phenothrin 20:80, 2.17 g/kg piperonyl butoxide, 3.18 g/kg n-octyl bicycloheptene dicarboximide
Applicant name:	Drake Supermarkets Pty Ltd
Applicant ACN:	109 544 416
Summary of use:	For protection against flying and crawling insects
Date of registration:	6 June 2019
Product registration no.:	87938
Label approval no.:	87938/119844

Application no.:	117860
Product name:	Imtrade Triallate 625 EC Herbicide
Active constituent/s:	625 g/L triallate
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control of wild oats in wheat, triticale, chickpeas, barley, peas, linseed, lupins, canola (rapeseed), faba beans and safflower
Date of registration:	6 June 2019
Product registration no.:	87243
Label approval no.:	87243/117860

Application no.:	119645
Product name:	Conquest Yakka Spray Adjuvant
Active constituent/s:	440 g/L methyl esters of canola oil fatty acids
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use:	To assist the performance of Pinyon 100 EC Selective Herbicide and other crop protection products in grain, legume and oilseed crops and pastures
Date of registration:	7 June 2019
Product registration no.:	87875
Label approval no.:	87875/119645

3. VARIATIONS OF REGISTRATION

Application no.:	120312
Product name:	Lantana 600 Herbicide
Active constituent/s:	600 g/L dichlorprop present as the potassium salt
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To change the product and label name from ‘Agricrop Lantana 600 Herbicide’ to ‘Lantana 600 Herbicide’, to add a 10L pack size, to include the updated product name for Activator in the Directions for use section and to update the Storage and Disposal Instructions in line with the latest labelling code
Date of variation:	13 May 2019
Product registration no.:	57899
Label approval no.:	57899/120312

Application no.:	120321
Product name:	Surefire Starox 400 Herbicide
Active constituent/s:	400 g/L fluroxypyr as the methyl heptyl ester
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of variation:	To change the distinguishing product name and the name that appears on the label from ‘Surefire Flurox 400 Herbicide’ to ‘Surefire Starox 400 Herbicide’
Date of variation:	15 May 2019
Product registration no.:	84324
Label approval no.:	84324/120321

Application no.:	118368
Product name:	Rancona Dimension Seed Treatment
Active constituent/s:	25 g/L ipconazole, 20 g/L metalaxyl
Applicant name:	Arysta Lifescience Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of variation:	To increase the application rate range for control of loose smut in barley
Date of variation:	3 June 2019
Product registration no.:	67985
Label approval no.:	67985/118368

Application no.:	119569
Product name:	Amistar 250 SC Fungicide
Active constituent/s:	250 g/kg azoxystrobin
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To add use instructions for anise myrtle leaves, carrot, lemon myrtle leaves, lettuce seedlings, cut flowers and foliage olives, pyrethrum, riberries and rubus fruit
Date of variation:	5 June 2019
Product registration no.:	58340
Label approval no.:	58340/119569

Application no.:	120451
Product name:	Zampro Fungicide
Active constituent/s:	300 g/L ametoctradin, 225 g/L dimethomorph
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of variation:	Removal of reference to methoxam in the DFU table
Date of variation:	27 May 2019
Product registration no.:	63651
Label approval no.:	63651/120451

Application no.:	119740
Product name:	Genfarm Azoxystrobin 250 SC Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of variation:	To add uses in anise myrtle, lemon myrtle, nursery stock and ornamentals, olives, pyrethrum, riberries, rubus crops, almonds, citrus, pistachio, garlic, shallots, beans, brassicas, brassica leafy vegetables, horseradish, leeks, lettuce, radish and peas
Date of variation:	6 June 2019
Product registration no.:	67483
Label approval no.:	67483/119740

Application no.:	120431
Product name:	Ranman 400 SC Fungicide
Active constituent/s:	400 g/L cyazofamid
Applicant name:	Ishihara Sangyo Kaisha Ltd
Applicant ACN:	N/A
Summary of variation:	To remove the turf use from the label instructions
Date of variation:	23 May 2019
Product registration no.:	66411
Label approval no.:	66411/120431

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.:	109517
Product name:	Cimalgex 30 mg Chewable Tablets For Dogs
Active constituent/s:	30 mg/Tb cimicoxib
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For use in the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery in dogs
Date of registration:	5 June 2019
Product registration no.:	84021
Label approval no.:	84021/109517

Application no.:	109542
Product name:	Cimalgex 8 mg Chewable Tablets for Dogs
Active constituent/s:	8 mg/Tb cimicoxib
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For use in the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery in dogs
Date of registration:	5 June 2019
Product registration no.:	84038
Label approval no.:	84038/109542

Application no.:	109543
Product name:	Cimalgex 80 mg Chewable Tablets for Dogs
Active constituent/s:	80 mg/Tb cimicoxib
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For use in the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery in dogs
Date of registration:	5 June 2019
Product registration no.:	84039
Label approval no.:	84039/109543

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	111706
Product name:	Bimepro 5 mg/ml Pour-on Solution for Cattle
Active constituent/s:	5 mg/mL eprinomectin
Applicant name:	Bimeda (Australia) Pty Limited
Applicant ACN:	058 196 508
Summary of use:	For the treatment and control of internal and external parasites of beef and dairy cattle, and internal parasites of deer
Date of registration:	28 May 2019
Product registration no.:	84893
Label approval no.:	84893/111706

Application no.:	113257
Product name:	Eficur Antibiotic Suspension For Injection For Cattle
Active constituent/s:	50 mg/mL ceftiofur (as ceftiofur hydrochloride)
Applicant name:	Laboratorios Hipra SA
Applicant ACN:	N/A
Summary of use:	For treatment of bacterial respiratory disease in cattle associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somnus*
Date of registration:	31 May 2019
Product registration no.:	85425
Label approval no.:	85425/113257

3. VARIATIONS OF REGISTRATION

Application no.:	117774
Product name:	Zolvix Monepantel Broad Spectrum Oral Anthelmintic For Sheep
Active constituent/s:	25 mg/mL monepantel
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	Variation of product registration and label approval to vary the export slaughter interval (ESI)
Date of variation:	29 May 2019
Product registration no.:	62752
Label approval no.:	62752/117774

Application no.:	110371
Product name:	Zolvix Plus Broad Spectrum Oral Anthelmintic For Sheep And Cattle
Active constituent/s:	25 mg/mL monepantel, 2 mg/mL abamectin
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	For the treatment and control of sensitive strains of nematodes (roundworms) in sheep, beef and non-lactating dairy cattle
Date of variation:	30 May 2019
Product registration no.:	69763
Label approval no.:	69763/110371

Application no.:	120331
Product name:	Bayer Viper Pour-On Lousicide for Sheep
Active constituent/s:	10 g/L thiacloprid
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Bayer Pour-on Lousicide for Sheep' to 'Bayer Viper Pour-on Lousicide for Sheep'
Date of variation:	16 May 2019
Product registration no.:	87489
Label approval no.:	87489/120331

Application no.:	119077
Product name:	Calbor 4 In 1 Mineral Injection For Cattle And Sheep
Active constituent/s:	27.4 g/L calcium (as calcium borogluconate), 4.8 g/L magnesium (as magnesium hypophosphite), 12.4 g/L phosphorus (as hypophosphite)
Applicant name:	Tasman Chemicals Pty Limited
Applicant ACN:	005 072 659
Summary of variation:	Variation of product registration and label approval to change the product name and align the label with the Vet Labelling Code
Date of variation:	31 May 2019
Product registration no.:	47647
Label approval no.:	47647/119077

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.:	117845
Active constituent/s:	methoxyfenozide
Applicant name:	UPL Australia Ltd
Applicant ACN:	066 391 384
Summary of use:	For use in agricultural chemical products
Date of approval:	30 May 2019
Approval no.:	87236

Application no.:	118164
Active constituent/s:	clofentezine
Applicant name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of use:	For use in agricultural chemical products
Date of approval:	5 June 2019
Approval no.:	87346

Application no.:	118173
Active constituent/s:	s-abscisic acid
Applicant name:	TGAC Australia Pty Ltd
Applicant ACN:	134 570 700
Summary of use:	For use in agricultural chemical products
Date of approval:	6 June 2019
Approval no.:	87352

Application no.:	116356
Active constituent/s:	indoxacarb
Applicant name:	Stotras Pty Ltd
Applicant ACN:	164 590 167
Summary of use:	For use in Agricultural chemical products
Date of approval:	7 June 2019
Approval no.:	86685

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	117996
Active constituent/s:	isofetamid
Applicant name:	Ishihara Sangyo Kaisha Ltd
Applicant ACN:	N/A
Summary of use:	Variation of relevant particulars or conditions of an approved active constituent
Date of approval:	30 May 2019
Approval no.:	81806

New Agricultural Chemical Product Elatus Ace Fungicide containing benzovindiflupyr

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent benzovindiflupyr. The product is **ELATUS ACE FUNGICIDE**.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	**ELATUS ACE FUNGICIDE**	
Applicant company:	Syngenta Australia Pty Ltd	
Name of active constituents:	Benzovindiflupyr Propiconazole	
Signal heading:	Schedule 6	
Summary of proposed use:	For the control of fungal diseases in wheat and barley.	
Pack sizes:	5 to 20 L	
Withholding period:	Harvest:	Not required when used a directed.
	Grazing:	DO NOT graze or cut for stock food for 10 days after application.

SUMMARY OF THE APVMA'S EVALUATION OF ELATUS ACE 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 the APVMA is satisfied that the proposed use of **ELATUS ACE FUNGICIDE**:

(i) would not be an undue hazard to the safety of people exposed to it during its handling and use

(ii) would not be an undue hazard to the safety of people using anything containing its residues

(iii) would not be harmful to human beings

(iv) would not be likely to have an unintended effect that is harmful to animals, plants 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) the APVMA is satisfied that data from trials 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:

(i) the APVMA is satisfied that the proposed use of **ELATUS ACE 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 APVMA website's 'Public Consultation' page, or by contacting the evaluator 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 **ELATUS ACE 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.

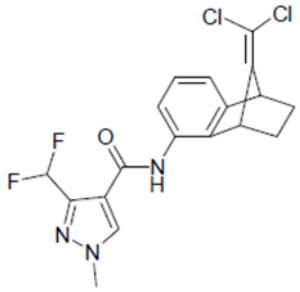
Written submissions should be addressed in writing to:

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 benzovindiflupyr

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

Common Name:	benzovindiflupyr
IUPAC Name:	*rac*-*N*-[(1*R*,4*S*)-9-(Dichloromethylidene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide
Chemical Abstracts Name:	*N*-[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide
CAS Number:	1072957-71-1
Molecular Formula:	$C_{18}H_{15}Cl_2F_2N_3O$
Molecular Weight:	398.2 g/mol
Structure:	
Chemical Family:	Pyrazole carboxamide
Mode of Action:	Inhibition of mitochondrial complex II respiration acting on the enzyme succinate dehydrogenase. Mainly a preventative fungicide with limited curative activity.

SUMMARY OF THE APVMA'S EVALUATION

The APVMA has evaluated the chemistry and manufacturing aspects of benzovindiflupyr active constituent (identification, physicochemical properties, manufacturing process, composition, 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 benzovindiflupyr active constituent:

Constituent	Specification	Level
benzovindiflupyr	benzovindiflupyr	960 g/kg minimum

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

The APVMA has considered the toxicological aspects of benzovindiflupyr, and concluded that there are no toxicological concerns to the approval of this active constituent. The ADI for benzovindiflupyr was established at 0.05 mg/kg bw/d. The ARfD for benzovindiflupyr was established at 0.1 mg/kg bw.

The Scheduling Delegate made a delegate-only decision to include benzovindiflupyr in Schedule 6 of the Poison Standard, with an implementation date of 1 February 2019.

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

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of benzovindiflupyr 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)***[1] material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Director Chemistry and Manufacture
Risk Assessment Capability Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

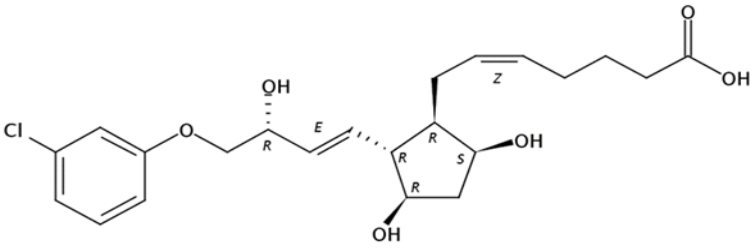
Phone: (02) 6210 4701
Fax: (02) 6210 4721
Email: enquiries@apvma.gov.au

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

New Agricultural Active Constituent and New Chemical Products DALMAZIN containing d-cloprostenol

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, d-cloprostenol, and an application for registration of a new product **DALMAZIN** containing the new active constituent. The product is indicated for the induction of oestrus, synchronization of oestrus and induction of parturition in cows, sows and mares.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	d-cloprostenol
IUPAC Name:	(5*Z*)-7-[(1*R*,2*R*,3*R*,5*S*)-2-[(1*E*,3*R*)-4-(3-chlorophenoxy)-3-hydroxybut-1-en-1-yl]-3,5-dihydroxycyclopentyl]-hept-5-enoic acid
Chemical Abstracts Name:	5-Heptenoic acid, 7-[(1*R*,2*R*,3*R*,5*S*)-2-[(1*E*,3*R*)-4-(3-chlorophenoxy)-3-hydroxy-1-buten-1-yl]-3,5-dihydroxycyclopentyl]-,(5Z)-
Manufacturer`s Code:	SUPE008
Molecular Formula:	$C_{22}H_{29}ClO_6$
Molecular Weight:	424.9 g/mol
Structure:	
Chemical Family:	$F_{2\alpha}$ prostaglandin synthetic analogue
Mode of Action:	It is a potent luteolytic agent; within hours of administration, it causes the corpus luteum to stop production of progesterone, and to reduce in size over several days. This effect is used in animals to induce oestrus and/or to cause abortion.

SUMMARY OF THE APVMA'S EVALUATION D-CLOPROSTENOL ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of d-cloprostenol (physico-chemical properties, spectroscopic identification, manufacturing process, quality control procedures, specifications, batch analysis results and analytical methods) and found them to be acceptable. There is no pharmacopeia monograph for d-cloprostenol.

The APVMA has considered the toxicological aspects of d-cloprostenol, and concluded that there are no toxicological concerns to the approval of this active constituent. An Acceptable Daily Intake (ADI) has been established at 0.075 µg/kg bw/d. An Acute Reference Dose (ARfD) was considered to be unnecessary due to its low acute toxicity.

d-cloprostenol is covered by the existing entry for cloprostenol in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). A reference to a substance in the SUSMP includes every stereoisomer of the substance, and therefore the Schedule 4 listing is applicable for d-cloprostenol.

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

PARTICULARS OF THE PRODUCT

Proposed product name(s):	DALMAZIN
Applicant company:	ETHICAL AGENTS AUSTRALIA PTY LTD
Name of active constituent:	d-cloprostenol
Signal heading:	Schedule 4
Summary of proposed use:	For use in the induction of oestrus in mares, synchronisation or induction of oestrus in cows and induction of parturition in cows and sows. The product is also indicated for the expulsion of mummified foetus, induction of abortion, ovarian dysfunction (persistent corpus luteum, luteal cyst) treatment, endometritis/pyometra and delayed uterine involution treatment in cows.
Dosage and route of administration:	The proposed dose of DALMAZIN is 2 mL given intramuscularly in cows and 1 mL given intramuscularly in sows and mares. For synchronisation of oestrus in cows, up to 2 intramuscular (IM) doses will be being given 11 days apart, and for the induction of farrowing in pigs 2 IM doses will be given 6 hours apart. DALMAZIN is also proposed for various therapeutic reproductive indications in cows, with dosing frequency ranging from a single dose to up to 3 doses given on consecutive days.
Pack sizes:	20 mL vial, 100 mL bag
Withholding period:	CATTLE & PIGS MEAT: DO NOT USE less than 1 day before slaughter for human consumption. MILK: Zero (0) days. HORSES: DO NOT USE in horses that may be used for human consumption
Side effects:	When used in cows for induction of parturition and dependent on the time of treatment relative to the date of conception, the incidence of retained placenta may be increased. Behavioural changes seen after treatment for induction of farrowing are similar to those changes associated with natural farrowing and usually cease within one hour. Occurrence of anaerobic infection is likely if anaerobic bacteria penetrate the tissue of the injection site. Typical local reactions due to anaerobic infection are swelling and crepitus at the injection site.

SUMMARY OF THE APVMA'S EVALUATION OF DALMAZIN 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

The APVMA has evaluated the proposed product DALMAZIN and is satisfied that the proposed chemical product meets the safety (s 5A), efficacy (s 5B) and the trade (s 5D) criteria if used according to label instructions.

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria has 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 DALMAZIN would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment for the product and in conjunction with the estimated hazard profile, determined whether the proposed use of the product would not be an undue health hazard to humans. The APVMA estimated the acute toxicity of DALMAZIN based on information provided by the applicant. The acute toxicity of the proposed product was ascertained from toxicological studies in laboratory animals using the active constituent and the product formulation. Based on the findings of the acute toxicological studies, the active constituent, d-cloprostenol, and the product present a low acute oral and dermal toxicity. On genotoxicity, d-cloprostenol is unlikely to be genotoxic in vivo. The active was also not found to have reproductive and developmental toxicity.

The APVMA recommends the following first aid statement (a) – *If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.* The APVMA also recommends the following safety directions: *Repeated exposure may cause allergic disorders. Wash hands after use.* The first aid instruction and safety directions will be included on the product label.

(ii) The APVMA is satisfied that the proposed use of DALMAZIN will not be an undue hazard to the safety of people using anything containing their residues. d-cloprostenol is rapidly eliminated from pigs and cattle and that animals are unlikely to be sent for slaughter immediately after treatment with indications for reproduction. Coverage of the proposed uses in the APVMA Maximum Residue Limits (MRL) Standard as a Table 5 entry was considered appropriate. Table 5 lists uses of substances where MRLs are not necessary. MRLs are not necessary in situations where residues do not or should not occur in foods or animal feeds; or where the residues are identical to or indistinguishable from natural food components; or otherwise are of no toxicological significance.

(iii) The APVMA is satisfied that the proposed use of DALMAZIN containing the active constituent d-cloprostentol is not likely to be harmful to human beings if used according to the product label directions.

d-cloprostenol is listed in Schedule 4 of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). The Schedule 4 signal heading is PRESCRIPTION ANIMAL REMEDY. The product will be administered principally by veterinarians, although it is expected that the product will also be used by dairy, pig and equine farmers/operators. If the latter is the case, it would be expected that these operators would also be experienced in the handling of veterinary drugs.

(iv) The APVMA is satisfied that the proposed use of DALMAZIN 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.

The environmental assessment applied the standard VICH GL6 guidance for a Phase 1 assessment which applies the total residue approach. The total residue approach assumes 100% of d-cloprostenol administered to the animal is

excreted in the waste matrices. The assessment considered both intensively reared animals and pasture animals. Two days of treatment were assumed for cows and sows, while one day of treatment was assumed for mares. The environmental risks of the proposed use of DALMAZIN were determined to be acceptable.

The results of the target animal safety studies indicated that, at the proposed label dose rate of 0.15 mg d-cloprostenol (2 mL DALMAZIN) per animal in cattle and 0.075 mg d-cloprostenol (1 mL DALMAZIN) in pigs and mares, DALMAZIN is unlikely to cause serious adverse reactions in cattle, pigs and horses. The following contraindications: non-use in gestating and dystocic animals, non-use in animals suffering from cardiovascular, respiratory and gastrointestinal tract disease are listed in the proposed label. The APVMA will approve the following side effects to be listed on the DALMAZIN label: occurrence of anaerobic infection and typical reactions at injection sites, increase in the incidence of retained placentas when used in cattle, and behavioural changes when used during farrowing in sows. An increased mortality in piglets when the product is used for the induction of parturition in sows before the 112th day of gestation is listed as a precaution.

2. The APVMA has evaluated the applications 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 5B (2)(a), the APVMA is satisfied that data from trials supporting the efficacy of the products adequately demonstrate that if used according to the product label directions, the product is effective for the proposed uses.

The efficacy data submitted included dose determination, dose confirmation and field studies. The trial designs, treatment group sizes, ages and types of animal used, experimental conditions, administration of test and reference products, sample collection and analysis of data were generally appropriate for establishing the efficacy of the test product under normal use conditions for various reproductive indications in cattle, pigs and horses. The proposed dose of 2 mL DALMAZIN given intramuscularly in cows, and 1 mL given intramuscularly in sows and mares demonstrated efficacy in all the trials that were submitted.

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:

(i) DALMAZIN residues are not expected in cattle meat, offal or milk or pig meat and offal following the proposed use. It is considered that the risk to international trade associated with the proposed use in cattle and pigs with the withholding periods is low.

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 active constituent d-cloprostenol should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether DALMAZIN 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:

Enquiries
Registration Management and Evaluation
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