Commonwealth of Australia

Gazette

No. APVMA 19, Tuesday, 20 September 2016

Published by The Australian Pesticides and Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

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

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. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	106649
Product name:	Taser 200 Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	FDC Eco Solutions Pty Ltd
Applicant ACN:	608 235 187
Summary of use	For the non-residual control of broadleaf and grass weeds in various situations
Date of registration/approval:	30 August 2016
Product registration no.:	82751
Label approval no.:	82751/106649

Application no.:	106750
Product name:	Genfarm MCPA LV 570 Herbicide
Active constituent/s:	570 g/L MCPA present as the 2–ethylhexyl ester
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For the selective control of certain weeds in agricultural crops
Date of registration/approval:	30 August 2016
Product registration no.:	82786
Label approval no.:	82786/106750

Application no.:	106395
Product name:	Venom Professional 100 SC Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Adama Australia Pty Ltd
Applicant ACN:	050 328 973
Summary of use	For use in turf and ornamentals for control of various pests
Date of registration/approval:	30 August 2016
Product registration no.:	82667
Label approval no.:	82667/106395

Application no.:	107727
Product name:	Hovex Fast Knockdown Flying Insect Spray Odourless
Active constituent/s:	1.1 g/kg esbiothrin, 0.5 g/kg permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of flying insects
Date of registration/approval:	31 August 2016
Product registration no.:	83206
Label approval no.:	83206/107727

Application no.:	106950
Product name:	Coles Multi Insect Killer Automatic Refill Indoor and Outdoor
Active constituent/s:	9 g/kg pyrethrins, 45 g/kg piperonyl butoxide
Applicant name:	Aaron Laboratories Pty Ltd
Applicant ACN:	004 856 848
Summary of use	For the control of crawling and flying insects
Date of registration/approval:	31 August 2016
Product registration no.:	82850
Label approval no.:	82850/106950

Application no.:	106868
Product name:	Relyon Rush Spray Adjuvant
Active constituent/s:	700 g/L ethyl and methyl esters of vegetable oil
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	To assist the effectiveness of other agricultural chemicals
Date of registration/approval:	31 August 2016
Product registration no.:	82828
Label approval no.:	82828/106868

Application no.:	106515
Product name:	Relyon Ramdon 75–D Herbicide
Active constituent/s:	300 g/L 2,4–D present as the triisopropanolamine salt, 75 g/L picloram, present as the triisopropanolamine salt
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of a wide range of annual and perennial broadleaf weeds
Date of registration/approval:	31 August 2016
Product registration no.:	82711
Label approval no.:	82711/106515

Application no.:	106976
Product name:	Radchem Expedite Spray Adjuvant
Active constituent/s:	704 g/L ethyl and methyl esters of fatty acids derived from refined canola oil
Applicant name:	Radical Chemicals Pty Ltd
Applicant ACN:	609 190 918
Summary of use	To enhance the penetrating properties of certain herbicides and pyrethroid insecticides
Date of registration/approval:	31 August 2016
Product registration no.:	82860
Label approval no.:	82860/106976

Application no.:	103270
Product name:	Effect Rodent Wax Block Baits
Active constituent/s:	0.05 g/kg difenacoum
Applicant name:	Unichem D.O.O
Applicant ACN:	N/A
Summary of use	For the control of brown or Norway rats and mice, including those resistant to other anticoagulants
Date of registration/approval:	1 September 2016
Product registration no.:	81513
Label approval no.:	81513/103270

Application no.:	105052
Product name:	Titan Butroxydim 250 WG Herbicide
Active constituent/s:	250 g/kg butroxydim
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use	For the control of certain grasses in a range of broad acre crops
Date of registration/approval:	2 September 2016
Product registration no.:	82121
Label approval no.:	82121/105052

Application no.:	105161
Product name:	Titan Imazapyr 750WG Herbicide
Active constituent/s:	750 g/kg imazapyr
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use	For the control of various annual and perennial weeds in non-crop situations
Date of registration/approval:	7 September 2016
Product registration no.:	82198
Label approval no.:	82198/105161

Application no.:	106748
Product name:	Genfarm 2,4–D Ester 680 LV Herbicide
Active constituent/s:	680g/L 2,4–D present as the 2–ethylhexyl ester
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For selective control of various weeds in crops, pastures and non agricultural areas
Date of registration/approval:	7 September 2016
Product registration no.:	82784
Label approval no.:	82784/106748

Application no.:	107337
Product name:	Agsure Diuron 900 Herbicide
Active constituent/s:	900 g/kg diuron
Applicant name:	Elders Rural Services Australia Limited
Applicant ACN:	004 045 121
Summary of use	For the control of weeds in asparagus, bananas, cereals, cotton, lucerne, lupins, pulse crops and sugar cane
Date of registration/approval:	8 September 2016
Product registration no.:	83023
Label approval no.:	83023/107337

Application no.:	107534
Product name:	Apparent Spread—Insect and Scale Spray RTU
Active constituent/s:	19.46 g/L paraffin oil
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of use	For the control of various scales, mites, mealy bugs, leafminers, whiteflies and aphids in citrus, grapes, roses, indoor and outdoor ornamentals, stone fruits and pome fruits
Date of registration/approval:	8 September 2016
Product registration no.:	83102
Label approval no.:	83102/107534

Application no.:	103385
Product name:	Imtrade Linuron 800 WG Herbicide
Active constituent/s:	800 g/kg linuron
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use	For the selective control of weeds in carrots, coriander, parsnips, cereals, onions, potatoes, soybeans, sweet corn and maize
Date of registration/approval:	8 September 2016
Product registration no.:	81574
Label approval no.:	81574/103385

Application no.:	102180
Product name:	AIRONE WG Fungicide/Bactericide
Active constituent/s:	280 g/kg copper (cu) present as copper oxychloride and copper hydroxide
Applicant name:	Isagro Australia Pty Ltd
Applicant ACN:	066 736 114
Summary of use	For the control of certain diseases of fruit trees, vines and vegetables
Date of registration/approval:	8 September 2016
Product registration no.:	81027
Label approval no.:	81027/102180

Application no.:	107131
Product name:	Apparent Ant-Assassin Ant Sand Insecticide
Active constituent/s:	2.0 g/kg bifenthrin
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use	For the control of certain pests in turf; ants, fleas and ticks in external surrounds of buildings and structures
Date of registration/approval:	9 September 2016
Product registration no.:	82922
Label approval no.:	82922/107131

Application no.:	105051
Product name:	Conquest Racer 250 WG Selective Herbicide
Active constituent/s:	250 g/kg butroxydim
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use	For the control of certain grasses in a range of broadacre crops
Date of registration/approval:	9 September 2016
Product registration no.:	82120
Label approval no.:	82120/105051

2. VARIATIONS OF REGISTRATION

Application no:	107482
Product name:	Vetsense Stable & Kennel Disinfectant
Active constituent/s:	30 g/L benzalkonium chloride (a quaternary ammonium compound)
Applicant name:	Vetsense Pty Ltd
Applicant ACN:	150 968 871
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'VALUE PLUS STABLE AND KENNEL DISINFECTANT' to 'VETSENSE STABLE & KENNEL DISINFECTANT'
Date of variation:	2 August 2016
Product registration no.:	57786
Label approval no.:	57786/107482

Application no:	107497
Product name:	Huilong Atrazine 900 WDG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY ATRAZINE 900 WDG HERBICIDE' to 'HUILONG ATRAZINE 900 WDG HERBICIDE'
Date of variation:	3 August 2016
Product registration no.:	66326
Label approval no.:	66326/107497

Application no:	107500
Product name:	Huilong Azoxystrobin 250 SC Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY AZOXYSTROBIN 250 SC FUNGICIDE' to 'HUILONG AZOXYSTROBIN 250 SC FUNGICIDE'
Date of variation:	3 August 2016
Product registration no.:	66965
Label approval no.:	66965/107500

Application no:	107504
Product name:	Huilong Chlorpyrifos 500 EC Insecticide
Active constituent/s:	500 g/L chlorpyrifos (an anti-cholinesterase compound)
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY CHLORPYRIFOS 500EC INSECTICIDE' to 'HUILONG CHLORPYRIFOS 500 EC INSECTICIDE'
Date of variation:	3 August 2016
Product registration no.:	60611
Label approval no.:	60611/107504

Application no:	107513
Product name:	Huilong Glyphosate Ready To Use Weedspray
Active constituent/s:	7.2 g/L glyphosate present as the isopropylamine salt
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY GLYPHOSATE READY TO USE WEEDSPRAY' to 'HUILONG GLYPHOSATE READY TO USE WEEDSPRAY'
Date of variation:	4 August 2016
Product registration no.:	67001
Label approval no.:	67001/107513

Application no:	107514
Product name:	Huilong Metsulfuron-Methyl 600 WG Herbicide
Active constituent/s:	600 g/kg metsulfuron-methyl
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY METSULFURON-METHYL 600 WG HERBICIDE' to 'HUILONG METSULFURON-METHYL 600 WG HERBICIDE'
Date of variation:	4 August 2016
Product registration no.:	66310
Label approval no.:	66310/107514

Application no:	107521
Product name:	Huilong Paraquat 250 Herbicide
Active constituent/s:	250 g/L paraquat present as paraquat dichloride
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY PARAQUAT 250 HERBICIDE' to 'HUILONG PARAQUAT 250 HERBICIDE'
Date of variation:	4 August 2016
Product registration no.:	66309
Label approval no.:	66309/107521

Application no:	107543
Product name:	Huilong Glufosinate 200 Non-Selective Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY GLUFOSINATE 200 NON-SELECTIVE HERBICIDE' to 'HUILONG GLUFOSINATE 200 NON-SELECTIVE HERBICIDE'
Date of variation:	4 August 2016
Product registration no.:	66325
Label approval no.:	66325/107543

Application no:	107102
Product name:	Country Bifenthrin 100 SC Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Garrards Pty Ltd
Applicant ACN:	010 648 325
Summary of variation:	To extend the use for control of a range of pests in turf and ornamental plants
Date of variation:	6 September 2016
Product registration no.:	67299
Label approval no.:	67299/107102

Application no:	107568
Product name:	Bromakil Pellet Bait For Rats And Mice
Active constituent/s:	0.05 g/kg bromadiolone
Applicant name:	De Sangosse Australia Pty Ltd
Applicant ACN:	601 609 545
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RENTOKIL BROMAKIL-P PELLET BAIT FOR RATS AND MICE' to 'BROMAKIL PELLET BAIT FOR RATS AND MICE'
Date of variation:	8 August 2016
Product registration no.:	33911
Label approval no.:	33911/107568

Application no:	107571
Product name:	Bromakil Grain Bait For Rats And Mice
Active constituent/s:	0.05 g/kg bromadiolone
Applicant name:	De Sangosse Australia Pty Ltd
Applicant ACN:	601 609 545
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RENTOKIL BROMAKIL GRAIN BAIT FOR RATS AND MICE' to 'BROMAKIL GRAIN BAIT FOR RATS AND MICE'
Date of variation:	8 August 2016
Product registration no.:	48145
Label approval no.:	48145/107571

Application no:	107572
Product name:	Bromakil Super Rat Drink
Active constituent/s:	0.05 g/kg bromadiolone
Applicant name:	De Sangosse Australia Pty Ltd
Applicant ACN:	601 609 545
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RENTOKIL BROMAKIL SUPER RAT DRINK' to 'BROMAKIL SUPER RAT DRINK'
Date of variation:	8 August 2016
Product registration no.:	47484
Label approval no.:	47484/107572

3. LABEL APPROVAL

Application no.:	107001
Product name:	Aquatain AMF Liquid Mosquito Film
Active constituent/s:	754 g/L polydimethylsiloxane
Applicant name:	Aquatain Products Pty Ltd
Applicant ACN:	131 287 271
Summary of use:	To approve a new label for the product with the label name 'MOSQUITO DROPS—LIQUID MOSQUITO FILM'
Date of approval:	5 September 2016
Label approval no.:	62820/107001

Application no.:	106838
Product name:	Rentokil Bromard
Active constituent/s:	0.1 g/kg bromadiolone
Applicant name:	Rentokil Initial Pty Ltd
Applicant ACN:	000 034 597
Summary of use:	To approve a new label for the product with the label name 'RUDDUCK DEADLINE PASTE RODENTICIDE'
Date of approval:	5 September 2016
Label approval no.:	39461/106838

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.:	61979
Product name:	Abantel Broad Spectrum Wormer For Dogs
Active constituent/s:	545 mg/tablet oxantel embonate, 140 mg/tablet pyrantel embonate, 50 mg/tablet praziquantel
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use	For the treatment and control of roundworms, hookworms, whipworms and tapeworms in dogs
Date of registration/approval:	6 September 2016
Product registration no.:	69893
Label approval no.:	69893/61979

Application no.:	60667
Product name:	Bimectin Plus (Ivermectin Plus Clorsulon) Solution For Injection For Cattle
Active constituent/s:	10 mg/mL ivermectin, 100 mg/mL clorsulon
Applicant name:	Bimeda (Australia) Pty Limited
Applicant ACN:	058 196 508
Summary of use	For the treatment and control of ivermectin and clorsulon sensitive strains of internal and external parasites of cattle, including adult liver flukes
Date of registration/approval:	6 September 2016
Product registration no.:	69395
Label approval no.:	69395/60667

Application no.:	103412
Product name:	Euthanimal 40% Euthanasia Injection
Active constituent/s:	400 mg/mL pentobarbitone sodium (equivalent to 365 mg pentobarbitone)
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use	For rapid euthanasia of pigs, sheep, goats, cattle, horses, cats and dogs
Date of registration/approval:	6 September 2016
Product registration no.:	81585
Label approval no.:	81585/103412

Application no.:	103364
Product name:	DIB-H
Active constituent/s:	Each device contains 0.5 g progesterone
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of use	For the regulation, synchrony and re-synchrony of oestrus and the treatment of post-partum anoestrus in breeding cattle
Date of registration/approval:	8 September 2016
Product registration no.:	81565
Label approval no.:	81565/103364

Application no.:	103198
Product name:	Strikeforce-S Spray-On Sheep Blowfly Treatment
Active constituent/s:	50 g/L dicyclanil
Applicant name:	Jurox Pty Limited
Applicant ACN:	000 932 230
Summary of use	For the protection of sheep, either off-shears or with any length wool, against fly strike (by *lucilia cuprina*) and for the protection of mulesing and marking wounds on sheep against fly strike (by *lucilia cuprina*) during the wound healing process
Date of registration/approval:	9 September 2016
Product registration no.:	81483
Label approval no.:	81483/103198

2. VARIATIONS OF REGISTRATION

Application no:	107487
Product name:	Vetsense Medicated Shampoo For Dogs And Cats
Active constituent/s:	10 g/L selenium sulfide
Applicant name:	Vetsense Pty Ltd
Applicant ACN:	150 968 871
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'VETSENSE ITCH WASH FOR DOGS AND CATS' to 'VETSENSE MEDICATED SHAMPOO FOR DOGS AND CATS'
Date of variation:	2 August 2016
Product registration no.:	58983
Label approval no.:	58983/107487

Approved Active Constituents

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

1. ACTIVE CONSITUTENT

Application no.:	58116
Active constituent/s:	Flupyradifurone
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	For use in agricultural chemical products
Date of approval:	30 August 2016
Approval no.:	68328

Application no.:	61739
Active constituent/s:	Mandestrobin
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of use:	For use in agricultural chemical products
Date of approval:	30 August 2016
Approval no.:	69788

Application no.:	101521
Active constituent/s:	Quintozene
Applicant name:	AMVAC C.V.
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	31 August 2016
Approval no.:	80740

Application no.:	105282
Active constituent/s:	Metsulfuron-methyl
Applicant name:	Rotam Agrochemical Co, Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	1 September 2016
Approval no.:	82252

Application no.:	105366
Active constituent/s:	Bentazone
Applicant name:	Grow Choice Pty Limited
Applicant ACN:	069 839 961
Summary of use:	For use in agricultural chemical products
Date of approval:	2 September 2016
Approval no.:	82286

Application no.:	105489
Active constituent/s:	Diflufenican
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	For use in agricultural chemical products
Date of approval:	7 September 2016
Approval no.:	82352

Application no.:	105435
Active constituent/s:	Carbaryl
Applicant name:	Agrinova New Zealand Ltd. t/a Gro-Chem
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	8 September 2016
Approval no.:	82325

Application no.:	105466
Active constituent/s:	Glufosinate-ammonium
Applicant name:	Profeng Australia Pty Ltd
Applicant ACN:	156 055 533
Summary of use:	For use in agricultural chemical products
Date of approval:	12 September 2016
Approval no.:	82337

Application no.:	105391
Active constituent/s:	Maleic hydrazide
Applicant name:	Arysta Lifescience Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of use:	For use in agricultural chemical products
Date of approval:	12 September 2016
Approval no.:	82300

Approved Active Constituents

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

1. ACTIVE CONSITUTENT

Application no.:	101521
Active constituent/s:	Quintozene
Applicant name:	AMVAC C.V
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	31 August 2016
Approval no.:	80740

SUMMARY OF THE APVMA'S EVALUATION OF QUINTOZENE ACTIVE CONSTITUENT

Quintozene suspensions (2010)

The APVMA became aware of information in 2009 indicating the presence of undeclared dioxins as impurities in products that contain quintozene as the active constituent. Dioxins are classified by the APVMA as compounds of toxicological concern (see apvma.gov.au/node/10706), and as a result of a human health risk assessment, the approval of all quintozene active constituents were suspended from 9 April 2010 due to human health concerns.

Assessment of current application (number 101521)

In considering the current application, the APVMA has evaluated the chemistry and manufacturing related aspects of the quintozene active constituent, with a focus on the potential presence of impurities of toxicological concern including dioxins, hexachlorobenzene and pentachlorobenzene.

The APVMA also commissioned a human health assessment to evaluate whether this quintozene active constituent meets the safety criteria when used in products according to currently approved permit conditions[1].

As an outcome of the chemistry and human health assessments, the APVMA is satisfied that this quintozene active constituent meets the safety criteria as it would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and would not be likely to have an effect that is harmful to human beings, provided that certain conditions of approval are met as outlined below.

CONDITIONS OF APPROVAL

The approval of the active constituent is subject to:

- the conditions prescribed by the regulations (whether or not the conditions are prescribed at the time the constituent is approved); and
- the amendment of the APVMA Standard for quintozene active constituent as follows:
    - addition of a maximum level of total dioxins (PCDDs, PCDFs) (expressed as the TCDD toxic equivalence (TEQ) of the mixture) of 0.005 mg/kg[2];
    - reduction of the maximum level of hexachlorobenzene to 350 mg/kg; and
    - addition of a maximum level of pentachlorobenzene of 0.3 mg/kg.

[1] Several quintozene product permits have been issued under strict conditions including significant restrictions on use and the requirement for batch by batch analysis to ensure that dioxin concentrations remain at acceptable levels.

[2] Dioxin TEQ of the mixture should be calculated in accordance with the method described by Van den Berg et al (1998) Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environ Hlth Persp 106: 775–792.

Licensing of Veterinary Chemical Manufacturers

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

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

1. NEW LICENCES

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

4 SEASON COMPANY PTY LTD

ACN: 075 508 664

9–11 Platinum Street

CRESTMEAD QLD 4132

LICENCE NO: 4099

Product Types:*

- *Category 4*: medicated blocks

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, compression of blocks, filling, packaging, labelling, analysis and testing (physical), storage and release for supply

Licence Issued: 25 August 2016

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

AUSTRALIAN ANIMAL BLOOD BANK PTY LTD

ACN: 140 128 990

50 Wills Road

LONG POINT NSW 2564

LICENCE NO: 1101

Product Types: *

- *Category 1*: immunobiologicals (canine red blood cells) and immunobiologicals (canine plasma)

Step(s) of Manufacture: Quality assurance (QA) of raw materials, selection and screening of donor animals, blood collection, plasma separation, packaging, labelling, analysis and testing (haematological), storage and release for supply

Amended Licence Issued: 2 August 2016

* Category 1: *Immunobiologicals and sterile veterinary preparations*
Category 2: *Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements*
Category 3: *Ectoparasiticides*
Category 4: *Premixes and supplements*
Category 5: *Exempt*
Category 6: *One-step manufacturer*

BALHAN INDUSTRIAL CO. PROPRIETARY LIMITED

ACN: 004 705 435

81–89 Buckley Grove

MOOLAP VIC 3220

LICENCE NO: 2111

Product Types: *

- *Category 2*: pastes, powders and liquids

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply

Amended Licence Issued: 3 August 2016

SCENTAL PACIFIC PTY. LTD.

ACN: 073 481 419

53 Jersey Road

BAYSWATER VIC 3153

LICENCE NO: 2112

Product Types: *

- *Category 2*: creams/lotions, ointments, gels, pastes, sprays and liquids
- *Category 3:* liquids, pastes and sprays

Step(s) of Manufacture: Formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, analysis and testing (physical and chemical), storage and release for supply

Amended Licence Issued: 9 August 2016

FARM BALANCE PTY. LTD.

ACN: 007 368 069

Mountford Road

KERANG VIC 3579

LICENCE NO: 4018

Product Types: *

- *Category 4*: premixes, supplements and block licks

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

Amended Licence Issued: 26 August 2016

* Category 1: *Immunobiologicals and sterile veterinary preparations*
Category 2: *Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements*
Category 3: *Ectoparasiticides*
Category 4: *Premixes and supplements*
Category 5: *Exempt*
Category 6: *One-step manufacturer*

3. LICENCE CANCELLATIONS

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

ORION LABORATORIES PTY. LTD.
ACN: 009 293 136
25–29 Delawney St
BALCATTA WA 6021

LICENCE NO: 2177
Date Cancelled: 17 August 2016

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].

CHARLES I.F.E. PROPRIETARY LIMITED
ACN: 004 994 629
'Berrybank Farm'
34 Hendersons Road
WINDERMERE VIC 3352

LICENCE NO: 6155
Date Suspension Revoked: 24 August 2016

APVMA CONTACT

Manufacturing Quality and Licensing Section
Legal and Compliance Program
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*

Revocation of Suspension of a Product Containing Dimethoate to allow Approval of new Label

On 14 September 2016 the APVMA revoked the suspension of the following dimethoate product registration to allow approval of a new product label that has instructions consistent with the previous suspension instructions as published on 6 October 2015 to mitigate the dietary risks identified in the review of dimethoate.

Table 1: Registered product containing dimethoate and new approved label

Product no	Product name	Holder	Label approval that remains suspended	New approved label number that is not suspended
55441	4Farmers Dimethoate 400 Systemic Insecticide	4 Farmers Australia Pty Ltd	55441/0402	55441/107381

Please note that the label approval listed in column 4 of table 1 remains suspended. Product bearing this suspended label must continue to be used only in accordance with the instructions issued by the APVMA to allow continued use of suspended dimethoate products*. See permit PER 13155 for the current instructions for the use of suspended dimethoate products and products bearing suspended labels.* The new approved label listed in column 5 of table 1 may be used according to its label instructions.

FURTHER CHANGES TO INSTRUCTIONS FOR USE MAY BE REQUIRED

Please note that the review of all dimethoate products is ongoing and further changes to the status of registrations and the instructions for use of dimethoate products may be required prior to finalisation of the review.

APVMA CONTACT

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

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

Phone: +61 2 6210 4749
Fax: +61 2 6210 4776
Email: chemicalreview@apvma.gov.au

Cancellation of Product Registration and Label Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the registration and the associated label approval of the following product:

Product no	Product name	Approval holder	Date of effect
60435	AMGROW CHEMSPRAY INSECT CONTROL ANTISCALE INSECTICIDE	AMGROW PTY LTD	13 September 2016

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

SUPPLY

A person may supply or cause to be supplied product manufactured prior to 13 September 2016 at wholesale and retail level, until the 13 September 2017.

After 13 September 2017 it will be an offence against the Agvet Codes to have possession or custody of the product with the intention to supply, or to supply the product.

USE

A person may continue to use the product according to its label instructions until 13 September 2017.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product 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 after the registration has been cancelled until 13 September 2017.

The supply and use of the product 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 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:

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

Phone: +61 2 6210 4749
Fax: +61 2 6210 4773
Email: chemicalreview@apvma.gov.au

New Veterinary Chemical Product Containing a New veterinary Active Constituent Human Insulin (Recombinant) in Prozinc Insulin Injection for Cats

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Boehringer Ingelheim Pty Limited, Vetmedica Division for the approval of a new active constituent human insulin. The APVMA also has before it an application from the same applicant for the registration of the new product prozinc insulin injection for cats containing the new active constituent. prozinc insulin injection for cats is proposed to be registered for the treatment of diabetes mellitus in cats to achieve reduction of hyperglycaemia and improvement of associated clinical signs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name: Human insulin

IUPAC name: See structure below

CAS name: Insulin (human)

CAS registry number: 11061-68-0

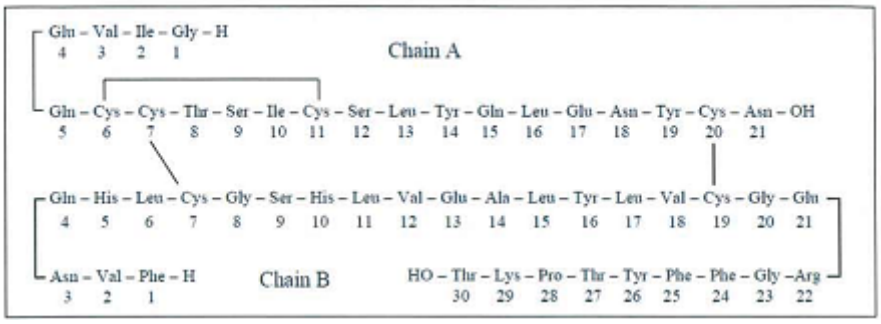
Manufacturer's codes: Not applicable

Assay (dried basis): 95.0–105.0%

Molecular formula: $C_{257}H_{383}N_{65}O_{77}S_6$

Molar mass: 5808 Da

Structure:



Chemical family: Polypeptide

Mode of action: Hormone

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT HUMAN INSULIN IN ACCORDANCE WITH SECTION 5A 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 new active constituent human insulin under sections 5A(1)(a),(b) and (c) of the Agvet Code and proposes to be satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry and manufacturing aspects of human insulin in prozinc insulin injection for cats through data provided by the applicant (including the physico-chemical properties, spectral identification, manufacturing and quality control aspects, impurity formation, active constituent specification, stability, batch analysis data, analytical methods and packaging information) and is satisfied that the safety criteria relevant to the approval of the active constituent and registration of the product has been met.

The Department of Health has evaluated the toxicological profile of human insulin (recombinant) through data provided by the applicant. Given that recombinant human insulin is identical to endogenous human insulin and is not expected to produce toxic responses other than those associated with its physiological and pharmacological properties, a full toxicological data package was not required. The assessment was therefore undertaken on information on the pharmacokinetics and pharmacodynamics of insulin, as well as summaries of publically available toxicity studies conducted with insulin and published papers relating to the toxicity of insulin and its use in humans.

Human insulin is unlikely to enter the food chain and therefore the determination of an acceptable daily intake, acute reference dose and maximum residue limits is not considered necessary.

Insulins are listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) without exemptions or cut-offs. The current listing for insulins is determined to be appropriate. The appropriate Schedule 4 signal heading will appear on the product label.

The APVMA has considered and accepted the findings and recommendations of the advice providers.

PARTICULARS OF THE PRODUCT

Proposed product name:	Prozinc insulin injection for cats
Applicant company:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Name of active constituent:	Human insulin
Signal heading:	Prescription animal remedy—Schedule 4
Summary of proposed use:	For the treatment of diabetes mellitus in cats to achieve reduction of hyperglycaemia and improvement of associated clinical signs
Pack sizes:	10 mL
Withholding period:	N/A

SUMMARY OF THE APVMA'S EVALUATION OF THE PRODUCT IN ACCORDANCE WITH SECTION 5A, 5B AND 5C 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 applications 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 prozinc insulin injection for cats would not be an undue hazard to the safety of people exposed to it during its handling.

   The Department of Health has conducted a risk assessment using the information provided by the applicant. The applicant provided a comprehensive summary of the biochemistry, pharmacokinetics, pharmacodynamics and toxicity of insulin from publically available sources. The Department of Health

found that the submitted data support the safe use of the product from a toxicological perspective. The toxicity of the product was estimated based on information related to the active constituent, as well as from data on the excipients. Based on this extrapolation, the product is expected to be of low acute oral, acute dermal and acute inhalational toxicity. It is not expected to be a skin or eye irritant and is considered unlikely to be a skin sensitiser.

No ADI has been established for insulin. As the product is intended only for veterinary use by subcutaneous injection in non-food producing animals, and the active constituent is identical to naturally produced human insulin, an ADI is not considered necessary. In addition, insulin is degraded in the gastrointestinal tract and is therefore not orally bioavailable.

The APVMA has considered and accepted the findings and recommendations of the external reviewer.

(ii) The APVMA is satisfied that the proposed use of prozinc insulin injection for cats will not be an undue hazard to the safety of people using anything containing their residues.

Prozinc insulin injection for cats is proposed to be registered for use in companion animals (cats) only. Human insulin is unlikely to enter the food chain and therefore the determination of an acceptable daily intake, acute reference dose and maximum residue limits is not considered necessary.

(iii) The APVMA is satisfied that the proposed use of prozinc insulin injection for cats containing the active constituent human insulin is not likely to be harmful to human beings if used according to label directions.

Insulins are listed in Schedule 4 of the SUSMP without exemptions or cut-offs. The existing Schedule 4 entry for insulins is appropriate for prozinc insulin injection for cats. The appropriate Schedule 4 signal headings and the following first aid instructions will appear on the product label.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

(iv) The APVMA is satisfied that the proposed use of prozinc insulin injection for cats 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 Department of the Environment has evaluated the environmental aspects of prozinc insulin injection for cats and has advised that it meets the criteria for the environmental risk assessment to stop at VICH phase I (where the potential for environmental exposure is assessed based on the intended use of the product—in this case for companion animals only). The Department of the Environment has recommended to the APVMA that the use of prozinc insulin injection for cats in cats under the proposed use pattern is unlikely to have an unintended effect that is harmful to animals, plants or the environment. The APVMA has considered these findings and accepts the recommendations of the Department of the Environment. The product labels will contain a suitable disposal statement.

An external reviewer evaluated the data provided by the applicant to substantiate the safety of the proposed product in cats. The applicant provided published data and clinical trial data to support the safety of the product in cats. The extended efficacy study described below was also carried out as a field safety study to evaluate target animal safety. Owing to the pharmacological properties of insulin, a margin of safety study was not considered appropriate.

Two subjective variables that provided supportive data to judge both overall safety and adequate glycaemic control were investigator assessments on day 136 of the cat's overall condition and weekly owner observations throughout the study period of the cat's appetite, water consumption, urination, and attitude. For the field safety assessment, on day 136, haematology, clinical chemistry and urinalysis variables were compared to both normal laboratory ranges and the day 0 values. The comparative results showed only one variable, glucose, had a day 136 mean that was outside the normal reference range. In addition, the day 136 mean values for blood urea nitrogen and fructosamine moved into the normal reference range, while the day 0 mean values were outside the normal reference range.

As observed during the effectiveness study, the most common adverse event attributable to the product was hypoglycaemia. This finding was expected because all insulin can induce hypoglycaemia. In addition, many of the hypoglycaemic episodes were induced when the product was administered to cats that were not eating well or were anorexic. Another adverse event attributable to the product was injection site reactions. Two cats out of 176 had resolving injection site reactions on day 0 that were first observed in the clinical efficacy study. One of those cats had additional injection site reactions during this study.

The field safety study, together with the published literature provided, demonstrate that the product will be safe for administration to cats according to the label directions. Contraindications, precautions and side effects statements will be included on the label to inform the prescribing veterinarian.

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:

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.

An external reviewer evaluated the data provided by the applicant to substantiate the effectiveness of the proposed product. This included published data and clinical trial data.

The applicant submitted two small GLP pilot efficacy studies. Both studies were a crossover design using cats with stable diabetes mellitus and undergoing therapy with bovine/porcine insulin. They were switched to the test product insulin at the same dose and dose interval. The results show that the test product insulin provided good glycaemic control during these two 30 day pilot field efficacy studies. These conclusions were based upon the stable body weights and serum fructosamine levels seen in these diabetic cats.

Two pivotal efficacy studies were undertaken. The first was conducted to evaluate the effectiveness of the product for the reduction of hyperglycaemia and hyperglycaemia-associated clinical signs in cats with diabetes mellitus. The cats were required to have clinical signs of polyuria and polydipsia, and/or weight loss. The diagnosis of diabetes mellitus was confirmed by documenting both that the blood glucose nadir was greater than 250 mg/dl and that glucose was present in the urine. Blood, serum, and urine samples were collected and submitted to a central reference laboratory for haematology, serum chemistry (including T4 and fructosamine levels) and urinalysis testing.

The primary end-point for efficacy was significant improvement at day 45 as compared to day 0 in the 'control of diabetes', which was defined as a case that had improvement in at least one blood variable (fructosamine, glucose nadir or glucose mean) and at least one clinical sign (body weight, polyuria or polydipsia). Based on this definition, 83.5% included in the pivotal efficacy analysis were treatment successes.

The second study was a continuation of the efficacy study discussed above. Cats enrolled in this study were diabetic cats that completed the efficacy listed above and were considered regulated by the investigators. Upon presentation on day 0 (which also served as the day 45 visit for the previous study), physical examinations and injection site evaluations were performed. Blood, serum, and urine samples were collected and submitted to a central reference laboratory for haematology, serum chemistry (including fructosamine) and urinalysis testing. A new vial of the product was dispensed and treatment was continued at a dose rate selected based on the ending dose in the previous study, combined with the clinical judgment of the investigator.

Owners returned their cats for evaluations on days 34, 68, 102 and 136. At each visit a physical examination was performed, injection sites were evaluated, and the cat's condition was assessed by the investigator. Dose adjustments were made as appropriate based on clinical judgment and a new vial of the product was dispensed as necessary. A new dosing diary was provided after the previous diary was collected and reviewed. In addition, serum was collected at the day 68 visit for fructosamine analysis. At the day 136 visit, serum, blood, and urine were collected for final haematology, serum chemistry (including fructosamine), and urinalysis testing.

Objective variables used to evaluate the extended effectiveness of the product were fructosamine values and body weight. 86.4% cases with both day 0 and day 136 fructosamine data had day 136 values that stayed within the same interpretive category or improved at least one interpretive category compared to day 0 values. 93.8% of cats either gained more than 5% of their body weight or maintained their weight, while only 6.2% lost more than 5% of their body weight.

The studies submitted, in conjunction with the published literature, support the effectiveness of the product as for the treatment of diabetes mellitus in cats to achieve reduction of hyperglycaemia and improvement of associated clinical signs. The APVMA is therefore satisfied that the product would be effective when used according to label directions.

3. The APVMA has evaluated the applications 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 prozinc insulin injection for cats would not adversely affect trade between Australia and places outside Australia as it is not to be registered for use in animals producing any major Australian export commodities.

FURTHER INFORMATION

MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether human insulin should be approved and whether the application for registration of prozinc insulin injection for cats should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to approve the active or grant the registration application for prozinc insulin injection for cats. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for prozinc insulin injection for cats: the safety, efficacy and trade criteria. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

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

Relevant comments will be taken into account by the APVMA in deciding whether the active constituent should be approved and whether prozinc insulin injection for cats 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)*[3] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to approve the active constituent and grant the application for registration that relate to the grounds for active approval and/or product registration 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 4700
Fax: +61 2 6210 4741
Email: enquiries@apvma.gov.au

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