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AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

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

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GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, www.apvma.gov.au/news-and-publications/publications/gazette

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

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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 NEW ACTIVE CONSTITUENTS

Application no.:	62643
Product name:	Amicus Blue Fungicide
Active constituent/s:	32 g/L amisulbrom, 180 g/L copper (Cu) present as tribasic copper sulphate
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use	For the control of downy mildew in grapes and white blister and downy mildew in brassicas
Date of registration/approval:	2 August 2016
Product registration no.:	70161
Label approval no.:	70161/62643

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	106484
Product name:	Ragamuffin 700 Herbicide
Active constituent/s:	700 g/kg imazethapyr
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of use	For the pre-or post-emergence control of certain weeds in centrosema (*cavalcade*), chickpeas, faba beans, field peas, lucerne, mung beans, peanuts, serradella, soybeans
Date of registration/approval:	18 July 2016
Product registration no.:	82684
Label approval no.:	82684/106484

Application no.:	106254
Product name:	Haloprem 520 Herbicide
Active constituent/s:	520 g/L haloxyfop present as the haloxyfop-r-methyl ester
Applicant name:	Premier Shukuroglou AU Pty Ltd
Applicant ACN:	603 303 939
Summary of use	For the post-emergent control of a wide range of annual and perennial grass weeds in grain legume and oilseed crops, lucerne, medic and clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops
Date of registration/approval:	18 July 2016
Product registration no.:	82615
Label approval no.:	82615/106254

Application no.:	103110
Product name:	Bastnate Xtra 800 SG Herbicide
Active constituent/s:	800 g/kg glufosinate-ammonium
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For use as a herbicide to control broadleaf and grass weeds
Date of registration/approval:	19 July 2016
Product registration no.:	81432
Label approval no.:	81432/103110

Application no.:	59238
Product name:	Pool Oxidiser & Algaecide Smart Shock Xtra Blue
Active constituent/s:	405 g/kg available chlorine (Cl) present as sodium dichloroisocyanurate, 2.6 g/kg copper present as copper citrate
Applicant name:	BioLab Australia Pty Ltd
Applicant ACN:	005 878 017
Summary of use	For use in residential pools only to kill and prevent bacteria and algae
Date of registration/approval:	19 July 2016
Product registration no.:	68862
Label approval no.:	68862/59238

Application no.:	106756
Product name:	Relyon Century 1000 Wetter
Active constituent/s:	1000 g/L nonyl phenol and alcohol ethoxylates
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For increased spray contact, coverage and penetration of herbicides, fungicides and insecticides
Date of registration/approval:	20 July 2016
Product registration no.:	82788
Label approval no.:	82788/106756

Application no.:	101722
Product name:	Termidor HE Residual Termiticide
Active constituent/s:	96 g/L fipronil
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use	For the protection of structures from subterranean termite damage and for the control of subterranean termites around domestic and commercial structures
Date of registration/approval:	21 July 2016
Product registration no.:	80820
Label approval no.:	80820/101722

Application no.:	104827
Product name:	Pontiac Seed Treatment
Active constituent/s:	180 g/L imidacloprid, 15 g/L metalaxyl-m, 6.25 g/L flutriafol
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of use	For control of various diseases in winter cereals, the prevention of spread of barley yellow dwarf virus and for protection against insect pests of stored seed grain
Date of registration/approval:	22 July 2016
Product registration no.:	82028
Label approval no.:	82028/104827

Application no.:	104783
Product name:	Farmalinx Missile Fungicide
Active constituent/s:	250 g/kg fludioxonil, 375 g/kg cyprodinil
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For control of grey mould in grapes
Date of registration/approval:	26 July 2016
Product registration no.:	82003
Label approval no.:	82003/104783

3. VARIATIONS OF REGISTRATION

Application no:	107229
Product name:	Apparent Shout 720 Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'APPARENT CHLOROTHALONIL 720 FUNGICIDE' to 'APPARENT SHOUT 720 FUNGICIDE'
Date of variation:	5 July 2016
Product registration no.:	81801
Label approval no.:	81801/107229

Application no:	107277
Product name:	Weedpro Bioaqua 360 Herbicide
Active constituent/s:	360 g/L glyphosate present as the isopropylamine salt
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 'WEEDPRO 360 BIO HERBICIDE' to 'WEEDPRO BIOAQUA 360 HERBICIDE'
Date of variation:	8 July 2016
Product registration no.:	82251
Label approval no.:	82251/107277

Application no:	107278
Product name:	Surefire Kult Plant Growth Regulator
Active constituent/s:	250 g/L paclobutrazol
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 CULTAR PLANT GROWTH REGULATOR' to 'SUREFIRE KULT PLANT GROWTH REGULATOR'
Date of variation:	8 July 2016
Product registration no.:	80149
Label approval no.:	80149/107278

Application no:	107295
Product name:	Rophosate 510 Herbicide
Active constituent/s:	510 g/L glyphosate present as the isopropylamine salt
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RHOPHOSATE 510 HERBICIDE' to 'ROPHOSATE 510 HERBICIDE'
Date of variation:	11 July 2016
Product registration no.:	81521
Label approval no.:	81521/107295

Application no:	107330
Product name:	Farmalinx Accelerate 200 SG Growth Regulant
Active constituent/s:	200 g/kg gibberellic acid
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'FARMALINX GBR ACID 200 SG GROWTH REGULANT' to 'FARMALINX ACCELERATE 200 SG GROWTH REGULANT'
Date of variation:	12 July 2016
Product registration no.:	69753
Label approval no.:	69753/107330

Application no.:	101720
Product name:	Legend Fungicide
Active constituent/s:	250 g/L quinoxyfen
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of use	To extend the uses into barley for the control of powdery mildew
Date of variation:	13 July 2016
Product registration no.:	53607
Label approval no.:	53607/101720

Application no:	107376
Product name:	Huilong Trifluralin 480 Herbicide
Active constituent/s:	480 g/L trifluralin
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 TRIFLURALIN 480 SELECTIVE HERBICIDE' to 'HUILONG TRIFLURALIN 480 HERBICIDE'
Date of variation:	18 July 2016
Product registration no.:	67301
Label approval no.:	67301/107376

Application no:	107377
Product name:	Huilong 2,4-D Amine 625 Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
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 2,4-D AMINE 625 HERBICIDE' to 'HUILONG 2,4-D AMINE 625 HERBICIDE'
Date of variation:	18 July 2016
Product registration no.:	67300
Label approval no.:	67300/107377

Application no:	107384
Product name:	Huilong MCPA 500 Herbicide
Active constituent/s:	500 g/L MCPA present as the dimethylamine 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 MCPA 500 SELECTIVE HERBICIDE' to 'HUILONG MCPA 500 HERBICIDE'
Date of variation:	18 July 2016
Product registration no.:	66308
Label approval no.:	66308/107384

Application no:	107385
Product name:	Huilong Bifenthrin 80 SC Insecticide
Active constituent/s:	80 g/L bifenthrin
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 BIFENTHRIN 80 SC INSECTICIDE' to 'HUILONG BIFENTHRIN 80 SC INSECTICIDE'
Date of variation:	18 July 2016
Product registration no.:	67140
Label approval no.:	67140/107385

Application no.:	103515
Product name:	Sharpen WG Herbicide
Active constituent/s:	700 g/L saflufenacil
Applicant name:	BASF Australia Pty Ltd
Applicant ACN:	008 437 867
Summary of use	To extend use into weed control in lucerne and as a harvest aid for pulse crops and add additional weed claims
Date of registration/approval:	21 July 2016
Product registration no.:	62853
Label approval no.:	62853/103515

Application no.:	105619
Product name:	Titan Chlorothalonil 720 Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use	To extend the use to include control of various fungal diseases of chickpeas and lentils
Date of registration/approval:	21 July 2016
Product registration no.:	62668
Label approval no.:	62668/105619

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.:	61465
Product name:	Elanco Ovugel (triptorelin acetate) Gel for Intravaginal use In Sows
Active constituent/s:	100 mcg/mL triptorelin (as triptorelin acetate)
Applicant name:	Elanco Animal Health A Division Of Eli Lilly Australia Pty Ltd
Applicant ACN:	000 233 992
Summary of use	For the synchronisation of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination
Date of Registration/approval:	26 July 2016
Product registration no.:	69700
Label approval no.:	69700/61465

2. VARIATIONS OF REGISTRATION

Application no:	107319
Product name:	EXITRAZ WP Cattle Dip And Spray
Active constituent/s:	500 g/kg amitraz
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of variation:	To change the distinguishing product name and the name that appears on the label from ‘SAICOM ANTIC WP CATTLE DIP AND SPRAY’ to ‘EXITRAZ WP CATTLE DIP AND SPRAY’
Date of variation:	12 July 2016
Product registration no.:	64458
Label approval no.:	64458/107319

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.:	104124
Active constituent/s:	Fenbutatin oxide
Applicant name:	Industrial Quimica Key, S.A
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	19 July 2016
Approval no.:	81822

Application no.:	103945
Active constituent/s:	S-metolachlor
Applicant name:	Zhejiang Zhongshan Chemical Industry Group Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	20 July 2016
Approval no.:	81748

Application no.:	103937
Active constituent/s:	Clostridium chauvoei AWC667
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	21 July 2016
Approval no.:	82889

Application no.:	105990
Active constituent/s:	Triptorelin acetate
Applicant name:	Elanco Animal Health A Division Of Eli Lilly Australia Pty Ltd
Applicant ACN:	000 233 992
Summary of use:	For use in veterinary chemical products
Date of approval:	26 July 2016
Approval no.:	82524

Application no.:	105110
Active constituent/s:	Cloquintocet mexyl
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of use:	For use in agricultural chemical products
Date of approval:	27 July 2016
Approval no.:	82159

Application no.:	59947
Active constituent/s:	Topramezone
Applicant name:	BASF Australia
Applicant ACN:	008 437 867
Summary of use:	For use in agricultural chemical products
Date of approval:	27 July 2016
Approval no.:	69090

Cancellation of Label Approval at the Request of the Holder

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

Product No	Product Name	Holder	Cancelled Label	Date of effect
63676	IMTRADE OMEN 290 INSECTICIDE	IMTRADE AUSTRALIA PTY LTD	63676/0609	14 July 2016

The other label approvals have not been cancelled.

The following instructions set out how a person can deal with the associated label approval.

SUPPLY

A person may supply or cause to be supplied product bearing the label 63676/0609 manufactured prior to 14 July 2016 at wholesale and retail level, until the 14 July 2017.

After 14 July 2017 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the label 63676/0609 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 14 July 2017.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing the label 63676/0609 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 14 July 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:

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Cancellation of Registration and Approval at the Request of the Holder

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

Product no.	Product name	Registrant holder	Date of effect
49058	Kemzyme W Dry	Kemin (Aust) Pty Limited	26 July 2016

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

The APVMA has been notified that this product no longer requires registration as it meets the requirements for exemption as an Excluded Nutritional or Digestive product under Agricultural and Veterinary Chemicals Code Regulations 1995.

SUPPLY AND USE OF PRODUCT

Under section 45B (2)(C) The APVMA declares that s45B (1) of the Agricultural and Veterinary Chemicals Code Act 1994 does not apply in this case because the product meets the requirements for exemption from registration as an Excluded Nutritional or Digestive product as per Division 3.2 of Part 3 of Schedule 3AA to the Agricultural and Veterinary Chemicals Code Regulations 1995.

After 26 July 2016 a person may supply or cause to be supplied the product only if it continues to meet the requirements for exemption from registration as an Excluded Nutritional or Digestive product.

APVMA CONTACT

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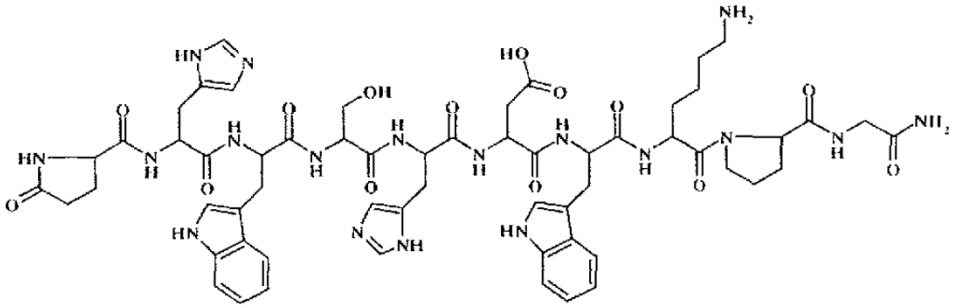
New Active Constituent and New veterinary Chemical Product Maprelin Containing Peforelin

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, peforelin, and an application for registration of a new product containing the new active constituent, Maprelin.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name:	Peforelin
IUPAC name:	5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-histidyl-L-α-aspartyl-L-tryptophyl-L-lysyl-L-prolyl-glycinamide
Chemical abstracts name:	5-oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-histidyl-L-α-aspartyl-L-tryptophyl-L-lysyl-L-prolyl-glycinamide
CAS number:	147859-97-0
Molecular formula:	C59H74N18O14
Molecular weight:	1259.33

Structure:



Chemical family:	Synthetic analogues of the Gonadotropin Releasing Hormone
Mode of action:	Responsible for the release of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) from the anterior pituitary.

SUMMARY OF THE APVMA'S EVALUATION OF PEFORELIN ACTIVE CONSTITUENT IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(b) 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 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, proposes to determine that:

(i) The APVMA proposes to determine that peforelin would not be an undue hazard to the safety of people exposed to it during its handling or use, and would not be likely to have an effect that is harmful to human beings.

Peforelin is a new active constituent for which there is no compendial specification available.

The APVMA has evaluated the chemistry aspects of peforelin active constituent. The assessment includes consideration of the manufacturing process and quality control procedures, the impurities, analysis of the chemical composition (batch analysis and analytical method inclusive), specifications, stability and packaging. The APVMA found these details of the active constituent acceptable.

The Office of Chemical Safety (OCS) in the Department of Health and Ageing has considered the toxicological aspects of peforelin. Information provided supported the minimal human toxicity for this class of compounds. A series of studies on other GnRH analogues indicated good tolerance of the compounds when used clinically, although the expected side effects of oestrogen deprivation were frequently noted. Genotoxicity studies have been submitted for other GnRH analogues which show a lack of genotoxicity. It would be expected a small, chemically non-reactive peptide such as the GnRH analogues would not be genotoxic. There is some data suggesting that GnRH analogues may affect pre-natal development in mice. A conservative interpretation suggests that peforelin, as a GnRH analogue, would share a similar developmental toxicity profile. The OCS advised that there are no toxicological objections to the approval of this active constituent.

An Acceptable Daily Intake and an Acute Reference Dose are not considered necessary and have not been established in this assessment as the active constituent has very low bioavailability.

Peforelin is a 'gonadotrophic hormone' and encapsulated within the Schedule 4 entry for gonadotrophic hormones in the SUSMP:

(i) The APVMA proposes to determine that peforelin would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The environment assessment considered the peforelin concentration in soils following subsequent application of treated effluent to cropland for pigs under the proposed use patterns. The results on worst case conservative assumptions indicate that levels of peforelin are so low they are unlikely to pose an environmental risk when treated effluent is applied to cropland and when a subsequent run-off from cropland is considered.

No ecotoxicity and bioaccumulation data were provided for assessment. The available information indicates that peforelin is rapidly metabolised into smaller inactive peptides and amino acids in animals.

The APVMA accepts the findings and recommendations of its advisers on the safety criteria. The APVMA is satisfied that the proposed use of peforelin would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

PARTICULARS OF THE PRODUCT

Proposed product name(s):	Maprelin
Applicant company:	VEYX-PHARMA GMBH
Name of active constituent:	Peforelin
Signal heading:	Schedule 4
Summary of proposed use:	For induction and synchronisation of the oestrous cycles in sows after weaning and for induction of oestrus in sexually mature gilts following therapy to inhibit the oestrous cycle with progestagens.
Pack sizes:	10 mL; 6 x 10 mL; 50 mL; 100 mL
Withholding period:	Zero (0) days

SUMMARY OF THE APVMA'S EVALUATION OF MAPRELIN 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, proposes to determine that:

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

The Office of Chemical Safety (OCS) in the Department of Health and Ageing has conducted a risk assessment on the product and concluded that it can be used safely.

The OCS advises that Maprelin is expected to have low acute oral toxicity along with very low oral bioavailability. While no data on acute dermal, inhalational, irritancy or sensitisation were available it is recognised that the product is for injection only. Acute dermal, inhalational and ocular exposures are not considered to be likely under normal conditions of product use.

Maprelin will be used by veterinary surgeons or animal handlers as an intramuscular injection for pigs. As the product is only available for use as an injection by individuals trained in how to administer the product, under the instructions of a veterinary surgeon, user exposure is expected to be minimal when observing normal workplace precautions to avoid self-injection. Therefore, a full quantitative exposure assessment was not required in this instance.

Based on the submitted data the active constituent and the product were identified as possible hazards to reproduction and development and the following warning statement will be included on the product label: *Caution: Accidental self-injection may affect fertility in both men and women and pregnancy. Care should be taken to avoid accidental self-injection and needle stick injury when administering this product. In the event of accidental self-injection, seek medical advice immediately. Not to be used by pregnant women.*

Based on the risk assessment, first aid statement (a)—*if poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11* 26 and Safety Directions—a*void contact with eyes and skin. Wash hands after use*—will be included on the product label.

The APVMA has considered and has accepted the findings of the OCS.

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

The applicant has proposed that the use of peforelin for induction of oestrus in sows after weaning and induction of oestrus in sexually mature gilts following therapy to inhibit the oestrous cycle with progestagens is eligible for a Table 5 entry in the MRL standard.

Peforelin residues should not occur in pig commodities since only very small quantities of the product are used; treated pigs are unlikely to be made available for human consumption in the short term since they will be used for breeding; peforelin residues will be indistinguishable from natural food components

If commodities from treated animals are consumed, peforelin residues in these commodities will be of no toxicological significance since peforelin is absorbed and rapidly metabolised by the animal into small peptides with negligible biological activity. Peforelin has low oral bioavailability since peforelin is rapidly inactivated by the gastrointestinal enzymes.

The APVMA proposes to include peforelin in Table 5 of the MRL standard under 'Gonadotrophin Releasing Hormone (GnRH) and analogues'. This entry supports the proposed withholding period of zero (0) days.

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

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) currently includes a Schedule 4 entry for gonadotrophic hormones which would capture synthetic analogues of naturally occurring hormones such as peforelin. Since the product, Maprelin, contains a gonadotrophic hormone analogue, it therefore is classified as a Schedule 4 compound and should be available by veterinary prescription only.

(iv) The APVMA is satisfied that the proposed use of the new product Maprelin containing the active constituent peforelin would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The environment assessment considered the peforelin concentration in soils following subsequent application of treated effluent to cropland for pigs under the proposed use patterns. The results on worst case conservative assumptions indicate that levels of peforelin are so low they are unlikely to pose an environmental risk when treated effluent is applied to cropland and when a subsequent run-off from cropland is considered.

No ecotoxicity and bioaccumulation data were provided for assessment. The available information indicates that peforelin is rapidly metabolised into smaller inactive peptides and amino acids in animals.

The label will contain a disposal statement as follows: *Dispose of empty container by wrapping with paper and putting in garbage*.

The tolerance of Maprelin was tested in a target animal safety study in pigs, with single intramuscular administration of either saline or the test product at 1X and 3X the recommended dose rate. No adverse injection site reactions were observed in the study. There were no adverse effects on weight gain or general health, and no changes in haematological or biochemical parameters. No gross or histopathological changes were observed at any dose rate.

The APVMA is satisfied that Maprelin would not have an unintended effect that is harmful to the target animals (sows). Appropriate contraindication and precaution statements will be included on the label.

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 proposes to determine that:

(i) In relation to its assessment of efficacy, 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.

Maprelin is intended for use in induction of the oestrous cycle in sows after weaning, and for induction of oestrus in sexually mature gilts following therapy to inhibit the oestrous cycle with progestogens. The product is a solution for intramuscular injection containing 75 µg/mL peforelin to be administered at a dose of 150 µg for pluriparous sows or gilts, and 37.5 µg for primiparous sows.

The efficacy studies included one dose determination study, five clinical efficacy studies and published supporting information. The trials were conducted overseas but since the reproductive management and husbandry of intensively farmed pigs is similar overseas and in Australia, it is considered that the data is relevant to the Australian situation.

The series of pivotal and non-pivotal studies supported that 150 µg (pluriparous sows or gilts) or 37.5 µg (primiparous sows) peforelin administered by intramuscular injection 24 hours after weaning (pluriparous or primiparous sows) or 48 hours after termination of the medication for oestrus inhibition (gilts) is effective in induction of the oestrous cycle after weaning or induction of oestrus in sexually mature gilts following therapy to inhibit the oestrus cycle with progestagens.

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 considering whether the proposed use of Maprelin would not adversely affect trade between Australia and places outside Australia.

Peforelin residues should not occur in foods and is of no toxicological significance if humans consume treated animals. Therefore, there are no residues related risks to Australia's export trade in pork.

The APVMA proposes to be satisfied that use of Maprelin, in accordance with the recommended relevant label particulars, meets the trade criteria, provided the following Trade Advice statement is included on the relevant label particulars: *Export Slaughter Interval (ESI): Zero (0) days*.

FURTHER INFORMATION

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

MAKING A SUBMISSION

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the active constituent peforelin 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 the product Maprelin 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 set out in section 5A, 5B and 5C 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.

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

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]

RABAR PTY. LTD.

ACN: 010 969 776

152 Enterprise Drive

BEAUDESERT QLD 4285

LICENCE NO: 2233

Product Types:*

- *Category 2*: Powders, granules and poultice
- *Category 4:* Premixes (liquids and powders) and supplements (liquids and powders)

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

Licence Issued: 15 July 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]

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: 4 July 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*

VETAFARM MANUFACTURING PTY LTD

ACN: 152 427 453

50 Webb Street

BOMEN NSW 2650

LICENCE NO: 2239

Product Types: *

- *Category 2*: Tablets, bolus, gels, powders, liquids and medicated seed
- *Category 3:* Liquids and sprays

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, granulation, dry milling, vacuum drying, packaging, labelling, tableting, analysis and testing (chemical, physical and antibiotic assay), storage and release for supply

Amended Licence Issued: 14 July 2016

OLSSON INDUSTRIES PTY LTD

ACN: 000 130 263

33 Manton Street

MORNINGSIDE QLD 4170

LICENCE NO: 4057

Product Types: *

- *Category 4*: Supplements

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

Amended Licence Issued: 21 July 2016

LUINA BIO PTY LTD

ACN: 074 656 509

2806 Ipswich Road

DARRA QLD 4076

LICENCE NO: 1086

Product Types: *

- *Category 1*: vaccine

Step(s) of Manufacture: Quality assurance (QA) of raw materials, cell propagation, virus cultivation, filling, packaging, labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat, filtration, chemical), analysis and testing (physical), release for supply, storage.

Amended Licence Issued: 26 July 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*

NUTRIMENT HEALTH PTY LTD

ACN: 138 061 266

Unit 4

25–37 Huntingdale Road

BURWOOD VIC 3125

LICENCE NO: 6178

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Quality assurance (QA) of raw materials, quality assurance (QA) of packaging materials, storage and release for supply.

Amended Licence Issued: 27 July 2016

AGRICURE PTY LIMITED

ACN: 000 178 790

End Gantry Place

Braemar

Via MITTAGONG NSW 2575

LICENCE NO: 2161

Product Types: *

- *Category 2*: creams/lotions, ointments, pastes, powders, sprays and liquids
- *Category 4:* premixes and supplements

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

Amended Licence Issued: 29 July 2016

3. LICENCE CANCELLATIONS

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

MEGA LIFESCIENCES (AUSTRALIA) PTY LTD

ACN: 076 713 392

60 National Avenue

PAKENHAM VIC 3810

LICENCE NO: 4095

Date Cancelled : 4 July 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

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

5. REVOCATION OF LICENCE CANCELLATION

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

Nil

6. REVOCATION OF LICENCE SUSPENSION

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

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Section
Legal and Compliance Program
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*

Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012*. The *MRL Standard* lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard)* Amendment Instrument 2016 (No. 9).

The amendments will be incorporated into the compilation of the Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012.

The *MRL Standard* is accessible via the ComLaw website www.comlaw.gov.au or the links above.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4897
Fax: +61 2 6210 4840
Email: enquiries@apvma.gov.au

Proposal to amend Schedule 20 in the Australia New Zealand Food Standards Code

In the previous notice, the APVMA gazetted amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*, have been made.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard)* Amendment Instrument 2016 (No. 9)) to MRLs into Schedule 20–Maximum residue limits in the *Australia New Zealand Food Standards Code*.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and FSANZ are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.

PROPOSED AMENDMENT (*AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD)* AMENDMENT INSTRUMENT 2016 (NO. 9))

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunsetting.

To commence: on gazettal of variation

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] inserting in alphabetical order

Agvet chemical: Amisulbrom	
Permitted residue: Amisulbrom	
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	2
Dried grapes (currants, raisins and sultanas)	1
Edible offal (mammalian)	*0.01
Eggs	*0.01
Grapes	0.5
Meat (mammalian)	*0.01
Milks	*0.01
Poultry, edible offal of	*0.01
Poultry meat	*0.01

Agvet chemical: Mandestrobin	
Permitted residue: Mandestrobin	
Stone fruits	3

[1.2] omitting from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Abamectin	
Permitted residue: Avermectin B1a	
Potato	T0.01

Agvet chemical: Buprofezin	
Permitted residue: Buprofezin	
Fruiting vegetables, other than cucurbits	T2

Agvet chemical: Chlorothalonil	
Permitted residue—commodities of plant origin: Chlorothalonil	
Permitted residue—commodities of animal origin: 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite, expressed as chlorothalonil	
Herbs [except fennel, leaf]	T20

[1.3] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Abamectin	
Permitted residue: Avermectin B1a	
Dried grapes (currants, raisins and sultanas)	T0.03
Pineapple	T*0.002

Agvet chemical: Acibenzolar-S-methyl	
Permitted residue: Acibenzolar-S-methyl and all metabolites containing the benzo[1,2,3]thiadiazole-7-carboxyl moiety hydrolysed to benzo[1,2,3]thiadiazole-7-carboxylic acid, expressed as acibenzolar-S-methyl	
Cucumber	T0.5
Squash, summer (including zucchini)	T0.5

Agvet chemical: Boscalid	
Permitted residue—commodities of plant origin: Boscalid	
Permitted residue—commodities of animal origin: Sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl) nicotinamide and the glucuronide conjugate of 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl) nicotinamide, expressed as boscalid equivalents	
Onion, bulb	0.5

Agvet chemical: Buprofezin	
Permitted residue—Buprofezin	
Fruiting vegetables, other than cucurbits [except tomato]	T2
Tomato	0.5

Agvet chemical: Chlorantraniliprole	
Permitted residue—plant commodities and animal commodities other than milk: Chlorantraniliprole	
Permitted residue—milk: Sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[(hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole	
Linseed	T0.5

Agvet chemical: Chlorothalonil	
Permitted residue—commodities of plant origin: Chlorothalonil	
Permitted residue—commodities of animal origin: 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite, expressed as chlorothalonil	
Parsley	T20

Agvet chemical: Difenoconazole	
Permitted residue: Difenoconazole	
Brassica leafy vegetables	T5
Mizuna	T5

Agvet chemical: Etoxazole	
Permitted residue: Etoxazole	
Almonds	*0.01

Agvet chemical: Flubendiamide	
Permitted residue—commodities of plant origin: Flubendiamide	
Permitted residue—commodities of animal origin: Sum of flubendiamide and 3-iodo-N-(2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl) phthalimide, expressed as flubendiamide	
Strawberry	0.3

Agvet chemical: Iprodione	
Permitted residue: Iprodione	
Parsley	T20
Podded pea (young pods) (snow and sugar snap)	T2

[1.4] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Dithiocarbamates	
Permitted residue—Total dithiocarbamates, determined as carbon disulphide evolved during acid digestion and expressed as milligrams of carbon disulphide per kilogram of food	
Citrus fruits	T7

Agvet chemical: Saflufenacil	
Permitted residue—commodities of plant origin: Sum of saflufenacil, N'-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl-N-isopropyl sulfamide and N-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino} carbonyl)phenyl]urea, expressed as saflufenacil equivalents	
Permitted residue—commodities of animal origin: Saflufenacil	
Edible offal (mammalian)	7
Pulses	0.2

INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20–Maximum residue limits in the *Australia New Zealand Food Standards Code.* Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: **6 pm (AEST) 6 September 2016**

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4897
Fax: +61 2 6210 4840
Email: enquiries@apvma.gov.au