Commonwealth of Australia

Gazette

No. APVMA 22, Tuesday, 1 November 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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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.:	107467
Product name:	Apparent Rose Fungicide/Insecticide RTU
Active constituent/s:	0.1 g/L tau-fluvalinate, 0.05 g/L myclobutanil
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use	For the control of various insects and fungal diseases on roses and ornamentals
Date of registration/approval:	12 October 2016
Product registration no.:	83080
Label approval no.:	83080/107467

Application no.:	107148
Product name:	Apparent Sinister Hose-On Lawn Insecticide
Active constituent/s:	15 g/L imidacloprid
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use	For the control of curl grubs and billbug larvae in domestic lawns
Date of registration/approval:	12 October 2016
Product registration no.:	82933
Label approval no.:	82933/107148

Application no.:	105357
Product name:	Repel New Era Roll-on Insect Repellent
Active constituent/s:	199.4 g/L picaridin
Applicant name:	Skin Shield Products Ltd
Applicant ACN:	N/A
Summary of use	For use as a personal insect and tick repellent
Date of registration/approval:	17 October 2016
Product registration no.:	82281
Label approval no.:	82281/105357

Application no.:	107468
Product name:	Apparent Sinister—Systemic Insecticide RTU
Active constituent/s:	0.125 g/L imidacloprid
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use	For the systemic control of various insect pests on flowers, shrubs, trees, fruit trees and vegetables in the home garden
Date of registration/approval:	18 October 2016
Product registration no.:	83081
Label approval no.:	83081/107468

Application no.:	104417
Product name:	Zenithor Gel Cockroach Bait
Active constituent/s:	6 g/kg indoxacarb
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of use	For the control of cockroaches in commercial, industrial and residential premises
Date of registration/approval:	18 October 2016
Product registration no.:	81919
Label approval no.:	81919/104417

Application no.:	104418
Product name:	Zenithor Gel Ant Bait
Active constituent/s:	0.5 g/kg indoxacarb
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of use	For the control of ants in various situations
Date of registration/approval:	18 October 2016
Product registration no.:	81920
Label approval no.:	81920/104418

Application no.:	107245
Product name:	Imtrade Triclopyr 750 EC Herbicide
Active constituent/s:	750 g/L triclopyr
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use	For the control of various woody and broadleaf weeds
Date of registration/approval:	19 October 2016
Product registration no.:	82974
Label approval no.:	82974/107245

Application no.:	105358
Product name:	Repel New Era Pump Spray Insect Repellent
Active constituent/s:	201.95 g/L picaridin
Applicant name:	Skin Shield Products Ltd
Applicant ACN:	N/A
Summary of use	For use as a personal insect and tick repellent
Date of registration/approval:	19 October 2016
Product registration no.:	82282
Label approval no.:	82282/105358

Application no.:	103512
Product name:	Hoprole 300 WG Insecticide
Active constituent/s:	300 g/kg indoxacarb
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of lepidopteran species of insect pests in certain vegetable and fruit crops
Date of registration/approval:	20 October 2016
Product registration no.:	81638
Label approval no.:	81638/103512

Application no.:	107147
Product name:	Country Bifenthrin Sand Insecticide
Active constituent/s:	2 g/kg bifenthrin
Applicant name:	Garrards Pty Ltd
Applicant ACN:	010 648 325
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:	24 October 2016
Product registration no.:	82932
Label approval no.:	82932/107147

2. VARIATIONS OF REGISTRATION

Application no:	107494
Product name:	Huilong Aphid Guard 200 SC Aphicide/Insecticide
Active constituent/s:	200 g/L imidacloprid
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 APHID GUARD 200 SC APHICIDE/INSECTICIDE' to 'HUILONG APHID GUARD 200 SC APHICIDE/INSECTICIDE'
Date of variation:	3 August 2016
Product registration no.:	59037
Label approval no.:	59037/107494

Application no:	107766
Product name:	Potus Yield & Quality Enhancer
Active constituent/s:	250 g/L trinexapac-ethyl
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CROP CULTURE POTUS YIELD & QUALITY ENHANCER' to 'POTUS YIELD & QUALITY ENHANCER'
Date of variation:	31 August 2016
Product registration no.:	67883
Label approval no.:	67883/107766

Application no:	107930
Product name:	Amgrow Grasshopper and Caterpillar Spray Insecticide
Active constituent/s:	50 g/L esfenvalerate
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AMGROW GARDEN INSECT CONTROL' to 'AMGROW GRASSHOPPER AND CATERPILLAR SPRAY INSECTICIDE'
Date of variation:	15 September 2016
Product registration no.:	65411
Label approval no.:	65411/107930

Application no:	107906
Product name:	Mortein Naturgard Multi-Insect Automatic Spray Indoor Eucalyptus
Active constituent/s:	8.0 g/kg permethrin, 6.0 g/kg transfluthrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MORTEIN NATURGARD MULTI-INSECT AUTOMATIC SPRAY INDOOR EUCALYPTUS HOUSEHOLD PROTECTION' to 'MORTEIN NATURGARD MULTI-INSECT AUTOMATIC SPRAY INDOOR EUCALYPTUS'
Date of variation:	15 September 2016
Product registration no.:	70102
Label approval no.:	70102/107906

Application no:	107921
Product name:	Mortein Naturgard Control Bomb Household Protection
Active constituent/s:	10 g/kg permethrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MORTEIN NATURGARD CRAWLING INSECT CONTROL BOMB HOUSEHOLD PROTECTION' to 'MORTEIN NATURGARD CONTROL BOMB HOUSEHOLD PROTECTION'
Date of variation:	16 September 2016
Product registration no.:	66283
Label approval no.:	66283/107921

Application no:	107968
Product name:	Trusinate Xtra Herbicide
Active constituent/s:	800 g/kg glufosinate-ammonium
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'BASTNATE XTRA 800 SG HERBICIDE' to 'TRUSINATE XTRA HERBICIDE'
Date of variation:	21 September 2016
Product registration no.:	81432
Label approval no.:	81432/107968

Application no.:	103567
Product name:	Sumitomo Samurai Systemic Insecticide
Active constituent/s:	500 g/kg clothianidin
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of variation:	To extend the use to include the control of Queensland and Mediterranean fruit flies in persimmons, pome and stone fruit and grapes
Date of variation:	13 October 2016
Label approval no.:	60687/103567

Application no:	105178
Product name:	Bactex CF Sanitiser
Active constituent/s:	100 g/L benzalkonium chloride
Applicant name:	Whiteley Corporation Pty Ltd
Applicant ACN:	000 906 678
Summary of variation:	To extend the use for the control of *fusarium oxysporum f.sp. cubense* in various situations
Date of variation:	20 October 2016
Product registration no:	59643
Label approval no:	59643/105178

Application no:	106355
Product name:	Assurant 200 Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of variation:	To extend use to include control of mole cricket and argentine stem weevil in turf and re-instate claims for control of a range of insect pests on asparagus, forestry, ginger, mushrooms, pasture and sorghum, sweet potatoes, swede and turnips
Date of variation:	21 October 2016
Product registration no.:	66873
Label approval no.:	66873/106355

3. VARIATION OF LABEL APPROVAL

Application no.:	107355
Product name:	Aquaklenz HV Concentrate Low Foam Acid Detergent Sanitiser
Active constituent/s:	425 g/L phosphoric acid, 453 g/L sulfuric acid
Applicant name:	Ecolab Pty Limited
Applicant ACN:	000 449 990
Summary of variation	To amend directions of use to do not rinse after application
Date of variation:	13 October 2016
Label approval no.:	69804/107355

Application no:	107884
Product name:	Roundup CT Broadacre Herbicide By Monsanto
Active constituent/s:	450 g/L glyphosate present as the isopropylamine salt
Applicant name:	Monsanto Australia Ltd
Applicant ACN:	006 725 560
Summary of variation:	To change the name that appears on the label from ‘ROUNDUP CT BROADACRE HERBICIDE BY MONSANTO’ to ‘ROUNDUP CT BROADACRE HERBICIDE’
Date of variation:	14 September 2016
Label approval no.:	31394/107884

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.:	53656
Product name:	Antinol PCSO—524 Joint Support Formula
Active constituent/s:	50 mg/capsule NZ green lipped mussel oil
Applicant name:	Pharmalink Marketing Australia Pty Ltd
Applicant ACN:	056 217 040
Summary of use	For use to assist in the relief of arthritic signs in dogs
Date of registration/approval:	14 October 2016
Product registration no.:	66445
Label approval no.:	66445/53656

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	107445
Product name:	Equistar Equipe Broadspectrum Worming Paste For Horses
Active constituent/s:	245 mg/g morantel tartrate, 175 mg/g oxfendazole
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use	For the treatment and control of susceptible strains of small strongyles (including arterial larval stages of strongylus vulgaris and benzimidazole resistant small strongyles) in horses
Date of registration/approval:	17 October 2016
Product registration no.:	83075
Label approval no.:	83075/107445

3. LABEL APPROVAL

Application no.:	107488
Product name:	The Original Redene Iodophor Teat Dip and Spray
Active constituent/s:	20 g/L iodine, 58.6 g/L glycerol
Applicant name:	Dasco Proprietary Limited
Applicant ACN:	004 581 113
Summary of use:	To approve a new label for the product with the label name ‘GOLDENE IODOPHOR TEAT DIP AND SPRAY’
Date of approval:	11 October 2016
Label approval no.:	36102/107488

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.:	105802
Active constituent/s:	2,4-D-2-Ethylhexyl Ester
Applicant name:	Gold Zone Enterprises Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	13 October 2016
Approval no.:	82465

Application no.:	105594
Active constituent/s:	Pyraclostrobin
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For use in agricultural chemical products
Date of approval:	19 October 2016
Approval no.:	82373

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. 14).

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:

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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. 14)) 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. 14))

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

Agvet chemical: Propamocarb	
Permitted residue: Propamocarb (base)	
Leafy vegetables	T20

Agvet chemical: Sulfoxaflor	
Permitted residue: Sulfoxaflor	
Dried grapes (currants, raisins and sultanas)	10
Fruiting vegetables, other than cucurbits	1
Grapes [except wine grapes]	3
Wine grapes	*0.01

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Mung bean (dry)	T0.2
Pulses [except mung bean (dry); soya bean (dry)] [1]	T1

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

Agvet chemical: Azoxystrobin	
Permitted residue: Azoxystrobin	
Adzuki bean (dry)	T0.7
Common bean (dry) [navy bean]	T0.7
Mung bean (dry)	T0.7

Agvet chemical: Fluopicolide	
Permitted residue: Fluopicolide	
All other foods	T0.01
Bulb vegetables [except onion, bulb]	T3
Edible offal (mammalian)	T*0.01
Eggs	T*0.01
Fruiting vegetables, cucurbits	T0.5
Lettuce, head	T30
Lettuce, leaf	T30
Meat (mammalian) (in the fat)	T*0.01
Milks	T*0.01

[1] This proposed variation to Schedule 20 of the Australia New Zealand Food Standards Code was previously gazetted (APVMA Gazette No. 20, Tuesday 4 October 2016, see pages 43–46), and has not yet been incorporated into Schedule 20. The proposed variation has since been superseded by a new proposal (see footnote 2 below).

Onion, bulb	T0.1
Poppy seed	T0.5
Potato	T0.05
Poultry, edible offal of	T*0.01
Poultry meat (in the fat)	T*0.01

Agvet chemical: Propamocarb	
Permitted residue: Propamocarb (base)	
Bulb vegetables [except onion, bulb]	T30
Edible offal (mammalian)	T*0.01
Eggs	T*0.01
Fruiting vegetables, cucurbits	T5
Leafy vegetables [except lettuce, head; lettuce, leaf]	T20
Lettuce, head	T70
Lettuce, leaf	T70
Meat (mammalian)	T*0.01
Milks	T*0.01
Onion, bulb	T0.5
Poppy seed	T5
Potato	T0.05
Poultry, edible offal of	T*0.01
Poultry meat	T*0.01

Agvet chemical: Propiconazole	
Permitted residue: Propiconazole	
Pulses	T0.3

Agvet chemical: Sulfoxaflor	
Permitted residue: Sulfoxaflor	
Beans (dry)	0.7
Fruiting vegetables, other than cucurbits [except sweet corn (corn-on-the-cob)]	1
Grapes	*0.01
Sweet corn (corn-on-the-cob)	*0.01
Tree nuts [except macadamia nuts]	0.02

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Pulses [except soya bean (dry)][2]	T1

[2] This proposed variation replaces an earlier proposed variation (gazetted on 4 October 2016 and not yet incorporated into Schedule 20). See also footnote 1 above.

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

Agvet chemical: Clothianidin	
Permitted residue: Clothianidin	
Fruiting vegetables, cucurbits	T0.5
Fruiting vegetables, other than cucurbits [except mushrooms; sweet corn (corn-on-the-cob)]	T0.7

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 (ADST) 29 November 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:

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New Veterinary Chemical Product Containing a New veterinary Active Constituent Sometribove Zinc in Elanco Posilac

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Elanco Animal Health a Division of Eli Lilly Australia Pty Ltd for the approval of a new active constituent sometribove zinc. The APVMA also has before it an application from the same applicant for the registration of the new product Elanco Posilac containing the new active constituent. Elanco Posilac is proposed to be registered as an injection for increased milk production in lactating dairy cows.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	Sometribove Zinc (sometribove is an INN)
IUPAC Name:	1-L-Methionine-127-L-leucine growth hormone (Ox), for sometribove
CAS Name:	1-L-Methionine-127-L-leucine growth hormone (Cattle), for sometribove
CAS Registry Number:	102744-97-8 (for sometribove)
Molecular Formula:	$C_{978}H_{1537}N_{265}O_{286}S_9$ (for sometribove)
Molar Mass:	21,872.29 g/mol (for sometribove)
Structure:	MFPAMSLSGL FANAVLRAQH LHQLAADTFK EFERTYIPEG QRYSIQNTQV AFCFSETIPA PTGKNEAQQK SDLELLRISL LLIQSWLGPL QFLSRVFTNS LVFGTSDRVY EKLKDLEEGI LALMRELEDG TPRAGQILKQ TYDKFDTNMR SDDALLKNYG LLSCFRKDLH KTETYLRVMK CRRFGEASCA F
Chemical Family:	Polypeptides
Mode of Action:	Bovine growth hormones

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT SOMETRIBOVE ZINC 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 sometribove zinc 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 chemistry and manufacturing section of the APVMA evaluated the chemistry and manufacturing aspects of sometribove zinc. All the information (including the physico-chemical properties, spectral identification, manufacturing and quality control aspects, impurity formation, active constituent specification, stability, batch analysis data and analytical methods information) necessary for the approval of this new active constituent has been provided. The chemistry and manufacturing section is satisfied that the quality of the active constituent is satisfactory for use in a veterinary chemical product.

The APVMA has considered the toxicological aspects of sometribove zinc. Sometribove zinc showed low acute oral toxicity in rats (LD50 > 5000 mg/kg bodyweight) and low acute subcutaneous toxicity in mice (LD50 > 500 mg/kg bodyweight). The active constituent was a mild skin irritant in rabbits, and a mild to moderate eye irritant in the same species. No animal studies were conducted to investigate skin sensitisation, but allergic reactions have been reported in a manufacturing setting.

The consumption of milk and tissues from cows treated with sometribove zinc is not considered to be hazardous to human health. Recombinant bovine somatotropins have little or no activity at the human somatotropin receptor, and are largely, if not completely, destroyed by pasteurisation and cooking, as well as by gastrointestinal digestive processes. Further, the concentrations of recombinant bovine somatotropins in the milk and tissues of treated cows were comparable to those in the milk of untreated cows.

An ADI has not been established for sometribove zinc. An ADI was not considered necessary as the consumption of milk and tissues from cows treated with sometribove zinc was not considered to be hazardous to human health. An ARfD was not established for sometribove zinc because the consumption of milk and tissues from cows treated with sometribove zinc was not considered to be hazardous to human health.

The Department of the Environment and Energy risk assessment considered that sometribove zinc is a natural substance (protein) that will be rapidly degraded upon entry into the environment and consequently not alter the concentration of distribution of the substance in the environment. Material entering the environment from either the urine or faeces from treated cattle is likely to be fully metabolised and indistinguishable from metabolites of the naturally occurring bovine somatotropin.

The APVMA accepts the findings and recommendations of its advisers on the safety criteria. The APVMA proposes to be satisfied that the use of sometribove zinc in a veterinary chemical product 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 human beings, animals, plants or things or to the environment.

PARTICULARS OF THE PRODUCT

Proposed Product Name:	Elanco Posilac
Applicant Company:	Elanco Animal Health a Division of Eli Lilly Australia Pty Ltd
Name of Active Constituent:	Sometribove zinc
Signal Heading:	FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Summary of Proposed Use:	For increased milk production in lactating dairy cows
Pack Sizes:	25 x 1.33 g, 100 x 1.33 g
Withholding Period:	Zero (0) days

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 Elanco Posilac would not be an undue hazard to the safety of people exposed to it during its handling.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely. Elanco Posilac will be supplied in single-dose syringes. One entire syringe (500 mg sometribove) will be administered subcutaneously to an individual animal every 14 days. Recommended injection sites are the neck area and the depression on either side of the tailhead.

No exposure studies were submitted with this application, but the occurrence of repeated exposure during use is highly unlikely because the product is presented in a single dose, ready-to-use syringe. While the use of gloves is normally recommended for the handling of products which are slight skin irritants, given that Elanco Posilac is presented in a single-dose, ready-to-use syringe and is of low acute toxicity and low skin irritancy, and that gloves are not typically used for animal injections in the general veterinary or farming scenarios unless handling highly toxic products, it is considered appropriate to waive the safety direction requirement for gloves when injecting Elanco Posilac.

The following First Aid Instructions and Safety Directions will be included on the label:

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

Safety Directions: May irritate the eyes. May irritate the skin. Avoid contact with eyes and skin. Wash hands after use.

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

The Australian toxicological evaluation of sometribove zinc and the JECFA monographs for bovine somatotropins indicate that the proposed use of sometribove zinc as an injectable to lactating dairy cows should not pose a hazard to human health for the following reasons:

1. The concentrations of recombinant bovine somatotropin (rbST) and insulin-like growth factor-1 (IGF-1) in the milk and tissues of treated cows lie within the normal range and are comparable to those in the milk of untreated cows.

2. rbSTs and IGF-1 are largely destroyed by gastrointestinal digestive processes and are of low toxicity.

3. The establishment of an ADI and ARfD for sometribove-zinc was not considered to be necessary by the Australian and JECFA toxicological evaluations as the consumption of milk and tissues from cows treated with sometribove-zinc was not considered to be hazardous to human health.

Sometribove-zinc, when used as an injection for the improvement of milk production in lactating dairy cattle, fulfils the requirement that ‘Residues are otherwise of no toxicological significance’ and is therefore, eligible for a Table 5 entry in MRL Standard.

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

Sometribove zinc is not specifically listed in the current Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). However, the broader class of bovine somatotropins is listed under Appendix B, Part 3 'Substances considered not to require control by scheduling'. Given the high degree of structural similarity of the bovine somatotropins, this entry is considered adequate to cover sometribove zinc. The product will therefore be unscheduled.

(iv) The APVMA is satisfied that the proposed use of Elanco Posilac 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 and Energy has conducted an environmental risk assessment of Elanco Posilac containing sometribove zinc. Sometribove zinc is a natural substance (protein) that will be rapidly degraded upon entry into the environment and consequently not alter the concentration of distribution of the substance in the environment. Material entering the environment from either the urine or faeces from treated cattle is likely to be fully metabolised and indistinguishable from metabolites of the naturally occurring bovine somatotropin. The product therefore meets the VICH Phase 1 criteria and no further environmental assessment is required. The APVMA has considered these findings and accepts the recommendations of the Department of the Environment and Energy. The product label will contain a suitable disposal statement.

An external efficacy and safety reviewer evaluated the data provided by the applicant, which included published literature, a drug tolerance study, a margin of safety study and a clinical efficacy and safety confirmatory study. The extensive target animal safety data package submitted with the application provided evidence that the product would be safe for use as proposed on the draft label. However the data provided also indicated that adverse events, such as increased incidence of clinical mastitis, lameness, increased non-pregnancy rates, and increased culling rates, may occur under some management conditions. Warnings to this effect are proposed for inclusion on the product labelling.

The APVMA agrees with the advice of the external reviewer and proposes to be satisfied that Elanco Posilac would not have an unintended effect that is harmful to the target animals (cows) if used according to label directions.

2. The APVMA has evaluated the applications and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

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

Elanco Posilac, based on a new active ingredient, sometribove zinc, is intended to be registered to increase milk production in lactating dairy cows. One syringe of product is to be injected subcutaneously into the neck or tailhead every 14 days, starting from 57–70 days after calving and continuing until the end of lactation. An external efficacy and safety reviewer evaluated the data provided by the applicant, which included published literature describing independently conducted studies, overseas dose determination studies, overseas dose confirmation studies, overseas confirmatory clinical studies for efficacy and one Australian based clinical efficacy and safety confirmatory study.

The studies demonstrated that administration of Elanco Posilac at subcutaneous doses of 500 mg each 14 days, starting at day 57–70 of lactation gives rise to greater milk production than control cows.

The external reviewer therefore recommended that the APVMA be satisfied that the product would be effective when used according to label directions. The APVMA accepts the findings and recommendations of the external reviewer in relation to the efficacy criteria.

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 Elanco Posilac would not adversely affect trade between Australia and places outside Australia.

Export of treated produce containing finite (measurable) residues of sometribove zinc may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

The concentrations of recombinant bovine somatotropin (rbST) in the milk and tissues of treated cows are comparable to those in the milk of untreated cows. A Table 5 entry is considered appropriate for sometribove-zinc with a use 'For increasing milk production in lactating dairy cows'. The use of recombinant bovine somatotropin (rbST) does not present a dietary intake concern to consumers, however its use in dairy cows is not permitted within some overseas jurisdictions.

There are no MRLs for rbST or other bovine growth hormones in any overseas jurisdiction, including the US and South Korea which currently have the use of sometribove zinc approved in dairy cattle. Codex MRLs for sometribove have been proposed by JECFA as 'not specified', but are not currently established.

While the use of rbST within the European Union and New Zealand is not currently approved, no regulatory restrictions have been identified in those markets that are not known to restrict the import of dairy products from rbST-treated cows. No major export market is known to currently restrict the import of dairy product and meat from dairy cows supplemented with rbST. The use of rbST in dairy cows is currently approved in the United States which like Australia is a significant global exporter of dairy products and beef.

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 sometribove zinc should be approved and whether the application for registration of Elanco Posilac 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 Elanco Posilac. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for Elanco Posilac: 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 Elanco Posilac 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 ***c****onfidential 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.