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**AGRICULTURAL AND
VETERINARY CHEMICALS**



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

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

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GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

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

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

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

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Agricultural Chemical Products and Approved Labels

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

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	105272
Product name:	Chem-Saver Swimming Pool and Spa System
Active constituent/s:	1000 g/kg copper (Cu) present as the metal copper
Applicant name:	Ecosmarte Planet Friendly Inc
Applicant ACN:	N/A
Summary of use:	For the control of algae in swimming pool and spas
Date of registration/approval:	29 September 2016
Product registration no.:	82244
Label approval no.:	82244/105272
Application no.:	107677
Product name:	Barmac Abamectin Insecticide
Active constituent/s:	18 g/L abamectin
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use:	For the control of certain mites on cotton, citrus, apples, capsicums, hops, pears, tomatoes, ornamentals and strawberries and native budworm on cotton
Date of registration/approval:	30 September 2016
Product registration no.:	83173
Label approval no.:	83173/107677
Application no.:	103290
Product name:	Venom 240 SC Insecticide
Active constituent/s:	240 g/L bifenthrin
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For the control of a range of insect pests and mites in some fruits and crops
Date of registration/approval:	30 September 2016
Product registration no.:	81526
Label approval no.:	81526/103290
Application no.:	105225
Product name:	Surefire Couma All Weather Blocks Rodenticide
Active constituent/s:	0.37 g/kg coumatetralyl
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of rodents in various situations
Date of registration/approval:	30 September 2016
Product registration no.:	82217
Label approval no.:	82217/105225

Application no.:	107023
Product name:	Apparent Buffalo Lawn Weeder
Active constituent/s:	200 g/L bromoxynil, 200 g/L MCPA
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of use:	For the control of bindii, clover, oxalis and other weeds in buffalo, couch and QLD blue couch in domestic lawns
Date of registration/approval:	4 October 2016
Product registration no.:	82872
Label approval no.:	82872/107023

Application no.:	57540
Product name:	Slasher Weedkiller
Active constituent/s:	525 g/L nonanoic acid
Applicant name:	Organic Crop Protectants Pty Ltd
Applicant ACN:	003 149 719
Summary of use:	For non-selective control of weeds, grasses, moss and algae in various crop and non-crop situations
Date of registration/approval:	6 October 2016
Product registration no.:	68118
Label approval no.:	68118/57540

Application no.:	103202
Product name:	Skope Insecticide
Active constituent/s:	218 g/L acetamiprid, 32.5 g/L emamectin present as emamectin benzoate
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For control of cotton aphid, green mirid, green vegetable bug, heliothis and silverleaf whitefly in cotton
Date of registration/approval:	11 October 2016
Product registration no.:	81486
Label approval no.:	81486/103202

2. VARIATIONS OF REGISTRATION

Application no:	107517
Product name:	Huilong MSMA 500 Herbicide
Active constituent/s:	500 g/L MSMA
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 MSMA HERBICIDE' to 'HUILONG MSMA 500 HERBICIDE'
Date of variation:	4 August 2016
Product registration no.:	47558
Label approval no.:	47558/107517

Application no:	107512
Product name:	Huilong Glyphosate 450 Herbicide
Active constituent/s:	450 g/L glyphosate present as the isopropylamine salt
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY GLYPHOSATE 450 HERBICIDE' to 'HUILONG GLYPHOSATE 450 HERBICIDE'
Date of variation:	4 August 2016
Product registration no.:	47273
Label approval no.:	47273/107512
Application no:	107764
Product name:	Unilon 600 Herbicide
Active constituent/s:	600 g/L triclopyr present as the butoxyethyl ester
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'UNI-LON 600 HERBICIDE' to 'UNILON 600 HERBICIDE'
Date of variation:	31 August 2016
Product registration no.:	57835
Label approval no.:	57835/107764
Application no:	107831
Product name:	Radchem Excite Spray Adjuvant
Active constituent/s:	704 g/L ethyl and methyl esters of fatty acids derived from refined canola oil
Applicant name:	Radical Chemicals Pty Ltd
Applicant ACN:	609 190 918
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RADCHEM EXPEDITE SPRAY ADJUVANT' to 'RADCHEM EXCITE SPRAY ADJUVANT'
Date of variation:	8 September 2016
Product registration no.:	82860
Label approval no.:	82860/107831
Application no.:	107471
Product name:	Sakura 850 WG Herbicide
Active constituent/s:	850 g/kg pyroxasulfone
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To extend the pack size range
Date of variation:	28 September 2016
Product registration no.:	63998
Label approval no.:	63998/107471
Application no.:	107344
Product name:	Eureka! Glufosinate 200 SL Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Eureka! Agresearch Pty Ltd
Applicant ACN:	086 194 738
Summary of variation:	To approve a new label for the product with the label name 'EUREKA! ROW GLUFOSINATE 200 SL HERBICIDE'
Date of variation:	4 October 2016
Product registration no.:	81653
Label approval no.:	81653/107344

Application no.:	107484
Product name:	Redene Ready-To-Use Teat Dip and Spray
Active constituent/s:	5 g/L iodine, 100 g/L glycerol
Applicant name:	Dasco Proprietary Limited
Applicant ACN:	004 581 113
Summary of variation:	To approve a new label for the product with the label name 'GOLDENE READY-TO-USE TEAT DIP AND SPRAY'
Date of variation:	11 October 2016
Product registration no.:	51706
Label approval no.:	51706/107484

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 variation:	To approve a new label for the product with the label name 'GOLDENE IODOPHOR TEAT AND DIP SPRAY'
Date of variation:	11 October 2016
Product registration no.:	36102
Label approval no.:	36102/107488

3. VARIATION OF LABEL APPROVAL

Application no.:	106114
Product name:	Starkle 200 SG Insecticide
Active constituent/s:	200 g/kg dinotefuran
Applicant name:	Agnova Technologies Pty Ltd
Applicant ACN:	097 705 158
Summary of variation:	To extend the use to include aerial application
Date of variation:	29 September 2016
Label approval no.:	69398/106114

Application no.:	107522
Product name:	Detia Gas EX B Fumigation Blankets
Active constituent/s:	330 g/kg phosphine present as aluminium phosphide
Applicant name:	Detia Degesch GMBH
Applicant ACN:	N/A
Summary of variation:	To amend label disposal instructions to provide for recycling of metal outer container
Date of variation:	10 October 2016
Label approval no.:	63587/107522

Veterinary Chemical Products and Approved Labels

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

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	101844
Product name:	Apex Benazepril Oral Solution
Active constituent/s:	5 mg/mL benazepril hydrochloride
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of use	For the treatment of heart failure and chronic kidney disease in dogs
Date of registration/approval:	5 October 2016
Product registration no.:	80867
Label approval no.:	80867/101844

2. VARIATIONS OF REGISTRATION

Application no:	107659
Product name:	Tik Bos Pour-On Tick Development Inhibitor
Active constituent/s:	25 g/L fluazuron
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'PROCARE TIK BOS POUR-ON TICK DEVELOPMENT INHIBITOR' to 'TIK BOS POUR-ON TICK DEVELOPMENT INHIBITOR'
Date of variation:	16 August 2016
Product registration no.:	62288
Label approval no.:	62288/107659

Application no:	107990
Product name:	CCD Trimetsulpha (Water Soluble)
Active constituent/s:	40 g/kg trimethoprim, 200 g/kg sulphadiazine
Applicant name:	CCD Animal Health Pty Ltd
Applicant ACN:	151 737 950
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'TRIMETSULPHA (WATER SOLUBLE)' to 'CCD TRIMETSULPHA (WATER SOLUBLE)'
Date of variation:	23 September 2016
Product registration no.:	42336
Label approval no.:	42336/107990

Application no.:	105925
Product name:	Vetmedin 5 mg Capsules For Dogs
Active constituent/s:	5 mg/capsule pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of application:	To extend the claim to include treatment of preclinical DCM in large breed dogs
Date of variation:	4 October 2016
Product registration no.:	53562
Label approval no.:	53562/105925

Application no.:	105938
Product name:	Vetmedin 1.25 mg Capsules for Dogs
Active constituent/s:	1.25 mg/capsule pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of application:	To extend the claim to include treatment of preclinical DCM in large breed dogs
Date of variation:	4 October 2016
Product registration no.:	55523
Label approval no.:	55523/105938

Application no.:	105956
Product name:	Vetmedin 2.5 mg Capsules For Dogs
Active constituent/s:	2.5 mg/capsule pimobendan
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of application:	To extend the claim to include treatment of preclinical DCM in large breed dogs
Date of variation:	5 October 2016
Product registration no.:	53561
Label approval no.:	53561/105956

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.:	105667
Active constituent/s:	Trifloxystrobin
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use:	For use in agricultural chemical products
Date of approval:	30 September 2016
Approval no.:	82405

Application no.:	105618
Active constituent/s:	Bifenthrin
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of use:	For use in agricultural chemical products
Date of approval:	6 October 2016
Approval no.:	82386

Application no.:	104829
Active constituent/s:	Butoxydim
Applicant name:	Jiangsu Agrochem Laboratory Co. Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	10 October 2016
Approval no.:	82029

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]

NUTRIMENT HEALTH PTY LTD

ACN: 138 061 266

17 Woosters Lane

NABIAC NSW 2312

LICENCE NO: 4097

Product Types:*

- *Category 4:* Premixes (powder), supplements (powder) and probiotics

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

Licence Issued: 19 September 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]

C. LIM CONSULTING PTY LTD

ACN: 093 947 945

2302/30 Glen Street

MILSONS POINT NSW 2061

LICENCE NO: 6183

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Release for supply

Amended Licence Issued: 1 September 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*

CHEMIKA PTY LIMITED

ACN: 093 373 534

119 Magowar Road

GIRRAWEEEN NSW 2145

LICENCE NO: 6176

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Analysis and testing (physical and chemical)

Amended Licence Issued: 7 September 2016

**METROPOLITAN HEALTH
SERVICE TRADING AS
PHARMACEUTICAL TESTING
FACILITY (PTF),
DEPARTMENT OF
MICROBIOLOGY, PATHWEST
LABORATORY MEDICINE WA**

ABN: 13 933 250 709

Level 3 Hay Street Building

Princess Margaret Hospital for
Children

Roberts Road

SUBIACO WA 6008

LICENCE NO: 6097

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Analysis and testing (microbiological, Limulus
Amoebocyte Lysate Assay [LAL])

Amended Licence Issued: 13 September 2016

**STARWARD PTY LTD,
TRADING AS INLINE
COSMETIC LABORATORIES**

ACN: 120 276 995

28 Horizon Drive

BEENLEIGH QLD 4207

LICENCE NO: 2198

Product Types: *

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

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

Amended Licence Issued: 14 September 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*

**MENTHOLATUM
AUSTRALASIA PTY. LTD.**

ACN: 005 414 488

12–16 Janine Street

SCORESBY VIC 3179

LICENCE NO: 2038

Product Types: *

- *Category 2:* Chocolate-based solid dosage forms

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: 16 September 2016

**ASUREQUALITY AUSTRALIA
PTY LTD**

ACN: 106 787 704

28 Mareno Road

TULLAMARINE VIC 3043

LICENCE NO: 1085

Product Types: *

- *Category 1:* Immunobiologicals

Step(s) of Manufacture: Quality assurance (QA) of raw materials, aseptic filling, sterilisation (heat), secondary packaging, labelling, storage and release for supply

Amended Licence Issued: 19 September 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].

Nil

4. LICENCE SUSPENSIONS

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

Nil

5. REVOCATION OF LICENCE CANCELLATION

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

Nil

* 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*

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
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Australian Pesticides and Veterinary Medicines Authority
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KINGSTON ACT 2604

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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*

New Active Constituent and New Chemical Products Sarolaner Palatable Chews for Dogs Containing Sarolaner

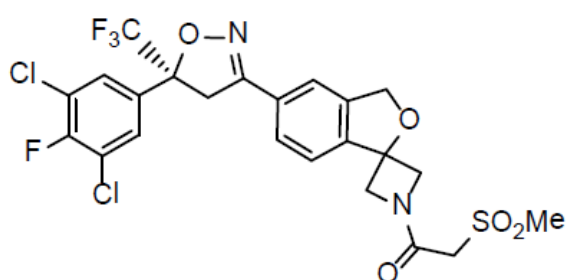
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, sarolaner, and an applications for registration of new products containing the new active constituent. The products are SIMPARICA CHEWS FOR DOGS 40.1–60 kg, SIMPARICA CHEWS FOR DOGS 20.1–40 kg, SIMPARICA CHEWS FOR DOGS 10.1–20 kg, SIMPARICA CHEWS FOR DOGS 5.1–10 kg, SIMPARICA CHEWS FOR DOGS 2.6–5 kg and SIMPARICA CHEWS FOR DOGS 1.3–2.5 kg. The suite of products will be referred to in this summary collectively as SIMPARICA CHEWS FOR DOGS.

PARTICULARS OF THE ACTIVE CONSTITUENT

The APVMA has before it an application for the approval of a new active constituent, sarolaner for use as an anti-tick and flea active constituent in veterinary products.

Common Name:	Sarolaner (WHO INN)
IUPAC Name:	1-[5'-[(5S)-5-(3,5-dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-3' <i>H</i> -spiro[azetidine-3,1'-[2]benzofuran]-1-yl]-2-methanesulfonylethan-1-one
Chemical Abstracts Name:	Ethanone, 1-[5'-[(5S)-5-(3,5-dichloro-4-fluorophenyl)-4,5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]spiro[azetidine-3,1'(3' <i>H</i>)-isobenzofuran]-1-yl]-2-(methylsulfonyl)-
CAS Registry Number:	1398609-39-6
Manufacturer's Code/s:	PF-06450567
Molecular Formula:	C ₂₃ H ₁₈ Cl ₂ F ₄ N ₂ O ₅ S
Molar Mass:	581.368 g/mol

Structure:



Chemical Family:	Isoxazoline
Mode of Action:	Inhibition of GABA- and glutamate-gated chloride channels

SUMMARY OF THE APVMA'S EVALUATION OF SAROLANER ACTIVE CONSTITUENT

The Scientific Assessment and Chemical Review Program of the APVMA has evaluated the chemistry aspects of sarolaner active constituent (identification and physico-chemical properties, manufacturing process and quality control procedures, specification, batch analysis and stability results and analytical methods) and found them to be acceptable.

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

The APVMA has considered the toxicological aspects of sarolaner, and concluded that there are no toxicological concerns to the approval of this active constituent. No Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) has been established in this assessment.

Sarolaner is included in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with an exemption to Schedule 5 for treatment, preventions and control of fleas and ticks in dogs in oral divided preparations each containing 120 mg or less of sarolaner per dosage unit. The APVMA considered that an S5 Poisons Schedule status is appropriate for sarolaner for use in veterinary products.

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

SUMMARY OF THE APVMA'S EVALUATION OF THE NEW CHEMOCAL PRODUCTS SIMPARICA CHEWS FOR DOGS CONTAINING SAROLANER

The APVMA has before it a suite of applications from ZOETIS AUSTRALIA PTY LTD for registration of six new products containing a new active constituent, sarolaner for the treatment, prevention and control of fleas and ticks in dogs. The products are SIMPARICA CHEWS FOR DOGS 40.1–60 kg, SIMPARICA CHEWS FOR DOGS 20.1–40 kg, SIMPARICA CHEWS FOR DOGS 10.1–20 kg, SIMPARICA CHEWS FOR DOGS 5.1–10 kg, SIMPARICA CHEWS FOR DOGS 2.6–5 kg and SIMPARICA CHEWS FOR DOGS 1.3–2.5 kg. The suite of products will be referred to in this summary collectively as SIMPARICA CHEWS FOR DOGS.

PARTICULARS OF THE PRODUCT APPLICATIONS

Proposed product name(s):	SIMPARICA CHEWS FOR DOGS 40.1–60 kg SIMPARICA CHEWS FOR DOGS 20.1–40 kg SIMPARICA CHEWS FOR DOGS 10.1–20 kg SIMPARICA CHEWS FOR DOGS 5.1–10 kg SIMPARICA CHEWS FOR DOGS 2.6–5 kg SIMPARICA CHEWS FOR DOGS 1.3–2.5 kg
Applicant company:	ZOETIS AUSTRALIA PTY LTD
Name of active constituent:	Sarolaner
Signal heading:	Schedule 5
Summary of proposed use:	For the treatment and prevention of flea infestations and the treatment and control of ticks on dogs and puppies
Pack sizes:	1, 3, 6 tablets
Withholding period:	Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF SIMPARICA CHEWS FOR DOGS 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 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 SIMPARICA CHEWS FOR DOGS would not be an undue hazard to the safety of people exposed to them during their handling and use.

The Office of Chemical Safety and Environmental Health (OCSEH) in the Department of Health and Ageing conducted a risk assessment for the products and in conjunction with the estimated hazard profile, determined whether the proposed use of the products would be an undue health hazard to humans.

The OCSEH estimated the acute toxicity of SIMPARICA CHEWS FOR DOGS based on information provided by the applicant. The acute toxicity of the proposed products was estimated from available toxicological information of the product ingredients, and the type of formulation. Based on the findings of the acute toxicological studies, the active constituent, sarolaner has low acute oral and dermal toxicity. On this basis, the products are expected to

have low acute oral and dermal toxicity. SIMPARICA CHEWS FOR DOGS is not expected to be irritating to skin or eyes and are not expected to sensitise skin.

The OCSEH recommended first aid statement (a)—*If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.* The OCSEH also recommended the following safety directions: *Will irritate the eyes. Avoid contact with eyes. Do not allow children to play with (dosing units). If product in eyes, wash it out immediately with water. Wash hands after use.* The first aid instruction and safety directions will be included on the product label.

- (ii) The APVMA is satisfied that the proposed use of SIMPARICA CHEWS FOR DOGS will not be an undue hazard to the safety of people using anything containing their residues.

The product is for use in companion animals (dogs) only. Sarolaner is unlikely to enter the food chain and therefore the determination of an ADI, ARfD and Maximum Residue Limits (MRL) were not considered necessary.

- (iii) The APVMA is satisfied that the proposed use of SIMPARICA CHEWS FOR DOGS containing the active constituent sarolaner is not likely to be harmful to human beings if used according to the product label directions.

From 1 June 2016, sarolaner is listed in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with an exemption to Schedule 5 for the treatment and prevention of fleas and ticks in dogs and puppies in oral divided preparations each containing 120 mg or less of sarolaner per dosage unit. The Schedule 5 signal heading is CAUTION. The precautionary statements *'Ingestion of sarolaner can be harmful for children upon accidental ingestion. To avoid accidental ingestion administer the chewable to the dog immediately after removal from the package'* and *'Keep out of reach of children'* will be included on the product label.

- (iv) The APVMA is satisfied that the proposed use of SIMPARICA CHEWS FOR DOGS 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 APVMA Environment Assessment Coordinator has conducted a Veterinary International Conference on Harmonization (VICH) Phase I Preliminary assessment to determine the potential for entry of sarolaner into the environment. The proposed use of sarolaner is not exempt from the need for an environmental risk assessment by legislation or regulation. Sarolaner is not a natural substance. Sarolaner will only be used in dogs, which are non-food producing animals. As dogs are not intensively reared and treatments are on an individual basis, environmental exposure is expected to be negligible. The VICH phase I assessment concluded that the proposed use of sarolaner will not present a significant risk to the environment.

However, because sarolaner has insecticidal properties, the environmental protection statement will be included on the product label. *'DO NOT contaminate wetlands or watercourses with this product or used containers.'* Disposal instructions consistent with the Vet Labelling Code for the appropriate package size(s) and material will also be included on the label.

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

- (i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the products adequately demonstrate that if used according to the product label directions, the products are effective for the proposed uses.

The suite of products, SIMPARICA CHEWS FOR DOGS is intended for the treatment and prevention of flea infestations, the treatment and control of tick infestations and for the treatment and control of ear mites, demodex

mites and sarcoptic mange on dogs and puppies. Six chewable tablet strengths are the basis for the six products in the range. The minimum sarolaner dose rate is 2 mg/kg bodyweight and the maximum dose rate 4 mg/kg bodyweight.

This efficacy data package comprised of scientific argument and the results from determination studies, dose confirmation studies, flea speed-of-kill studies, field efficacy studies and target animal safety studies. The APVMA has concluded that the data generated from the efficacy studies support the claims that the product would be effective for the treatment and prevention of flea infestations and the treatment and control of ticks on dogs and puppies. The products have persistent tick killing activity for up to 5 weeks, including Paralysis ticks (*Ixodes holocyclus*), Brown Dog ticks (*Rhipicephalus sanguineus*) and Bush ticks (*Haemaphysalis longicornis*). SIMPARICA CHEWS FOR DOGS was found to be effective the treatment and prevention of flea (*Ctenocephalides* spp.) infestations and demonstrated killing activity within four to eight hours of treatment. SIMPARICA CHEWS FOR DOGS were also found to be effective for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*), demodex mites (*Demodex canis*) and ear mites (*Otodectes cynotis*).

The results of the target animal safety studies indicated that, at the proposed label dose rate of 2.0–4.0 mg/kg bodyweight, SIMPARICA CHEWS FOR DOGS is unlikely to cause serious adverse reactions in dogs, including puppies from eight weeks of age and avermectin-sensitive collie breeds.

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (ii) The APVMA is satisfied that the proposed use of SIMPARICA CHEWS FOR DOGS would not adversely affect trade between Australia and places outside Australia. The product is for use on dogs, which are not food-producing animals and which do not produce any major Australian export commodities.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether SIMPARICA CHEWS FOR DOGS should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address
- the date you made the submission.

All personal and confidential commercial information (CCI) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Contact Officer
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