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of Australia**

Gazette

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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/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.

CONTENTS

Erratum Notice	3
Agricultural Chemical Products	4
Veterinary Chemical Products	10
Licensing of Veterinary Chemical Manufacturers	11
New Agricultural Active Constituent – Fluensulfone	19
New Veterinary Chemical Product – Startect Broad Spectrum Oral Drench For Sheep	21
Addendum to the Record of Approved Active Constituents.....	25
Application Summaries.....	27

Erratum Notice

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, No. APVMA 13, 1 July, 2014.

In the Notice, *Finalisation of Sheep Ectoparasiticides Review and Affirmation, Variation or Cancellation of Product Labels*, the incorrect wool harvest interval was listed for spinosad in table 1. The wool harvest interval for spinosad was listed as ‘6 months—short wool application’; the correct wool harvest interval is ‘NIL’.

The section headed ‘Label changes addressing environment concerns’ should therefore read:

Label changes addressing environment concerns

As a result of the environmental assessment conducted by the Department of the Environment, it is proposed that product labels be varied to include appropriate WHI (see Table 1). The wording of the label statement will be:

WOOL HARVEST INTERVAL: DO NOT use less than XX months before shearing or fibre collection.

Table 1: Recommended Wool Harvest Intervals (WHI) to manage environmental risks relating to the use of selected sheep ectoparasiticides

ACTIVE CONSTITUENT	RECOMMENDED WOOL HARVEST INTERVAL (WHI)
Cypermethrin and Alpha-cypermethrin ¹	2 months
Cyromazine	2 months
Chlorfenvinphos	1 month
Deltamethrin	2 months
Diazinon	2 months
Dicyclanil	3 months
Diflubenzuron	6 months
Ivermectin	3 months
Propetamphos	2 months
Temephos	6 months—short wool application only
Triflumuron	2 months
Spinosad	Nil (label statement may read ‘ <i>WOOL HARVEST INTERVAL: NONE.</i> ’)

Agricultural Chemical Products

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 registration in respect of the following products, with effect from the dates shown.

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name:	DD-95 Soil Fumigant
Active Constituent/s:	945 g/kg (1150 g/L) 1,3-dichloropropene
Applicant Name:	Kanesho Soil Treatment Sprl/Bvba
Applicant ACN:	N/A
Summary of Use:	For the control of plant parasitic nematodes in soil
Date of Registration:	16 July 2014
Label Approval No:	63434/45663
Product Name:	W Select Fly & Mosquito Coils
Active Constituent/s:	0.5 g/kg citronella oil, 4 g/kg d—allethrin
Applicant Name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of Use:	To repel house flies and mosquitoes around the home and garden
Date of Registration:	22 July 2014
Label Approval No:	70071/62433
Product Name:	Genfarm Sulfosulfuron 750 WG Herbicide
Active Constituent/s:	750 g/kg sulfosulfuron
Applicant Name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of Use:	For control of certain weeds in wheat and triticale in pre-emergent and post-emergent situations
Date of Registration:	22 July 2014
Label Approval No:	69828/61852
Product Name:	Wellfarm Haloxyfop 520 EC Herbicide
Active Constituent/s:	520 g/L haloxyfop present as the haloxyfop—R—methyl ester
Applicant Name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
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:	23 July 2014
Label Approval No:	70164/62655
Product Name:	EuroChem Kresta Strobilurin 500 WG Fungicide
Active Constituent/s:	500 g/kg kresoxim-methyl
Applicant Name:	TGAC Australia Pty. Ltd
Applicant ACN:	134 570 700
Summary of Use:	For the control of black spot (scab) and powdery mildew in apples and scab in pears
Date of Registration:	24 July 2014
Label Approval No:	67697/56658

Product Name:	Apparent Dimethoate 400 Insecticide
Active Constituent/s:	400 g/L dimethoate (an anticholinesterase compound).
Applicant Name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of Use:	For the control of a wide range of insect pests on fruit trees, certain vegetables, citrus, pastures, cotton, lucerne, peanuts and ornamentals
Date of Registration:	25 July 2014
Label Approval No:	70165/62662

Product Name:	Mortein Crawling Insect Surface Spray Kill & Protect High Performance Fast Direct Kill Easy Reach
Active Constituent/s:	0.70 g/kg imiprothrin, 2 g/kg cypermethrin
Applicant Name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of Use:	For the control of crawling insects in household situations
Date of Registration:	23 July 2014
Label Approval No:	70109/62529

Product Name:	Bronco MA-X Herbicide
Active Constituent/s:	280 g/L bromoxynil present as the n-octanoyl ester, 280 g/L MCPA present as the isooctyl ester
Applicant Name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of Use:	For the control of broadleaf weeds in cereals, linseed, grass pastures and turf
Date of Registration:	24 July 2014
Label Approval No:	69186/60163

Product Name:	Tracker Pro Spray Pattern Indicator
Active Constituent/s:	93 g/L sulphonated aromatic acid dye
Applicant Name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For use as a blue indicator dye with pesticides and fertilizers on turf and agricultural areas
Date of Registration:	28 July 2014
Label Approval No:	68789/68083

Product Name:	EuroChem Ethephon 720 Growth Regulator
Active Constituent/s:	720 g/L ethephon (an anti-cholinesterase compound)
Applicant Name:	PGR International Pty. Ltd
Applicant ACN:	113 610 352
Summary of Use:	For crop thinning, loosening or ripening in various crops and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton
Date of Registration:	28 July 2014
Label Approval No:	70064/62411

Product Name:	Oztec 2,4-D IPA 300 Herbicide
Active Constituent/s:	300 g/L 2,4-D present as the isopropylamine salt
Applicant Name:	Oztec Rural Pty Ltd
Applicant ACN:	056 693 095
Summary of Use:	For the control of emerged broadleaved weeds prior to sowing crops and pastures in conservation tillage situations and for selective weed control in various crops and situations
Date of Registration:	28 July 2014
Label Approval No:	69921/62060

Product Name:	Kenso Agcare Guru 750 WG Herbicide
Active Constituent/s:	750 g/kg tribenuron-methyl
Applicant Name:	Kenso Corporation (M) Sdn Bhd
Applicant ACN:	N/A
Summary of Use:	For the control of certain broadleaved weeds in fallows and pre-crop situations
Date of Registration:	28 July 2014
Label Approval No:	69651/61324
Product Name:	Radisson 100 Insecticide
Active Constituent/s:	100 g/L fipronil
Applicant Name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of Use:	For the control of ants around domestic and commercial structures and in commercial turf
Date of Registration:	28 July 2014
Label Approval No:	69556/61125
Product Name:	Mortein Fly & Mosquito Killer Fast Knockdown Low Allergenic
Active Constituent/s:	2.41 g/kg bioallethrin
Applicant Name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of Use:	For the control of household insects
Date of Registration:	29 July 2014
Label Approval No:	69855/61892
Product Name:	Brunnings Professional Surface Spray Indoor + Outdoor
Active Constituent/s:	0.50 g/L lambda-cyhalothrin
Applicant Name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of Use:	For the control of ants, cat fleas, cockroaches, flies, mosquitoes, silverfish, and spiders in and around the home
Date of Registration:	29 July 2014
Label Approval No:	70007/62286
Product Name:	Wellfarm Metolachlor 720 EC Herbicide
Active Constituent/s:	720 g/L metolachlor
Applicant Name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of Use:	For the selective control of certain annual grasses and broadleaved weeds in certain crops
Date of Registration:	29 July 2014
Label Approval No:	70151/62626
Product Name:	Surefire Alsetyl 800 WG Systemic Fungicide
Active Constituent/s:	800 g/kg fosetyl-aluminium
Applicant Name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of Use:	For the prevention and control of <i>Phytophthora</i> rots in apples, avocados, ornamentals, peaches and pineapples
Date of Registration:	30 July 2014
Label Approval No:	69400/60678

Product Name:	Gramoxone 360 Pro Herbicide
Active Constituent/s:	360 g/L paraquat present as paraquat dichloride
Applicant Name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of Use:	For use in numerous situations as a non-selective herbicide
Date of Registration:	31 July 2014
Label Approval No:	68577/58627
Product Name:	Amgrow Patrol Fixant Advanced Ant Control Bait
Active Constituent/s:	0.05 g/L imidacloprid
Applicant Name:	Sundew Solutions Pty Ltd
Applicant ACN:	135 400 261
Summary of Use:	For the control of various pest ants in indoor and outdoor situations
Date of Registration:	31 July 2014
Label Approval No:	69195/60206
Product Name:	Agrochina Carbendazim 500 SC Fungicide
Active Constituent/s:	500 g/L carbendazim
Applicant Name:	Shanghai Agrochina Chemical Co. Ltd
Applicant ACN:	N/A
Summary of Use:	For the control of fungal diseases on macadamia nuts, chickpeas, faba beans, lentils and vetch
Date of Registration:	31 July 2014
Label Approval No:	69222/60276
Product Name:	Graziers Tebulex 200GR Herbicide
Active Constituent/s:	200 g/kg tebuthiuron
Applicant Name:	PGR International Pty Ltd
Applicant ACN:	113 610 352
Summary of Use:	For control of brigalow regrowth, teatree regrowth, <i>Mimosa pigra</i> and certain problem woody weeds on grazing lands
Date of Registration:	1 August 2014
Label Approval No:	70100/62510
Product Name:	DISCO WG Fungicide
Active Constituent/s:	500 g/kg kresoxim-methyl
Applicant Name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of Use:	For the control of black spot (scab) and powdery mildew in apples and scab in pears
Date of Registration:	1 August 2014
Label Approval No:	69358/60587
Product Name:	Expedite FULL Insecticide
Active Constituent/s:	500 g/kg sulfoxaflor
Applicant Name:	Dow AgroSciences Australia Limited
Applicant ACN:	003 771 659
Summary of Use:	For the control of various insect pests in broadacre, vegetable and fruit crops
Date of Registration:	1 August 2014
Label Approval No:	65464/50988

Product Name:	Drive XL Herbicide
Active Constituent/s:	180 g/L quinclorac
Applicant Name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of Use:	For the post-emergence control of summer grass and white clover and the suppression of kikuyu in turf
Date of Registration:	1 August 2014
Label Approval No:	68601/58668

2. VARIATIONS

Product Name:	Tecto Flowable SC Fungicide
Applicant Name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of Variation:	To vary the directions for use for apples and pears
Date of Variation:	22 July 2014
Label Approval No:	49910/62009

Product Name:	Preschem Polesaver Rods
Applicant Name:	Preschem Pty. Ltd
Applicant ACN:	006 867 929
Summary of Variation:	To include localised treatment of pole service points
Date of Variation:	22 July 2014
Label Approval No:	30714/61032

Product Name:	Canopy Insecticide
Applicant Name:	Caltex Australia Petroleum Pty Ltd
Applicant ACN:	000 032 128
Summary of Variation:	To extend use situation to include GM cotton varieties: sicot 71 RR; bollgard; and bollgard II RR Flex
Date of Variation:	22 July 2014
Label Approval No:	60215/61084

Product Name:	Mortein NaturGard Fly & Mosquito Killer Odourless
Applicant Name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of Variation:	To add additional pack sizes
Date of Variation:	23 July 2014
Label Approval No:	67849/62366

Product Name:	Mortein NaturGard Fly & Mosquito Killer Eucalyptus
Applicant Name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of Variation:	To add additional pack sizes
Date of Variation:	23 July 2014
Label Approval No:	66960/62367

Product Name:	Apparent Turbo-Charged MCPA Herbicide
Applicant Name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of Variation:	To change the product name from 'APPARENT TERBUTRYN-MCPA HERBICIDE' to 'APPARENT TURBO-CHARGED MCPA HERBICIDE'
Date of Variation:	29 July 2014
Label Approval No:	69330/62660

Product Name:	Imtrade Octopus 800 WG Fungicide
Applicant Name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of Variation:	To add a pack size range
Date of Variation:	29 July 2014
Label Approval No:	68938/62573

Product Name:	DuPont Altacor Insecticide
Applicant Name:	Du Pont (Australia) Pty Ltd
Applicant ACN:	000 716 469
Summary of Variation:	To extend the use to include the control of a range of lepidopterous pests on pulse crops and control of caterpillar on cotton
Date of Variation:	30 July 2014
Label Approval No:	61824/60085

Product Name:	Cosavet-WG Fungicide/Miticide
Applicant Name:	Sulphur Mills Australia Pty Limited
Applicant ACN:	102 382 203
Summary of Variation:	To add additional pack sizes
Date of Variation:	30 July 2014
Label Approval No:	49938/60304

Veterinary Chemical Products

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 registration in respect of the following products, with effect from the dates shown.

1. VARIATIONS

Product Name:	Swish Pour-On Cattle Lice and Fly Treatment
Applicant Name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of Variation:	To extend the use to include the control of synthetic pyrethroid—susceptible buffalo fly (<i>Haematobia irritans exigua</i>) on cattle
Date of Variation:	22 July 2014
Label Approval No:	64199/62005
Product Name:	NV Pentosan Equine Injection
Applicant Name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of Variation:	To change the product name from 'PENTOSAN EQUINE INJECTION' to 'NV PENTOSAN EQUINE INJECTION'
Date of Variation:	22 July 2014
Label Approval No:	51986/62647

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]

**ASTRA MANUFACTURING
PTY. LTD.**

ACN: 164 506 147

894–906 Taylors Road

DANDENONG SOUTH VIC
3175

LICENCE NO: 2225

Product Types:*

- *Category 2:* Pastes, creams/lotions, powders, sprays and liquids
- *Category 3:* Pastes, powders, 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.

Licence Issued: 23 June 2014

**PARAFARM PTY LTD,
TRADING AS ALLFARM
ANIMAL HEALTH, AS
TRUSTEE FOR ALLFARM
ANIMAL HEALTHTRUST**

ACN: 161 661 696

2 Glendale Avenue

HASTINGS VIC 3915

LICENCE NO: 1102

Product Types:*

- *Category 1:* Immunobiologicals (Non-sterile Coccidial vaccine and gel).
- *Category 2:* Powders, liquids
- *Category 4:* Premixes, supplements

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

Licence Issued: 27 June 2014

* 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

MATCHLAND PTY. LTD.

LICENCE NO: 2226

ACN: 052 101 176

262 Evans Road

SALISBURY QLD 4107

Product Types:*

- *Category 2:* creams/lotions, ointments, pastes, sprays and liquids (oral and topical)
- *Category 3:* liquids, pastes and sprays
- *Category 4:* supplements (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

Licence Issued: 30 July 2014

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]

CATALENT AUSTRALIA PTY LTD

LICENCE NO: 2059

ACN: 007 219 990

217–221 Governor Road

BRAESIDE VIC 3195

Product Types: *

- *Category 2:* Tablets and capsules

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, premixing in powder or granular form, filling, packaging, labelling, blister packaging, soft gelatine capsule manufacture, hard shell capsule manufacture, tableting, tablet coating, analysis and testing (chemical), storage and release for supply.

Amended Licence Issued: 25 June 2014

VETLAB PTY. LIMITED

LICENCE NO: 2206

ACN: 003 962 196

39 Harris Street

ST MARYS NSW 2760

Product Types: *

- *Category 2:* Tablets, pastes, powders, liquids and granules
- *Category 3:* Liquids and Powders
- *Category 4:* Premixes and supplements

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, wet milling, dry milling, granulation, tableting, filling, packaging, labelling, microbiological reduction treatment (heat and chemical), analysis and testing (physical and chemical), storage and release for supply.

Amended Licence Issued: 25 June 2014

* 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*

ANIMAL PHARMA PTY LTD

ACN: 150 842 596

42–46 Somersby Falls Road

SOMERSBY NSW 2250

LICENCE NO: 2217

Product Types: *

- *Category 2: Palatable ingestible chews*

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, granulation, dry milling, filling, packaging, labelling, strip, blister or sachet packaging, tableting, analysis and testing (physical and chemical), storage and release for supply.

Amended Licence Issued: 25 June 2014

RANVET PTY. LIMITED

ACN: 001 606 033

10–12 Green Street

BANKSMEADOW NSW 2019

LICENCE NO: 2167

Product Types: *

- *Category 2: Powders and liquids*
- *Category 4: Supplements*

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

Amended Licence Issued: 27 June 2014

**MARS AUSTRALIA PTY LTD
TRADING AS MARS PETCARE
AUSTRALIA**

ACN: 008 454 313

Petcare Place

WODONGA VIC 3690

LICENCE NO: 2106

Product Types: *

- *Category 2: Palatable ingestible chews*

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, microbiological reduction treatment (heat), analysis and testing (physical and chemical), storage and release for supply.

Amended Licence Issued: 27 June 2014

* 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*

**GEORGE WESTON FOODS
LIMITED TRADING AS
GEORGE WESTON
TECHNOLOGIES ANALYTICAL
SERVICES**

ACN: 008 429 632
1 Braidwood Street
ENFIELD NSW 2136

LICENCE NO: 6100

Product Types: *

- *Category 6:* Single step

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

Amended Licence Issued: 28 June 2014

**BIONICHE ANIMAL HEALTH
(A/ASIA) PTY. LTD.**

ACN: 006 949 480
46 Seaton Street
ARMIDALE NSW 2350

LICENCE NO: 1059

Product Types: *

- *Category 1:* Sterile products
- *Category 2:* Hormone-impregnated foam sponges

Step(s) of Manufacture: Quality assurance (QA) of raw materials, management and immunisation of donor animals, formulation including blending, chemical synthesis, aseptic filling, freeze-drying, filling, packaging, labelling, repackaging, sterilisation (heat and filtration), microbiological reduction treatment (heat and filtration), analysis and testing (physiochemical and Limulus Amoebocyte Lysate [LAL] test), storage and release for supply.

Amended Licence Issued: 28 June 2014

**RIDLEY AGRIPRODUCTS PTY
LTD**

ACN: 006 544 145
34–48 Webb Drive
BOHLE QLD 4818

LICENCE NO: 4092

Product Types: *

- *Category 4:* Supplements (blocks and licks)

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: 28 June 2014

* 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*

ARISTOPET PTY LTD

ACN: 145 418 882

118 Links Avenue South

EAGLE FARM QLD 4009

LICENCE NO: 2211

Product Types: *

- *Category 2:* Tablets, creams/lotions, ointments, pastes, powders, sprays, liquids and suspensions
- *Category 3:* Liquids, sprays, powders and tablets (soluble for aquarium)

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

Amended Licence Issued: 28 June 2014

**AUSTRALIAN PET BRANDS
PTY LTD**

ACN: 138 614 150

12 Williamson Road

INGLEBURN NSW 2565

LICENCE NO: 4089

Product Types: *

- *Category 4:* Therapeutic Pet Foods

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, labelling, pellet extrusion, microbiological reduction treatment (heat), analysis and testing (physical, chemical and microbiological), storage and release for supply.

Amended Licence Issued: 28 June 2014

**AUSTRALIAN LABORATORY
SERVICES PTY. LTD.**

ACN: 009 936 029

22 Dalmore Drive

SCORESBY VIC 3179

LICENCE NO: 6181

Product Types: *

- *Category 6:* Single step

Step(s) of Manufacture: Analysis and testing (physical, chemical, microbiological, Limulus Amoebocyte Lysate [LAL] test).

Amended Licence Issued: 28 June 2014

* 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*

SYPHARMA PTY. LTD.

ACN: 114 895 064

27 Healey Road

DANDENONG VIC 3175

LICENCE NO: 1082

Product Types: *

- *Category 1:* Sterile products
- *Category 2:* Creams/lotions, ointments, pastes, powders, liquids and suspensions
- *Category 3:* Liquids
- *Category 4:* Premixes and supplements

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, aseptic filling, packaging, labelling, microbiological reduction treatment (filtration and heat), sterilisation (heat and filtration), analysis and testing (physical, chemical, microbiological, immunobiological, Limulus Amoebocyte Lysate [LAL] test and sterility testing), storage and release for supply.

Amended Licence Issued: 28 June 2014

**JOHN KOHNKE PRODUCTS
PTY LTD**

ACN: 095 561 505

8 Speedwell Place

SOUTH WINDSOR NSW 2756

LICENCE NO: 2216

Product Types:*

- *Category 2:* Powders, tablets
- *Category 4:* Supplements-powders

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

Amended Licence Issued: 29 June 2014

**LIENERT AUSTRALIA PTY.
LTD.**

ACN: 008 293 007

8 Roseworthy Road

ROSEWORTHY SA 5371

LICENCE NO: 4091

Product Types:*

- *Category 4:* Premixes, supplements and custom mixes

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

Amended Licence Issued: 29 June 2014

* 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*

**ARUMPO BENTONITE PTY
LIMITED**

ACN: 001 831 483

Arumpo Road

BURONGA NSW 2739

LICENCE NO: 4065

Product Types: *

- *Category 4:* supplements (bentonite)

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

Amended Licence Issued: 24 July 2014

LICENCE CANCELLATIONS

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

**PHARMACIA AUSTRALIA PTY
LIMITED**

ACN: 000 185 526

59 Kirby Street

RYDALMERE NSW 2116

LICENCE NO: 6029

Date Cancelled: 30 June 2014

**WYNOVALE PTY LTD
TRADING AS ROADWISE
LOGISTICS**

ACN: 003 669 341

27 Coombes Drive

PENRITH NSW 2751

LICENCE NO: 6159

Date Cancelled: 28 June 2014

**A.B. OXFORD COLD
STORAGE COMPANY
PROPRIETARY LIMITED**

ACN: 005 104 361

1 Hume Road

LAVERTON NORTH VIC 3026

LICENCE NO: 6138

Date Cancelled: 28 June 2014

* 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*

2. LICENCE SUSPENSIONS

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

AUSTRALIAN ANIMAL BLOOD BANK PTY LTD **LICENCE NO:** 1101
ACN: 140 128 990 **Date Suspended:** 13 June 2014 (to 9 October 2014)
50 Wills Road
LONG POINT NSW 2564

DR CHET'S PTY LTD **LICENCE NO:** 3033
ACN: 128 197 731 **Date Suspended:** 29 June 2014 (to 31 January 2015)
45 Aquila Street
REDLAND BAY QLD 4165

APVMA CONTACT

MQL Officer
Manufacturing, Quality and Licensing
Veterinary Medicines 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*

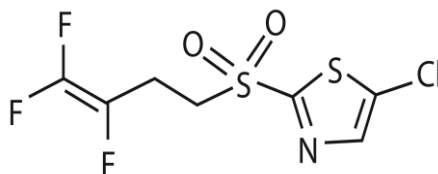
New Agricultural Active Constituent – Fluensulfone

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

Fluensulfone is a nematicide. It will be used to control root-knot nematodes in selected vegetable crops including cucumbers, melons, cantaloupes, tomatoes, capsicum, okra, and eggplant.

Common Name:	Fluensulfone
IUPAC Name:	5-Chloro-2-(3,4,4-trifluorobut-3-en-1-ylsulfonyl)-1,3-thiazole
CAS Name:	5-Chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole
CAS Registry Number:	318290-98-1
Manufacturer's Code:	MCW-2
Minimum Purity:	957 g/kg
Molecular Formula:	C ₇ H ₅ NO ₂ S ₂ ClF ₃
Molecular Weight:	291.7

Structures:



Chemical Family:	Heterocyclic fluoroalkenyl sulfones
Mode of Action:	Nematicide

SUMMARY OF THE APVMA'S EVALUATION OF FLUENSULFONE ACTIVE CONSTITUENT

The Pesticides Program of the APVMA has evaluated the chemistry aspects of fluensulfone active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for fluensulfone active constituent:

Constituent	Specification
Fluensulfone	Fluensulfone: 957 g/kg minimum

Other compounds of toxicological significance are not expected to occur in the fluensulfone TGAC.

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of fluensulfone

An Acceptable Daily Intake (ADI) of 0.015 mg/kg bw/d has been set, based on a No-Observed Effect Level (NOEL) of 1.5 mg/kg bw/d in female dogs in a 52-week oral study for decreased body weight and body weight gain, and applying a safety factor of 100.

An acute reference dose (ARfD) is established at 0.15 mg/kg bw (rounding down) from a 2-generation reproduction study, based on a NOAEL of 16.2 mg/kg bw in female offspring to account for post natal loss at 169.1 mg/kg bw, after applying a safety factor of 100.

The Advisory Committee on Chemicals Scheduling (ACCS) has considered Fluensulfone to be appropriate for inclusion in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with no cut-offs or exceptions, along with an implementation date of 1 June 2014.

The OCS has indicated that there are no objections on toxicological grounds to the approval of the active constituent fluensulfone.

The APVMA accepts the findings and recommendations of its advisers on these criteria.

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

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of fluensulfone should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. These grounds include **chemistry and manufacture, and toxicity**. 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

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

All personal and **confidential commercial information (CCI)**² material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant approval for fluensulfone that relate to the **grounds for approval** should be addressed in writing to:

Chemistry Manager
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4936

Fax: +61 2 6210 4840

Email: registration@apvma.gov.au

² A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

New Veterinary Chemical Product – Startect Broad Spectrum Oral Drench For Sheep

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Zoetis Australia Pty Ltd for registration of a new product, **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP**, containing the new active constituent derquantel and the existing active constituent abamectin. The product is for the treatment and control of a broad range of susceptible adult and immature gastrointestinal nematodes of sheep, including those resistant to levamisole, benzimidazoles, macrocyclic lactones and closantel.

PARTICULARS OF THE APPLICATION

Proposed Product Name(s):	STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP								
Applicant Company:	Pfizer Australia Pty Ltd								
Name of Active Constituent:	Derquantel								
Signal Heading:	Schedule 6								
Summary of Proposed Use:	For the treatment and control of a broad range of susceptible adult and immature gastrointestinal nematodes of sheep, including those resistant to levamisole, benzimidazoles, macrocyclic lactones and closantel.								
Pack Sizes:	1 L, 5 L, 15 L								
Maximum Residue Limits:	Proposed <table><tr><td>Sheep muscle</td><td>0.2 µg/kg</td></tr><tr><td>Sheep fat</td><td>0.2 µg/kg</td></tr><tr><td>Sheep kidney</td><td>0.2 µg/kg</td></tr><tr><td>Sheep liver</td><td>0.2 µg/kg</td></tr></table>	Sheep muscle	0.2 µg/kg	Sheep fat	0.2 µg/kg	Sheep kidney	0.2 µg/kg	Sheep liver	0.2 µg/kg
Sheep muscle	0.2 µg/kg								
Sheep fat	0.2 µg/kg								
Sheep kidney	0.2 µg/kg								
Sheep liver	0.2 µg/kg								
Residue Definition:	Table 3 parent compound – derquantel								
Withholding Period:	Withholding Periods: MEAT: DO NOT USE less than 14 days before slaughter for human consumption. MILK: DO NOT USE in female sheep which are producing or may in the future produce milk or milk products for human consumption. Retreatment interval: DO NOT re-treat less than 28 days after the last treatment with <i>STARTECT[®] Broad Spectrum Oral Drench for Sheep</i> . Trade Advice: EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 28 days after treatment before slaughter for export.								

SUMMARY OF THE APVMA'S EVALUATION OF STARTECT IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) 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 human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP** would not be an undue hazard to the safety of people exposed to it during its handling and use.

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

The active constituent, derquantel, has low acute oral, dermal and inhalational toxicity. It is a slight skin irritant but it is not an eye irritant. Studies showed that derquantel was neither a reproductive toxicant nor a developmental toxicant in rats or rabbits, and is not an *in vivo* genotoxicant. No carcinogenicity studies were submitted. However, as derquantel is a member of a chemical class (i.e. spiriondole) that is not known to be animal or human carcinogens, the weight of evidence suggests that it is not considered to be an *in vivo* genotoxicant.

The product, **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP**, has low acute oral, dermal and inhalational toxicity.

First aid instructions and safety directions are required and are included on the label.

The APVMA has considered the findings and recommendations of the OCSEH evaluation and accepts these findings and recommendations.

- (ii) The APVMA is satisfied that the proposed use of **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP** will not be an undue hazard to the safety of people using anything containing its residues. The APVMA has assessed the residues data and Maximum Residue Limits (MRLs) are recommended for **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP**. Withholding periods and re-treatment intervals have been established. The product is not for use in female sheep which are producing or may in the future produce milk or milk products for human consumption. The APVMA has conducted a dietary risk assessment and has found that the chronic dietary exposure to derquantel residues is acceptable.

- (iii) The APVMA is satisfied that the proposed use of **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP** containing the active constituent, derquantel is not likely to be harmful to human beings if used according to the product label directions.

The APVMA has evaluated and proposes to approve the active constituent, derquantel, and finds that the chemistry and manufacturing details of the product, **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP**, are acceptable. The Advisory Committee on Chemicals Scheduling (ACCS) has assessed derquantel and has included it in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons. The signal heading that corresponds to Schedule 6 and the first aid instructions and safety directions recommended by OCS appear on the product label.

Derquantel is not classified as a hazardous substance but **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP** is determined to be a hazardous substance.

The APVMA has considered the findings of its advisors on this criterion and accepts their recommendations.

- (iv) The APVMA is satisfied that the proposed use of **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP** containing the active constituent, derquantel is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label instructions. The APVMA is satisfied that the proposed use of the new product, **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP**, containing the new active constituent, derquantel and the existing active abamectin would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

Derquantel was rapidly and extensively degraded following administration to soils and did not persist in soils. Based on the determined log Kow of 2.96, it is unlikely to have the potential for bioaccumulation in aquatic organisms. Additionally, derquantel is not expected to bioaccumulate based on the extensive metabolism in sheep.

Ecotoxicity studies demonstrated derquantel is slightly toxic to fish, aquatic invertebrates and algae. Risk assessments of derquantel, together with abamectin, indicate an acceptable risk in the aquatic compartment as a result of discharge of excreta to streams in a pasture environment and from run-off in a feedlot situation. Given the low concentration of the active constituents present in treated soils, adverse effects on earthworms, soil micro-organisms and non-target vegetation are unlikely to occur from use in pastures or feedlots. The risks of the proposed product to dung beetles and dung flies under Australian conditions are mitigated by the fact that sheep faeces is not a preferred resource for these species due to the pelletised morphology of sheep faeces.

The Department of the Environment (DoE) has assessed the data in support of the proposed use and has concluded that the risks to the environment from the proposed use are acceptable.

The APVMA has considered the findings of DoE and accepts its recommendations on this criterion.

- (v) The APVMA is considering whether the proposed use of **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP** would not adversely affect trade between Australia and places outside Australia.

Codex MRLs have not been established for derquantel in sheep tissues. The European Union has established derquantel MRLs as follows: sheep liver 0.02 mg/kg; sheep kidney 0.005 mg/kg; sheep muscle 0.002 mg/kg; and sheep fat 0.04 mg/kg. Derquantel MRLs in sheep tissues have not been established by the USA, China, Japan and CIS. The APVMA has assessed the residues data and has determined that an export slaughter interval of 28 days would be required for derquantel residues to decline to below the LOQ.

The APVMA has concluded that the risk to Australia's export trade in sheep commodities is considered to be low when the recommended ESI of 28 days is observed for **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP**

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

FUTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Consultation' section, www.apvma.gov.au or by contacting the APVMA at the contact details below.

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 the application for approval of **STARTECT BROAD SPECTRUM ORAL DRENCH FOR SHEEP** should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the application. These grounds include **occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy**. 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

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

All personal and **confidential commercial information (CCI)**³ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant registration that relate to the **grounds for registration** should be addressed in writing to:

Veterinary Medicines Program
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](#).

Addendum to the Record of Approved Active Constituents

The current *Record of Approved Active Constituents for Registered Chemical Products* is also accessible from the APVMA website, www.apvma.gov.au.

APPROVED SINCE GAZETTE NO. 15, 29 JULY 2014

For use in agricultural and/or veterinary chemical products:

Common Name	Approval Holder	Manufacturer Site	Approval No.
CYPROCONAZOLE	JIANGSU FLAG CHEMICAL INDUSTRY CO., LTD	HUAIAN GLORY CHEMICAL CO., LTD NO 2. GUOQIAO ROAD SALT CHEMICAL INDUSTRY PARK HONGZE HUAIAN 223100 PR CHINA	69930
SODIUM 2-NITROPHENOLATE	ASAHI CHEMICAL MFG. CO. LTD	ASAHI CHEMICAL MFG. CO. LTD 4-15-1 KITATANBE HIGASHISUMIYOSHI-KU ASAKA CITY, OSAKA JAPAN	66206
CYPRODINIL	SHANDONG RAINBOW INTERNATIONAL CO., LTD.	SHANDONG WEIFANG RAINBOW CHEMICAL CO.LTD 600 HAIYUAN ROAD, BINHAI ECONOMIC DEVELOPMENT AREA, WEIFANG SHANDONG 262737 PR CHINA	69939
SODIUM 2-METHOXY-5-NITROPHENOLATE	ASAHI CHEMICAL MFG. CO. LTD	ASAHI CHEMICAL MFG. CO. LTD 4-15-1 KITATANBE HIGASHISUMIYOSHI-KU ASAKA CITY, OSAKA JAPAN	66205

2,4-D	GOLD ZONE ENTERPRISES LTD	CAC NANTONG CHEMICAL COMPANY LTD HUANGHAI 4 TH ROAD YANGKOU CHEMICAL INDUSTRIAL PARK RUDONG COUNTY 226407 NANTONG CITY JIANGSU PR CHINA	69783
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APVMA CONTACT

For further information please contact:

Case Management and Administration Unit (CMAU)
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

Application Summaries

The APVMA publishes complete application summaries on the APVMA website, www.apvma.gov.au/node/11061. They are published in weekly instalments using the date the application was accepted for assessment. If an application summary has been amended, the APVMA will publish the amended version on the website. A summary will be removed from the website 28 days after the application has been finalised.

APVMA CONTACT

For further information please contact:

Case Management and Administration Unit (CMAU)
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4701

Fax: +61 2 6210 4721

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