



**Commonwealth
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

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4870

For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

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Agricultural Chemical Products and Approved Labels

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

1. RESTRICTED PRODUCT

Application no.:	62938
Product name:	Wellfarm Bifenthrin 100 EC Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of use	For installation of chemical soil barriers for new building work in accordance with AS 3660.1; the post-construction management of subterranean termites in accordance with AS 3660.2 and the control of a range of other urban pests
Date of registration/approval:	2 April 2015
Product registration no.:	70288
Label approval no.:	70288/62938

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	100032
Product name:	Imark 700 WG Herbicide
Active constituent/s:	700 g/kg imazapic
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For the pre-emergence control of certain annual grass and broadleaf weeds in fallow situations and sugarcane
Date of registration/approval:	30 March 2015
Product registration no.:	80013
Label approval no.:	80013/100032

Application no.:	63470
Product name:	Bespray 500 Herbicide
Active constituent/s:	500 g/L 2,4-DB (present as the dimethylamine salt)
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of broadleaf weeds in seedling and established lucerne, medic and clover pasture, peanuts and cereal crops undersown with lucerne, medic or clover
Date of registration/approval:	30 March 2015
Product registration no.:	70446
Label approval no.:	70446/63470

Application no.:	62926
Product name:	Wellfarm Lambda-Cyhalothrin 250 CS Insecticide
Active constituent/s:	250 g/L lambda-cyhalothrin
Applicant name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of use	For the control of certain insect pests in cotton, barley, wheat and various field crops
Date of registration/approval:	30 March 2015
Product registration no.:	70282
Label approval no.:	70282/62926
Application no.:	100901
Product name:	Brunnings Citrus & Fruit Spray
Active constituent/s:	20 g/L petroleum oil
Applicant name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of use	For the control of scale on citrus, roses and ornamentals
Date of registration/approval:	30 March 2015
Product registration no.:	80462
Label approval no.:	80462/100901
Application no.:	62459
Product name:	Farmalinx Quinfen 250 SC Fungicide
Active constituent/s:	250 g/L quinoxyfen
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For use as a protectant against powdery mildew in grapevines
Date of registration/approval:	30 March 2015
Product registration no.:	70081
Label approval no.:	70081/62459
Application no.:	62690
Product name:	Wellfarm Trifluralin 480 EC Herbicide
Active constituent/s:	480 g/L trifluralin
Applicant name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of use	For the pre-emergent control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
Date of registration/approval:	31 March 2015
Product registration no.:	70183
Label approval no.:	70183/62690
Application no.:	62674
Product name:	Pilar-2,4-D 625 SL Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salt
Applicant name:	Pilarquim (Shanghai) Co Ltd
Applicant ACN:	N/A
Summary of use	For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugarcane, peanuts, and non-agricultural areas
Date of registration/approval:	31 March 2015
Product registration no.:	70174
Label approval no.:	70174/62674

Application no.:	63336
Product name:	Hy-Clor Super Algaecide
Active constituent/s:	400 g/L benzalkonium chloride
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of use	For the control of algae in swimming pools
Date of registration/approval:	31 March 2015
Product registration no.:	70386
Label approval no.:	70386/63336
Application no.:	62935
Product name:	GOKU Growth Regulator
Active constituent/s:	720 g/L ethephon (an anti-cholinesterase compound)
Applicant name:	Proplan Plant Protection Company S.L
Applicant ACN:	N/A
Summary of use	For anti-lodging in barley or crop thinning, loosening or ripening in various crops and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton
Date of registration/approval:	31 March 2015
Product registration no.:	70287
Label approval no.:	70287/62935
Application no.:	63489
Product name:	Hammersley Litter Beetle Insecticide
Active constituent/s:	12.75 g/L eucalyptus oil, 7.65 g/L tea tree oil
Applicant name:	Hammersley Industries Pty Limited
Applicant ACN:	001 919 973
Summary of use	To assist control of lesser mealworm (<i>alphitobius diaperinus</i>) in poultry sheds
Date of registration/approval:	31 March 2015
Product registration no.:	70464
Label approval no.:	70464/63489
Application no.:	63472
Product name:	Peroxsil395 Chlorine Free Pool Sanitiser
Active constituent/s:	395 g/L hydrogen peroxide, 0.33 g/L silver as silver nitrate
Applicant name:	Waterco Limited
Applicant ACN:	002 070 733
Summary of use	For control of bacteria and algae in private (domestic) swimming pools and spas
Date of registration/approval:	1 April 2015
Product registration no.:	70448
Label approval no.:	70448/63472
Application no.:	101171
Product name:	Weed Force Evict 700 Herbicide
Active constituent/s:	700 g/kg glyphosate (present as the mono-ammonium salt)
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of use	For use as a non-selective herbicide in various situations
Date of registration/approval:	1 April 2015
Product registration no.:	80586
Label approval no.:	80586/101171

Application no.:	100947
Product name:	Pest Defence Rat & Mouse Block Bait
Active constituent/s:	0.05 g/kg brodifacoum
Applicant name:	Zapi S.P.A
Applicant ACN:	N/A
Summary of use	For the control of rodents resistant to other anticoagulants, including warfarin, coumatetralyl and bromadiolone
Date of registration/approval:	1 April 2015
Product registration no.:	80485
Label approval no.:	80485/100947
Application no.:	101172
Product name:	Weed Force Longreach Herbicide
Active constituent/s:	900 g/kg simazine
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of use	For use in commercial and industrial areas, around agricultural buildings, fence lines, rights of way, forestry and a range of horticultural and broadacre crops to control certain annual and perennial weeds
Date of registration/approval:	2 April 2015
Product registration no.:	80587
Label approval no.:	80587/101172
Application no.:	101001
Product name:	Pest Defence Rat & Mouse Soft Bait
Active constituent/s:	0.05 g/kg brodifacoum
Applicant name:	Zapi S.P.A
Applicant ACN:	N/A
Summary of use	For effective control of rodents around industrial, commercial, agricultural and residential buildings. Controls rodents resistant to other anticoagulants, including warfarin, coumatetralyl and bromadiolone
Date of registration/approval:	7 April 2015
Product registration no.:	80508
Label approval no.:	80508/101001
Application no.:	100886
Product name:	Whitestar Flutriafol SC Fungicide
Active constituent/s:	500 g/L flutriafol
Applicant name:	Agricultural Product Services Pty Ltd
Applicant ACN:	092 350 279
Summary of use	For control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser
Date of registration/approval:	7 April 2015
Product registration no.:	80450
Label approval no.:	80450/100886
Application no.:	62664
Product name:	Wellfarm 2,4-D Amine 625 SL Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of use	For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugarcane, peanuts, and non-agricultural areas
Date of registration/approval:	7 April 2015
Product registration no.:	70166
Label approval no.:	70166/62664

3. VARIATIONS OF REGISTRATION

Application no:	101950
Product name:	Strident Insecticide
Active constituent/s:	440 g/L buprofezin
Applicant name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of variation:	To change the product name from 'PATRON INSECTICIDE' to 'STRIDENT INSECTICIDE'
Date of variation:	13 March 2015
Product registration no.:	62616
Label approval no.:	62616/101950
Application no:	101962
Product name:	Yates Weed N' Feed Hose On
Active constituent/s:	2.3 g/L dicamba present as the dimethylamine salt, 15 g/L MCPA present as the dimethylamine salt
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the product name from 'YATES DOUBLE ACTION WEED'N'FEED LIQUID' to 'YATES WEED N' FEED HOSE ON'
Date of variation:	16 March 2015
Product registration no.:	67217
Label approval no.:	67217/101962
Application no:	62534
Product name:	Temprid 75 Residual Insecticide
Active constituent/s:	50 g/L imidacloprid, 25 g/L beta-cyfluthrin
Applicant name:	Bayer CropScience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To include control of a range of insects in turf and ornamentals and add a pack size range (0.5 L—10 L)
Date of variation:	31 March 2015
Product registration no.:	64371
Label approval no.:	64371/62534
Application no:	100398
Product name:	Senator 600 Red Flowable Seed Treatment
Active constituent/s:	600 g/L imidacloprid
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To update registration details and to include protection against insect pests of stored cereal grain
Date of variation:	1 April 2015
Product registration no.:	61163
Label approval no.:	61163/100398

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.:	100936
Product name:	Paragard Allwormer Tablets For Large Dogs
Active constituent/s:	100 mg praziquantel, 450 mg oxibendazole
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use	To treat and control roundworm, hookworm, whipworm and tapeworm in large dogs
Date of registration/approval:	1 April 2015
Product registration no.:	80476
Label approval no.:	80476/100936

Application no.:	100937
Product name:	Paragard Allwormer Tablets For Small Dogs And Puppies
Active constituent/s:	25 mg praziquantel, 112.5 mg oxibendazole
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use	For the treatment and control of roundworm, hookworm, whipworm and tapeworm in small dogs and puppies
Date of registration/approval:	1 April 2015
Product registration no.:	80477
Label approval no.:	80477/100937

Application no.:	100938
Product name:	Paragard Allwormer Tablets For Medium Dogs
Active constituent/s:	50 mg praziquantel, 225 mg oxibendazole
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use	To treat and control roundworm, hookworm, whipworm and tapeworm in medium dogs
Date of registration/approval:	2 April 2015
Product registration no.:	80478
Label approval no.:	80478/100938

Application no.:	59748
Product name:	RevitaCAM 5mg/mL Oromucosal Spray for Dogs
Active constituent/s:	5 mg/mL meloxicam
Applicant name:	Abbott Laboratories
Applicant ACN:	N/A
Summary of use	For the alleviation of inflammation and pain in acute and chronic musculoskeletal disorders in dogs
Date of registration/approval:	7 April 2015
Product registration no.:	69059
Label approval no.:	69059/59748

2. VARIATIONS OF REGISTRATION

Application no.:	100037
Product name:	Voren Dexamethasone Ester for Injection
Active constituent/s:	1 mg/ml dexamethasone isonicotinate
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To remove use in cattle, sheep and pigs and intravenous dosage instruction
Date of variation:	7 April 2015
Product registration no.:	35959
Label approval no.:	35959/100037

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.:	80007
Active constituent/s:	Propyzamide
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	31 March 2015
Approval no.:	80007/100027

New Agricultural Active Constituent Approved Under Section 14a—Rosemary Oil

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing to add Rosemary oil to the list of Active Constituents Not Requiring Evaluation. Rosemary oil has been evaluated and has met the criteria under Section 14A of the Agvet Code.

Rosemary oil is listed on the US-EPA list of pesticides: Minimum Risk Exemptions. The following link is to the US-EPA www.regulations.gov/ Document ID: EPA-HQ-OPP-2010-0305-0006.

Rosemary oil is not toxicologically significant to humans: Journal of Food Protection, Vol. 71, No. 4, 2008, Pages 790–795 International Association for Food Protection.

The APVMA is satisfied of Section 14A(b) of the Agvet Code, which refers to having regard to matters (relevant matters) mentioned in subsection 14(4), specifically (a), (b), (c), (d), (e).

Common Name: Rosemary oil
Scientific Information: Extracted from *Rosmarinum officinalis*, Labiatae.

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission to the proposal to include Rosemary oil on the list of Active Constituents Not Requiring Evaluation. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval via the section 14A route. 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 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)*¹ material contained in submissions will be treated confidentially.

¹ A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

Written submissions on the APVMA's proposal to grant approval for clove oil that relate to the grounds for approval should be marked attention to the Director, Chemistry and Manufacture Section, Scientific Assessment and Chemical Review Program in writing to:

The Director
Chemistry and Manufacture Section
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4936

Fax: +61 2 6210 4840

Email: chemistry@apvma.gov.au

New Agricultural Active Constituent approved under Section 14a—Cedar Oil

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing to add Cedar oil to the list of Active Constituents Not Requiring Evaluation. Cedar oil has been evaluated and has met the criteria under Section 14A of the Agvet Code.

Cedar oil is an extract from the *Cupressaceae* family, which includes true cedars, junipers, and cypresses. As a biochemical active ingredient, products containing Cedar oil are approved as repellents in the United States of America. A non-toxic mode of action has been confirmed and risk assessments have accounted for the potential hazards posed by each use. Information submitted in support of USA registered products containing Cedar oil uniformly confirms that no adverse human health or ecological risk are expected as a result of exposure to this compound, when used according to label directions.

The following link to the US-EPA toxicology document was used in determining the toxicology of Cedar oil http://southwesterncedaroil.com/downloads/EPA_Cedar_Oil_Report.pdf

Cedar oil is not toxicologically significant to humans.

The APVMA is satisfied of Section 14A(b) of the Agvet Code, which refers to having regard to matters (relevant matters) mentioned in subsection 14(4), specifically (a), (b), (c), (d), (e).

Common Name: Cedar oil
Scientific Information: Cedar oil is an extract from the *Cupressaceae* family

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission to the proposal to include Cedar oil on the list of Active Constituents Not Requiring Evaluation. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval via the section 14A route. 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 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.

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

Written submissions on the APVMA's proposal to grant approval for Cedar oil that relate to the grounds for approval should be marked attention to the Director, Chemistry and Manufacture Section, Scientific Assessment and Chemical Review in writing to:

The Director
Chemistry and Manufacture Section
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4936

Fax: +61 2 6210 4840

Email: chemistry@apvma.gov.au

Licensing of Veterinary Chemical Manufacturers

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

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

1. NEW LICENCES

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

CCD ANIMAL HEALTH PTY LTD

ACN: 151 737 950

Unit 16

84–92 Barnes Street

TAMWORTH NSW 2340

LICENCE NO: 6195

Product Types:*

- *Category 6:* Single step manufacture

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

Licence Issued: 2 February 2015

EIMERIA PTY. LIMITED

ACN: 075 153 472

University of Melbourne

School of Veterinary Sciences

250 Princes Highway

WERRIBEE VIC 3030

LICENCE NO: 6157

Product Types:*

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Analysis and testing (immunobiological)

Licence Issued: 24 February 2015

DERMCARE-VET PTY. LTD.

ACN: 010 280 010

7 Centenary Road

Slacks Creek, QLD 4127

LICENCE NO: 1109

Product Types: *

- *Category 1:* Sterile and immunobiological products

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

Licence Issued: 10 March 2015

* 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*

**WSD AGRIBUSINESS PTY.
LTD.**

ACN: 600 111 135

7 Koojan Avenue

SOUTH GUILFORD, PERTH
WA 6055

LICENCE NO: 2231

Product Types: *

- *Category 2:* powders and liquids
- *Category 3:* liquids and powders
- *Category 4:* premixes and supplements

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

Licence Issued: 13 March 2015

**LANDMARK OPERATIONS
LIMITED**

ACN: 008 743 217

71 Colebard Street West

ACACIA RIDGE QLD 4110

LICENCE NO: 6202

Product Types:*

- *Category 6:* Single step manufacture

Step(s) of Manufacture: secondary packaging, secondary labelling, storage and release for supply

Licence Issued: 23 March 2015

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]

EQUIVET PTY. LIMITED

ACN: 003 837 492

37 Lord Fury Court

DARLING DOWNS WA 6122

LICENCE NO: 2034

Product Types: *

- *Category 2:* Pastes, powders

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

Amended Licence Issued: 2 February 2015

* 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*

**CUSTOM CHEMICALS
INTERNATIONAL PTY LTD**

ACN: 050 573 674

103–107 Potassium St

NARANGBA QLD 4504

LICENCE NO: 3030

Product Types: *

- *Category 3:* Liquids and sprays

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: 9 February 2015

BIOPROPERTIES PTY. LTD.

ACN: 007 303 728

11–15 Moores Road

GLENORIE NSW 2157

LICENCE NO: 1061

Product Types: *

- *Category 1:* Immunobiologicals, sterile diluents

Step(s) of Manufacture: Quality assurance (QA) of raw materials, management of donor animals, virus cultivation, mycoplasma cultivation, bacterial fermentation, oocyst antigen production, oocyst processing, formulation including blending, aseptic filling, filling, packaging, labelling, microbiological reduction treatment (heat, chemical, filtration), sterilisation (heat, chemical, filtration), freeze-drying, analysis and testing (physical, immunobiological, microbiological, oocyst counts), storage and release for supply.

Amended Licence Issued: 23 February 2015

**AUSTRALIAN CONTRACT
MANUFACTURING (ACM) PTY
LTD**

ACN: 052 052 196

92 Antimony Street

CAROLE PARK QLD 4300

LICENCE NO: 2065

Product Types: *

- *Category 2:* tablets, creams/lotions, ointments, pastes, powders, sprays and liquids
- *Category 3:* liquids, pastes, sprays and powders
- *Category 4:* liquids, powders and pastes

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

Amended Licence Issued: 2 March 2015

* 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*

**BOEHRINGER INGELHEIM
PTY LTD**

ACN: 000 452 308

Level 1, 78 Waterloo Road
NORTH RYDE NSW 2113

LICENCE NO: 6187

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Release for supply

Amended Licence Issued: 10 March 2015

TREIDLIA BIOVET PTY LTD

ACN: 150 496 138

Unit 76, Power Business Park
45 Powers Road
SEVEN HILLS NSW 2147

LICENCE NO: 1096

Product Types:*

- *Category 1:* Immunobiologicals (Inactivated autogenous or minor use bacterial, fungal and wart vaccines)

Step(s) of Manufacture: Quality assurance (QA) of raw materials, bacterial fermentation, fungal fermentation, wart tissue extraction, formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat, chemical and filtration), microbiological reduction treatment (heat, filtration and chemical), analysis and testing (physical, chemical, microbiological and sterility testing), storage and release for supply.

Amended Licence Issued: 10 March 2015

**AUSTASIA ANIMAL
PRODUCTS PTY LTD**

ACN: 083 458 566

29 Wongajong Road
FORBES NSW 2871

LICENCE NO: 4090

Product Types: *

- *Category 4:* Premixes and supplements

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

Amended Licence Issued: 13 March 2015

**CCD ANIMAL HEALTH PTY
LTD**

ACN: 151 737 950

Unit 16
84–92 Barnes Street
TAMWORTH NSW 2340

LICENCE NO: 6195

Product Types: *

- *Category 6:* Single step manufacture

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

Amended Licence Issued: 24 March 2015

* 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*

BAXTER HEALTHCARE PTY LTD

ACN: 000 392 781

1 Baxter Drive

OLD TOONGABBIE NSW 2146

LICENCE NO: 1026

Product Types: *

- *Category 1:* Sterile products (liquids)

Step(s) of Manufacture: Formulation including blending, filling, packaging, labelling, sterilisation (heat), analysis and testing (physical, chemical, Limulus Amoebocyte Lysate test [LAL] and microbiological), storage and release for supply.

Amended Licence Issued: 30 March 2015

**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: 31 March 2015

3. LICENCE CANCELLATIONS

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

NATIONAL CHEMICAL PTY LTD

ACN: 077 738 740

262 Evans Road

Salisbury QLD 4107

LICENCE NO: 2155

Date Cancelled: 27 February 2015

G S PACKAGING PTY LTD

ACN: 160 337 011

1/137 Long Street

SMITHFIELD NSW 2164

LICENCE NO: 6185

Date Cancelled: 12 March 2015

* 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*

**ROYAL MELBOURNE
INSTITUTE OF TECHNOLOGY
TRADING AS RMIT
UNIVERSITY**

LICENCE NO: 1060

ABN: 49 781 030 034

Date Cancelled: 24 March 2015

Department of Biotechnology
and Environmental Biology

Level 1, Building 223

RMIT University (Bundoora
Campus)

Plenty Road

BUNDOORA VIC 3083

4. LICENCE SUSPENSIONS

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

Nil

5. REVOCATION OF LICENCE CANCELLATION

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

Nil

6. REVOCATION OF LICENCE SUSPENSION

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

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Section
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4899

Fax: +61 2 6210 4813

Email: mls@apvma.gov.au

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

Amendments to the APVMA MRL Standard

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

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

The APVMA has amended the *MRL Standard* and the changes will have effect 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 2015 (No. 3)*.

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

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

For further information please contact:

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

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: enquiries@apvma.gov.au

Proposal to Amend Standard 1.4.2 of the Australia New Zealand Food Standards Code

In the previous notice, the APVMA gazetted that 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 2015 (No. 3)*) to MRLs into Standard 1.4.2. Maximum Residue Limits of the Australia New Zealand Food Standards Code.

MRLs contained in Standard 1.4.2 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Standard 1.4.2 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 Standard 1.4.2 in the *APVMA Gazette*. The variations will take effect as from the date of that subsequent notice.

DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

Note: The following amendments are in a format that accords with the proposed amending Legislative Instrument which, in turn, has to be consistent with the existing format of Standard 1.4.2 (Maximum Residue Limits) of the *Australia New Zealand Food Standards Code*.

PROPOSED AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2015 (NO. 3))

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 sunseting.

To commence: on gazettal of variation

Standard 1.4.2 of the *Australia New Zealand Food Standards Code* is varied by—

1. omitting from Schedule 1 all entries for the following chemicals with the associated chemical definitions—

Fluopyram	
Commodities of plant origin: Fluopyram	
Commodities of animal origin for enforcement: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram	
Commodities of animal origin for dietary exposure assessment: Sum of fluopyram, 2-(trifluoromethyl) benzamide and the combined residues of <i>N</i> -{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-(trifluoromethyl) benzamide and <i>N</i> -{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-(trifluoromethyl) benzamide, all expressed as fluopyram	

Fluopyram	
Fluopyram	

2. inserting in alphabetical order in Schedule 1—

Fenpyrazamine	
Fenpyrazamine	
Dried grapes (currants, raisins and sultanas)	20
Edible offal (mammalian)	*0.01
Eggs	*0.01
Meat (mammalian)	*0.01
Milks	*0.005
Poultry, edible offal of	*0.01
Poultry meat	*0.01
Table grapes	5
Wine grapes	0.05

Fluopyram	
Commodities of plant origin: Fluopyram	
Commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram	
Almonds	T0.5
Banana	0.1
Cherries	T5
Dried grapes (currants, raisins and sultanas)	15
Edible offal (mammalian)	T0.7
Grapes	2
Hops, dry	100
Meat (mammalian)	T0.05
Milks	T0.2
Pome fruits	T0.5
Stone fruits [except cherries]	T2

3. inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals—

Abamectin	
Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Fruiting vegetables, cucurbits [except cucumber and squash, Summer]	T*0.01
Litchi	T0.05

Azoxystrobin	
Azoxystrobin	
Oats	0.1

Difenoconazole	
Difenoconazole	
Coriander (leaves, stems, roots)	T20

Mandipropamid	
Mandipropamid	
Leafy vegetables	T20

Sulfoxaflor	
Sulfoxaflor	
Persimmon, Japanese	T1

4. omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals—

Abamectin	
Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Melons, except watermelon	T0.02
Watermelon	T0.02

5. omitting from Schedule 1, under the entries for the following chemicals, the maximum residue limit for the food, substituting—

Azoxystrobin	
Azoxystrobin	
Barley	0.2
Wheat	0.1
Cyfluthrin	
Cyfluthrin, sum of isomers	
Litchi	T0.3
Difenoconazole	
Difenoconazole	
Parsley	T20

INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Standard 1.4.2 Maximum Residue Limits of 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 Standard 1.4.2' and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: 6 pm (AEST) 19 May 2015

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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