



**Commonwealth
of Australia**

Gazette

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**AGRICULTURAL AND
VETERINARY CHEMICALS**



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

The *Agricultural and Veterinary Chemicals 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*.

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GENERAL INFORMATION

The *APVMA (Australian Pesticides & Veterinary Medicines Authority) Gazette* is published monthly and contains details of the registration of agricultural and veterinary chemical 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 53(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, web site and subscription

From November 1999, the APVMA is providing the printed version of the *APVMA Gazette* free of charge to APVMA registrants. It is also now freely available on the APVMA web site:

<http://www.apvma.gov.au>

APVMA CONTACTS

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Notice of Registrations

NOTICE OF REGISTRATION OF AGRICULTURAL AND 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.

Agricultural Chemical Products

1. RESTRICTED PRODUCT:

Product Name:
Active Constituent/s:
Applicant Name:
Applicant ACN:
Summary of Use:
Date of Registration:
Label Approval No:

No Entries

2. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS:

Product Name: Green Gold Neem Soluble Concentrate Insecticide
Active Constituent/s: 5 g/L azadiractin A & B present as 50 g/L azadirachta indica extract
Applicant Name: Friendly Ag-Products Pty Ltd
Applicant ACN: 074 088 752
Summary of Use: Control of false wireworm larvae in cotton at planting.
Date of Registration: 23 December 2008
Label Approval No: 51799/5L/0108, 51799/10L/0108, 51799/20L/0108

3. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS:

Product Name: Bioguard Spa Symmetry Sanitiser Tablets
Active Constituent/s: 650 g/kg bromine, 280 g/kg chlorine present as bromo-chloro-dimethylhydantoin
Applicant Name: Chemtura Australia Pty Ltd
Applicant ACN: 005 225 507
Summary of Use: For the control of algae and bacteria in spas and hot tubs
Date of Registration: 12 December 2008
Label Approval No: 62107/750/0608, 62107/2/0608, 62107/20/0608, 62107/22.6/0608

Product Name: Hempel's Antifouling Olympic 86901

Active Constituent/s: 654 g/L copper present as cuprous oxide
Applicant Name: Hempel (Australia) Pty Ltd
Applicant ACN: 004 721 902
Summary of Use: Antifouling for control of marine growth.
Date of Registration: 15 December 2008
Label Approval No: 61970/5BLUE/1108, 61970/5RED/1108, 61970/5BLACK/1108, 61970/10BLACK/1108, 61970/10BLUE/1108, 61970/10BROWN/1108, 61970/10RED/1108

Product Name: WSD Aplhacyper 100 EC Insecticide
Active Constituent/s: 100 g/L alpha-cypermethrin
Applicant Name: Rebop Holdings Pty Ltd T/A Western Stock Distributors
Applicant ACN: 009 372 525
Summary of Use: For the control of certain insect pests in a range of crops.
Date of Registration: 15 December 2008
Label Approval No: 62157/20L/0808, 62157/110L/0808, 62157/200L/0808, 62157/1000L/0808, 62157/0808

Product Name: Fyfanon 1000 EC Insecticide
Active Constituent/s: 1000 g/L maldison
Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169
Summary of Use: For the control of insect pests in a range of crops.
Date of Registration: 15 December 2008
Label Approval No: 62194/5L/1008, 62194/20L/1008, 62194/1008

Product Name: Pure Blue Heavy Duty Blackspot Remover & Algae Killer
Active Constituent/s: 900 g/kg available chlorine (Cl) present as trichloroisocyanuric acid
Applicant Name: Pool Products Of Australia Pty Ltd
Applicant ACN: 085 385 511
Summary of Use: For the control of algae and bacteria in swimming pools and spas.
Date of Registration: 16 December 2008
Label Approval No: 62903/1kg/0608, 62903/2kg/0608, 62903/10kg/0608

Product Name: AW Bromo 200 Herbicide
Active Constituent/s: 200 g/L bromoxynil present as the n-octanoyl ester
Applicant Name: Agri West Pty Limited
Applicant ACN: 108 899 181
Summary of Use: For the control of a wide variety of weeds in various situations.
Date of Registration: 17 December 2008
Label Approval No: 63130/5L/0808, 63130/20L/0808, 63130/110L/0808, 63130/200L/0808, 63130/1000L/0808, 63130/0808

Product Name: Heliocide Biological Insecticide

Active Constituent/s: 2 x 10⁹/mL polyhedral occlusion bodies (OBS) of the nucleopolyhedrosis virus of *Helicoverpa armigera* (native isolate)

Applicant Name: Bioflexus Pty Ltd

Applicant ACN: 113 715 950

Summary of Use: For the integrated control of *Helicoverpa spp* in chickpeas, sorghum, cotton, lettuce, maize and sweetcorn.

Date of Registration: 17 December 2008

Label Approval No: 60455/1/1107, 60455/5/1107, 60455/10/1107, 60455/20/1107, 60455/50/1107, 60455/100/1107

Product Name: Amgrow Erazo Biaquatic Total Weed Killer

Active Constituent/s: 360 g/L glyphosate present as the isopropylamine salt

Applicant Name: Ecofertiliser Pty Ltd

Applicant ACN: 100 684 786

Summary of Use: For the use in gardens and aquatic environments for the control of broad range of weeds.

Date of Registration: 17 December 2008

Label Approval No: 63061/1L/1108, 63061/2.5L/1108

Product Name: AW Muzzle Herbicide

Active Constituent/s: 500 g/L mcpa present as the dimethylamine salt.

Applicant Name: Agri West Pty Limited

Applicant ACN: 108 899 181

Summary of Use: For the control of broadleaf weeds in cereals, linseed, pastures, sugar cane and turf.

Date of Registration: 17 December 2008

Label Approval No: 63227/5L/0708, 63227/20L/0708, 63227/200L/0708, 63227/0708

Product Name: AW Akwit 900 WG Herbicide

Active Constituent/s: 900 g/kg atrazine

Applicant Name: Agri West Pty Limited

Applicant ACN: 108 899 181

Summary of Use: For the control of annual grasses and broadleaf weeds in a range of broadacre crops, fallow areas and tree plantations.

Date of Registration: 17 December 2008

Label Approval No: 63442/10kg/1008, 63442/15kg/1008, 63442/1008

Product Name: Whitestar Clopyralid 300 Herbicide

Active Constituent/s: 300 g/L clopyralid.

Applicant Name: Agricultural Product Services Pty Ltd

Applicant ACN: 092 350 279

Summary of Use: For use in wheat, barley, triticale, oats, pastures, canola, fallow land, forests and industrial situations for the control of a wide range of broadleaf weeds.

Date of Registration: 19 December 2008

Label Approval No: 63461/1008, 63461/5L/1008, 63461/20L/1008

Product Name: Crop Care Aura Herbicide

Active Constituent/s: 200 g/L proflaxydim.

Applicant Name: Crop Care Australasia Pty Ltd

Applicant ACN: 061 362 347

Summary of Use: For the post-emergent control of

barnyard grasses and silvertop grass in rice.

Date of Registration: 22 December 2008

Label Approval No: 63432/5-20L/1008, 63432/1008

Product Name: Kenso Agcare Ken-Star 450 Herbicide

Active Constituent/s: 450 g/L 2,4-D present as the isopropylamine salt

Applicant Name: Kenso Corporation (M) Sdn Bhd

Summary of Use: For the control of emerged broadleaf weeds prior to sowing crops and pastures in conservation tillage situations and for selective weed control in crops.

Date of Registration: 22 December 2008

Label Approval No: 61893/20L/0808, 61893/110L/0808, 61893/200L/0808, 61893/1000L/0808, 61893/0808

Product Name: Rygel Dasher Spray Adjuvant

Active Constituent/s: 700 g/L ethyl and methyl esters of vegetable oil, 116 g/L non-ionic surfactants

Applicant Name: Rygel Australia Pty Ltd

Applicant ACN: 106 839 007

Summary of Use: For use in various situations to assist the effectiveness of herbicides and other agricultural chemicals.

Date of Registration: 22 December 2008

Label Approval No: 63550/10L/1108, 63550/20L/1108, 63550/110L/1108, 63550/200L/1108, 63550/1108

Product Name: Country Ethephon 720 Growth Regulator

Active Constituent/s: 720 g/L ethephon

Applicant Name: Accensi Pty Ltd

Applicant ACN: 079 875 184

Summary of Use: For accelerated boll opening, defoliation and pre-conditioning before defoliation of cotton.

Date of Registration: 22 December 2008

Label Approval No: 63477/5-1000L/1108, 63477/1108

Product Name: Kendon Knockout 360 Herbicide

Active Constituent/s: 360 g/L glyphosate present as the isopropylamine salt

Applicant Name: Kendon Plant Care Pty Ltd

Applicant ACN: 065 737 948

Summary of Use: Product for the control of a broad range of annual and perennial weeds.

Date of Registration: 23 December 2008

Label Approval No: 62841/0508, 62841/1L/0508, 62841/5L/0508, 62841/10L/0508, 62841/15L/0508, 62841/20L/0508, 62841/200L/0508

Product Name: AW Stoush 900WG Herbicide

Active Constituent/s: 900 g/kg simazine

Applicant Name: Agri West Pty Limited

Applicant ACN: 108 899 181

Summary of Use: For use in fruit and vegetable crops, triazine tolerant canola, field crops, ornamentals, forestry and some non-crop situations for control of a range of grass and broadleaf weeds.

Date of Registration: 23 December 2008

Label Approval No: 63273/10kg/0708,
63273/15kg/0708, 63273/0708

Product Name: Spectra 2,4-D Amine 625 Herbicide
Active Constituent/s: 625g/L 2,4-d present as the dimethylamine and diethanolamine salts.

Applicant Name: Spectra Pacific (Australia) Pty Ltd
Applicant ACN: 127 711 479

Summary of Use: For the control of broadleaved weeds in fallow before direct drilling or sowing of cereal and pastures and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas.

Date of Registration: 23 December 2008

Label Approval No: 63397/20L/0908,
63397/1000L/0908, 63397/0908

Product Name: Country Amine 625 Dual Salt Selective Herbicide

Active Constituent/s: 625 g/L 2,4-D present as the dimethylamine and diethanolamine salts

Applicant Name: Accensi Pty Ltd

Applicant ACN: 079 875 184

Summary of Use: For use in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas for the control of broadleaf weeds.

Date of Registration: 24 December 2008

Label Approval No: 63495/5-1000L/1108,
63495/1108

Product Name: Spa World Lithium Sanitiser

Active Constituent/s: 350 g/kg available chlorine (Cl) presented as lithium hypochlorite

Applicant Name: Pool & Spa Poppits Pty Ltd

Applicant ACN: 101 519 439

Summary of Use: For the control of algae and bacteria in swimming pools.

Date of Registration: 5 January 2009

Label Approval No: 63270/500g/0906,
63270/1kg/0906, 63270/2kg/0906

Product Name: Cislin 25 Professional Insecticide

Active Constituent/s: 25 g/L deltamethrin

Applicant Name: Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of Use: For the control of a range of insect pests in commercial, industrial and domestic situations.

Date of Registration: 5 January 2009

Label Approval No: 62147/1/1008, 62147/1L/1008,
62147/5/1008, 62147/5L/1008

Product Name: Spectra Trifluralin 480 Herbicide

Active Constituent/s: 480 g/L trifluralin

Applicant Name: Spectra Pacific (Australia) Pty Ltd

Applicant ACN: 127 711 479

Summary of Use: For the control of broadleaf weeds and annual grasses in certain horticultural and agricultural crops.

Date of Registration: 5 January 2009

Label Approval No: 63438/1108, 63438/20L/1108

Product Name: Ethin Growth Regulator

Active Constituent/s: 480 g/L ethephon.

Applicant Name: Agrinova New Zealand Limited
T/A Gro-Chem

Summary of Use: For the crop thinning, loosening or ripening of various crops.

Date of Registration: 6 January 2009

Label Approval No: 62058/1-5/0808, 62058/20-
900/0808, 62058/0808

Product Name: Agricrop Spraybuff 700 Surfactant

Active Constituent/s: 350 g/L soyal phospholipids,
350 g/L propionic acid

Applicant Name: Agricrop Pty Ltd

Applicant ACN: 100 473 309

Summary of Use: For reduction of alkaline hydrolysis of dimethoate, to assist with uptake of foliar fertilizer and to assist in management of spray droplet size.

Date of Registration: 6 January 2009

Label Approval No: 63019/5L-1000L/0808

Product Name: Imtrade Smash 625 Selective Herbicide

Active Constituent/s: 625 g/L 2,4-D present as the dimethylamine and diethanolamine salts.

Applicant Name: Imtrade Australia Pty Ltd

Applicant ACN: 090 151 134

Summary of Use: For the control of broadleaved weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas.

Date of Registration: 7 January 2009

Label Approval No: 63282/5/1008, 63282/10/1008,
63282/20/1008, 63282/110/1008, 63282/200/1008,
63282/1000/1008, 63282/1008

Product Name: Country Quizalofop-P-Ethyl Herbicide

Active Constituent/s: 99.5 g/L quizalofop-P-ethyl

Applicant Name: Accensi Pty Ltd

Applicant ACN: 079 875 184

Summary of Use: For use in broadleaf crops for the control of certain grass weeds.

Date of Registration: 7 January 2009

Label Approval No: 63496/5-1000L/1208,
63496/1208

Product Name: Country Diuron 500 SC Herbicide

Active Constituent/s: 500 g/L diuron

Applicant Name: Accensi Pty Ltd

Applicant ACN: 079 875 184

Summary of Use: For the control of weeds in cereals, bananas, citrus, cotton, lucerne, pineapples, sugar cane, vineyards, rights-of-way, commercial and industrial areas.

Date of Registration: 8 January 2009

Label Approval No: 63621/5-1000L/1108,
63621/1108

Product Name: Country Dimethoate 400 Systemic Insecticide

Active Constituent/s: 400 g/L dimethoate

Applicant Name: Accensi Pty Ltd

Applicant ACN: 079 875 184

Summary of Use: For use on some fruit, vegetables,

citrus, pastures, cotton, lucerne, peanuts and ornamentals to control a wide range of insect pests.

Date of Registration: 8 January 2009

Label Approval No: 63470/1208, 63470/5-1000L/1208

Product Name: Spectra Paraquat 250 Herbicide
Active Constituent/s: 250 g/L paraquat present as paraquat dichloride

Applicant Name: Spectra Pacific (Australia) Pty Ltd

Applicant ACN: 127 711 479

Summary of Use: For control of a range of grasses and broadleaf weeds in various crop, pasture and non-agricultural situations.

Date of Registration: 8 January 2009

Label Approval No: 63521/20L/1008, 63521/1000L/1008, 63521/1008

Product Name: Conquest Knockout Blow 510 Herbicide

Active Constituent/s: 510 g/L glyphosate present as the isopropylamine salt.

Applicant Name: Conquest Agrochemicals Pty Ltd

Applicant ACN: 098 814 932

Summary of Use: For the control of annual and perennial weeds.

Date of Registration: 13 January 2009

Label Approval No: 63409/0908, 63409/20/0908, 63409/110/0908, 63409/200/0908, 63409/220/0908, 63409/1000/0908

Product Name: Vibral Herbicide Spray Adjuvant

Active Constituent/s: 432 g/L mineral oil

Applicant Name: SST Australia Pty Ltd

Applicant ACN: 052 845 833

Summary of Use: For use as an adjuvant with specific herbicides.

Date of Registration: 13 January 2009

Label Approval No: 63144/5L/0908, 63144/10L/0908, 63144/20L/0908, 63144/110L/0908, 63144/200L/0908

Product Name: Wadlan 480 Herbicide

Active Constituent/s: 480 g/L trifluralin

Applicant Name: Wadlong International Enterprise (Australia) Pty Ltd

Applicant ACN: 123 682 075

Summary of Use: For the pre-emergence control of annual grasses and certain broadleaf weeds in horticultural and agricultural crops.

Date of Registration: 13 January 2009

Label Approval No: 62437/20/1007, 62437/110/1007, 62437/200/1007, 62437/1000/1007, 62437/1007

Product Name: Serial 450 Herbicide

Active Constituent/s: 450 g/L glyphosate present as the isopropylamine salt

Applicant Name: Roundwell Ltd

Summary of Use: For use in various situations for the control of non-selective annual and perennial weeds.

Date of Registration: 14 January 2009

Label Approval No: 63443/5L/1008,

63443/10L/1008, 63443/20L/1008, 63443/110L/1008, 63443/200L/1008, 63443/1000L/1008, 63443/1008

Product Name: Mortein Do-It-Yourself Odourless High Performance Cockroach Killer

Active Constituent/s: 0.30 g/kg imiprothrin, 1.50 g/kg cypermethrin

Applicant Name: Reckitt Benckiser (Australia) Pty Limited

Applicant ACN: 003 274 655

Summary of Use: For protection against cockroaches, ants, fleas, silverfish, spiders, clothes moths, carpet beetles and bedbugs.

Date of Registration: 15 January 2009

Label Approval No: 62989/200g/0708, 62989/250g/0708, 62989/300g/0708, 62989/350g/0708

4. LISTED REGISTERED CHEMICAL PRODUCTS

Product Name:

Active Constituent/s:

Applicant Name:

Applicant ACN:

Summary of Use:

Date of Registration:

Product No:

No Entries

5. VARIATIONS

Product Name: Ospray Sparta 300 SL Herbicide

Applicant Name: Ospray Pty Ltd

Applicant ACN: 110 199 169

Summary of Variation: to change product name from "Tradelands Clopyralid 300 Herbicide" to "Ospray Sparta 300 SL Herbicide"

Date of Variation: 18 December 2008

Label Approval No: 61255/1L/0808, 61255/5L/0808, 61255/10L/0808, 61255/20L/0808, 61255/1LL/0808, 61255/0808

Product Name: Genfarm Cyper Plus 250 Insecticide

Applicant Name: Genfarm Crop Protection Pty Ltd

Applicant ACN: 115 327 378

Summary of Variation: Variation of label approval to change the product name from "Genfarm Boom Plus Insecticide" to "Genfarm Cyper Plus 250 Insecticide".

Date of Variation: 6 January 2009

Label Approval No: 61607/0808, 61607/20/0808, 61607/110/0808

Product Name: Allfire Trifluralin 480 Herbicide

Applicant Name: Agvantage Pty Ltd

Applicant ACN: 097 970 280

Summary of Variation: Variation of label approval to amend use rates as per APVMA request.

Date of Variation: 7 January 2009

Label Approval No: 56711/0708, 56711/1000L/0708, 56711/20L/0708,

56711/110L/0708, 56711/200L/0708,
56711/BULK/0708

Product Name: Home Brand Woolworths Pool
Tablets Pool Sanitiser

Applicant Name: Pool Resources Pty Limited

Applicant ACN: 062 201 441

Summary of Variation: Variation to registration and label approval to change product name from "Home Brand Pool Tablets Pool Sanitiser Money Back Guaranteed Smart Choice Quality Tested Low Price" to "Home Brand Woolworths Pool Tablets Pool Sanitiser".

Date of Variation: 8 January 2009

Label Approval No: 61340/2kg/1008

Product Name: Supracide 400 Emulsifiable
Concentrate Insecticide

Applicant Name: Syngenta Crop Protection Pty
Limited

Applicant ACN: 002 933 717

Summary of Variation: Variation to label approval to add additional restraints and critical comments for mangoes, amend instructions for turf, and other label updates.

Date of Variation: 8 January 2009

Label Approval No: 33041/5/1108, 33041/20/1108

Product Name: Aqueco 450 Herbicide

Applicant Name: Sipcam Pacific Australia Pty
Limited

Applicant ACN: 073 176 888

Summary of Variation: Change of product name from "Summit Glyphosate 450 Aqueco Herbicide" to "Aqueco 450 Herbicide".

Date of Variation: 9 January 2009

Label Approval No: 58820/20L/1208,
58820/110L/1208, 58820/1000L/1208, 58820/1208

Product Name: Home Brand Woolworths Pool
Chlorine Pool Sanitiser

Applicant Name: Pool Resources Pty Limited

Applicant ACN: 062 201 441

Summary of Variation: Change of product name from "Home Brand Pool Chlorine Pool Sanitiser Money Back Guaranteed Smart Choice Quality Tested Low Price" to "Home Brand Woolworths Pool Chlorine Pool Sanitiser".

Date of Variation: 12 January 2009

Label Approval No: 61338/2kg/1008,
61338/4kg/1008, 61338/10kg/1008

Product Name: Repellex Personal Insect Repellent
Tropical Strength 6 Hour Protection

Applicant Name: Reckitt Benckiser (Australia) Pty
Limited

Applicant ACN: 003 274 655

Summary of Variation: Change of product name from "Repellex 6 Hour Protection Personal Insect Repellent Tropical Strength" to "Repellex Personal Insect Repellent Tropical Strength 6 Hour Protection".

Date of Variation: 13 January 2009

Label Approval No: 61298/150g/1108

Product Name: Spray-Plant 250 Herbicide

Applicant Name: Sipcam Pacific Australia Pty Ltd

Applicant ACN: 073 176 888

Summary of Variation: Variation of registration to change product name from "Summit Spray-Plant 250 Herbicide" to "Spray-Plant 250 Herbicide" and minor changes to label including the registrant details.

Date of Variation: 14 January 2009

Label Approval No: 59098/20/1208,
59098/110/1208, 59098/1000/1208, 59098/1208

Product Name: Soccer 750 WG Herbicide

Applicant Name: Bayer Cropscience Pty Ltd

Applicant ACN: 000 226 022

Summary of Variation: To amend the application rate for Sugarcane (plant cane) and to add relevant statement.

Date of Variation: 15 January 2009

Label Approval No: 63020/5/1108, 63020/1108

Product Name: Targabolt 200 Herbicide

Applicant Name: Sipcam Pacific Australia Pty
Limited

Applicant ACN: 073 176 888

Summary of Variation: Change of product name from "Targabolt Herbicide" to "Targabolt 200 Herbicide".

Date of Variation: 15 January 2009

Label Approval No: 61862/20L/1208, 61862/1208

6. RESTRICTED PRODUCT VARIATION

Product Name:

Applicant Name:

Applicant ACN:

Summary of Variation:

Date of Variation:

Label Approval No:

No Entries

**NOTICE OF REGISTRATION OF
AGRICULTURAL AND 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.

Veterinary Chemical Products

1. RESTRICTED PRODUCT:

Product Name:
Active Constituent/s:
Applicant Name:
Applicant ACN:
Summary of Use:
Date of Registration:
Label Approval No:

No Entries

**2. VETERINARY PRODUCTS BASED ON
NEW ACTIVE CONSTITUENTS:**

Product Name:
Active Constituent/s:
Applicant Name:
Applicant ACN:
Summary of Use:
Date of Registration:
Label Approval No:

No Entries

**3. VETERINARY PRODUCTS BASED ON
EXISTING ACTIVE CONSTITUENTS:**

Product Name: Vitapet Pride Mite & Lice Bird Spray
Active Constituent/s: 6.25 g/L piperonyl butoxide, 1.25 g/L permethrin (25:75::cis:trans), 20 mg/L methoprene.
Applicant Name: Masterpet Australia Pty Limited
Applicant ACN: 000 333 353
Summary of Use: For the control of mites and lice in ornamental caged birds and their environments.
Date of Registration: 22 December 2008
Label Approval No: 63013/125mL/1108, 63013/250mL/1108

Product Name: Paracox-5 Anticoccidial Vaccine For Chickens
Active Constituent/s: Each dose contains: ≥ 500 oocysts *Eimeria acervulina* HP, ≥ 200 oocysts *Eimeria maxima* CP, ≥ 100 oocysts *Eimeria maxima* MFP, ≥ 1000 . oocysts *Eimeria mitis* HP, ≥ 500 oocysts *Eimeria tenella* HP
Applicant Name: Schering-Plough Pty Limited

Applicant ACN: 000 235 245
Summary of Use: Aids in control of coccidiosis in broiler chickens caused by *Eimeria acervulina*, *Eimeria Maxima* CP, *Eimeria maxima* MFP, *Eimeria mitis* and *Eimeria tenella*.
Date of Registration: 7 January 2009
Label Approval No: 62055/4mL/1208, 62055/20mL/1208, 62055/5X4mL/1208, 62055/5X20mL/1208

Product Name: Vitapet Pride Scaly Face & Leg Treatment
Active Constituent/s: 75 g/L benzyl benzoate, 790 g/L liquid paraffin
Applicant Name: Masterpet Australia Pty Limited
Applicant ACN: 000 333 353
Summary of Use: The product is an external liquid application for use against Scaly Face and Leg in caged birds.
Date of Registration: 12 January 2009
Label Approval No: 63014/25mL/1208

**4. LISTED REGISTERED CHEMICAL
PRODUCTS**

Product Name:
Active Constituent/s:
Applicant Name:
Applicant ACN:
Summary of Use:
Date of Registration:
Product No:

No Entries

5. VARIATIONS

Product Name: Obesity Management Feline
Applicant Name: Royal Canin Australia Pty Ltd
Applicant ACN: 092 020 178
Summary of Variation: Variation to registration particulars to change name from "Obesity S/O Management" to "Obesity Management Feline"
Date of Variation: 16 December 2008
Label Approval No: 58593/100g/1008, 58593/12x100g/1008

Product Name: Obesity Management Canine
Applicant Name: Royal Canin Australia Pty Ltd
Applicant ACN: 092 020 178
Summary of Variation: Variation to registration particulars to change name from "Obesity Management" to "Obesity management Canine"
Date of Variation: 17 December 2008
Label Approval No: 58573/410g/1008

Product Name: Interceptor Spectrum Tasty Chews For Very Small Dogs
Applicant Name: Novartis Animal Health Australasia Pty Limited
Applicant ACN: 076 745 198
Summary of Variation: Approval of name change from "Interceptor Spectrum Ultra Chews For Very

Small Dogs” to “Interceptor Spectrum Tasty Chews For Very Small Dogs”.

Date of Variation: 19 December 2008

Label Approval No: 60304/1T/0808, 60304/3T/0808, 60304/6T/0808, 60304/0808

Product Name: Home Brand Woolworths Heartworm Tablets 200mg

Applicant Name: Aristopet Pty Ltd

Applicant ACN: 009 697 152

Summary of Variation: Change Of product name from “Home Brand Heartworm Tablets 200mg” to “Home Brand Woolworths Heartworm Tablets 200mg”.

Date of Variation: 6 January 2009

Label Approval No: 46396/100 Tabs/1208

Product Name: Penethaject Antibiotic Injection

Applicant Name: Bomac Animal Health Pty Limited

Applicant ACN: 084 248 206

Summary of Variation: to change name from "Mastinject Ester Of Benzyl Penicillin for Intramuscular Injection" to "Penethaject Antibiotic Injection" and variation to label approval.

Date of Variation: 6 January 2009

Label Approval No: 59193/10g/1108, 59193/30mL/1108, 59193/5g/1108, 59193/15mL/1108, 59193/10x5g/1108, 59193/10x15mL/1108, 59193/10x10g/1108, 59193/10x30mL/1108

Product Name: Interceptor Spectrum Tasty Chews For Small Dogs

Applicant Name: Novartis Animal Health Australasia Pty Limited

Applicant ACN: 076 745 198

Summary of Variation: Approval of change to product name from "Interceptor Spectrum Ultra Chews for Small Dogs" to " Interceptor Spectrum Tasty Chews for Small Dogs", additional pack sizes (1&3 chewables) and change label layout.

Date of Variation: 7 January 2009

Label Approval No: 60303/0808, 60303/1T/0808, 60303/3T/0808, 60303/6T/0808

Product Name: Interceptor Spectrum Tasty Chews For Medium Dogs

Applicant Name: Novartis Animal Health Australasia Pty Limited

Applicant ACN: 076 745 198

Summary of Variation: Approval of change to product name from "Interceptor Spectrum Ultra Chews for Medium Dogs" to "Interceptor Spectrum Tasty Chews for Medium Dogs", additional pack sizes (1&3 chewable) and change label layout.

Date of Variation: 8 January 2009

Label Approval No: 60302/0808, 60302/1T/0808, 60302/3T/0808, 60302/6T/0808

Product Name: Interceptor Spectrum Tasty Chews For Large Dogs

Applicant Name: Novartis Animal Health Australasia Pty Limited

Applicant ACN: 076 745 198

Summary of Variation: Approval of change to product name from "Interceptor Spectrum Ultra Chews for Large Dogs" to "Interceptor Spectrum Tasty Chews for Large Dogs", additional pack sizes (1&3 chewables) and change to label layout.

Date of Variation: 8 January 2009

Label Approval No: 60301/0808, 60301/1T/0808, 60301/3T/0808, 60301/6T/0808

Product Name: Elanco AF0342 Rumensin 200 Monensin Sodium

Applicant Name: Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd

Applicant ACN: 000 233 992

Summary of Variation: Variation of registration to include claim for improved weight gain and feed efficiency in pasture cattle.

Date of Variation: 13 January 2009

Label Approval No: 46885/25kg/1108

Product Name: Elanco AF0510 Monteban 100 Narasin Premix

Applicant Name: Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd

Applicant ACN: 000 233 992

Summary of Variation: Variation of registration to include an additional manufacturing site, minor formulation change, to add the claim for improved feed conversion efficiency in lot fed cattle and variation to label approval for reorganization of restraints, contradictions, precautions and safety directions to the registered label.

Date of Variation: 13 January 2009

Label Approval No: 36784/25kg/1108

6.RESTRICTED PRODUCT VARIATION

Product Name:

Applicant Name:

Applicant ACN:

Summary of Variation:

Date of Variation:

Label Approval No:

No Entries

Notice – New Agricultural & Veterinary Active Constituents

NOTICE

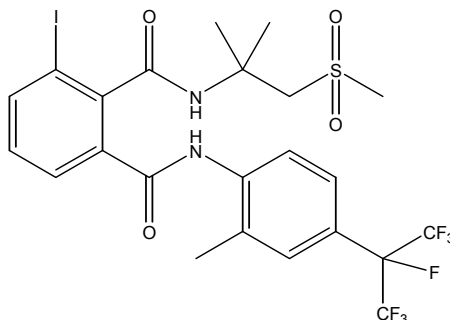
Flubendiamide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, Flubendiamide. Flubendiamide is the first member of a new chemical class of insecticides, the phthalic acid diamides (1,2-benzenedicarboxamides), which is proposed for use against a range of lepidopteran pests in brassica crops.

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for Flubendiamide approval should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to the matters that the APVMA is required to take into account in deciding whether to grant the approval. Comments must be received by the APVMA within 28 days of the date of this Gazette.

Particulars of Active Constituents

Common Name:	Flubendiamide
IUPAC Name:	3-iodo- <i>N</i> ² -(2-mesyl-1,1-dimethylethyl)- <i>N</i> -{4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]- <i>o</i> -tolyl}phthalamide
CAS Name:	<i>N</i> ² -[1,1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo- <i>N</i> ¹ -[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide
CAS Number:	272451-65-7
Molecular Formula:	C ₂₃ H ₂₂ F ₇ IN ₂ O ₄ S
Molecular Weight:	682.4 g/mol
Manufacturer's Codes:	NNI-0001
Structure:	



Chemical family:	Phthalic acid diamide
Mode of Action:	Lepidopteran larvicidal activity as an orally ingested toxicant by targeting and disrupting the Ca ²⁺ balance

Summary of the APVMA's Evaluation of Flubendiamide

The Chemistry Section of the APVMA has evaluated the chemistry aspects of Flubendiamide 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 Flubendiamide active constituent:

Constituent	Specification	Level
Flubendiamide	Flubendiamide	Not less than 960 g/kg

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

The Office of Chemical Safety of the Department of Health and Ageing has considered the toxicological aspects of Flubendiamide, and advised that there are no toxicological objections to the approval of this chemical.

An acceptable daily intake (ADI) was established at 0.01 mg/kg bw/day, based on a No Observed Effect Level (NOEL) of 1 mg/kg bw/day in a one year dietary rat study and using a 100-fold safety factor. An Acute Reference Dose (ARfD) has not been set as Flubendiamide did not display significant toxicity following a single dose in any study, was not a developmental toxicant, and is therefore unlikely to pose a human health risk from acute exposure.

The National Drugs and Poisons Schedule Committee (NDPSC) has included Flubendiamide in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

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

Written submissions on the APVMA's proposal to grant approval for Flubendiamide should be addressed in writing to:

Dr Paul Sethi
Principal Chemist
Chemistry Section
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4821
Fax: (02) 6210 4840

Notice – New Agricultural & Veterinary Chemical Products

NOTICE

Flubendiamide

in the products: **BELT 480 SC INSECTICIDE & BELT 240 WG INSECTICIDE**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd for registration of two new products containing the active constituent Flubendiamide. The products are *BELT 480 SC INSECTICIDE (BELT 480)* & *BELT 240 WG INSECTICIDE (BELT 240)*. Both products are proposed for use as foliar applied insecticide in brassica vegetables.

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 applications for registration should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the applications. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Application

Proposed product names:	BELT 480 SC INSECTICIDE BELT 240 WG INSECTICIDE
Applicant company:	Bayer CropScience Pty Ltd
Name of active constituent:	Flubendiamide
Signal heading:	Schedule 5
Statement of claims:	For the control of diamondback moth, cabbage white butterfly, cluster caterpillar, soybean looper and heliothis in brassica vegetables
Pack sizes:	1L & 5L (SC), 2kg & 10kg (WG)
Withholding period:	
<i>Harvesting:</i>	DO NOT harvest for 3 days after application.
<i>Grazing:</i>	DO NOT use on brassicas grown for forage or fodder. DO NOT graze treated brassica crops.

Summary of the APVMA's evaluation of *BELT 480* & *BELT 240* 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 *BELT 480* & *BELT 240* would not be an undue hazard to the safety of people exposed to them during their handling and use.

The Office of Chemical Safety (OCS) has conducted an occupational risk assessment on *BELT 480* & *BELT 240* and concluded that they can be used safely. The primary acute hazard arising from the acute toxicity studies conducted on both products was slight eye irritation and no personal protective equipment is indicated for this level of hazard.

Both products will be formulated overseas and repackaging will not be required in Australia.

Based on product toxicology information, neither **BELT 480** nor **BELT 240** is classified as a hazardous substance in accordance with NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004).

The APVMA has considered the OCS assessment and accepts their findings and recommendations.

- (ii) The APVMA is satisfied that the proposed use of **BELT 480 & BELT 240** will not be an undue hazard to the safety of people using anything containing their residues. Residue data was assessed by the APVMA and Maximum Residue Limits (MRLs) and Withholding Periods (WHPs) were set for Flubendiamide when used on brassica vegetables.
- (iii) The APVMA is satisfied that the proposed use of the **BELT 480 & BELT 240** containing the active Flubendiamide is not likely to be harmful to human beings if used according to the product label directions.

The active constituent has been evaluated and approved and the product is scheduled as 5. The appropriate Signal Heading is on the label. First Aid instructions and Safety Directions for Flubendiamide have been recommended by the OCS in the Commonwealth Department of Health and Ageing and have been included on the label.

The data submitted were complete and comprehensive, and included the full battery of studies currently required for registration purposes. They included toxicokinetics and acute, short-term, sub-chronic, and chronic studies, as well as some mechanistic and neurotoxicity studies. Studies were well conducted and conformed with current test guidelines and protocols. Additionally, a series of acute and genotoxicity studies were provided for the two products and the main metabolites. The scientific and regulatory quality of the toxicology database is high and is considered sufficient to clearly define the toxicity of Flubendiamide.

The APVMA has considered the OCS assessment and accepts their findings and recommendations on this criterion.

- (iv) The APVMA is satisfied that the proposed use of the new products **BELT 480 & BELT 240** containing the new active constituent Flubendiamide, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The Department of the Environment, Water, Heritage and the Arts (DEWHA) has assessed data in support of the proposed uses and has concluded that the risks to the environment from those uses are acceptable.

Flubendiamide degrades extremely slowly in water/sediment systems with the majority of the material moving to the sediment where it persists over time. Dissipation, rather than degradation, is the major route of dispersion. Soil metabolism showed limited degradation occurred with the projected soil half-lives well above a year. Field dissipation studies confirm that Flubendiamide degrades only slowly with the dissipation slowing markedly over time. However, Flubendiamide is only slightly bioaccumulative.

Flubendiamide is not expected to be toxic to birds, mammals, fish or aquatic and terrestrial plants. Terrestrial invertebrates were generally insensitive to Flubendiamide. Aquatic invertebrates are the most sensitive group of organisms, with daphnids sensitive to acute and chronic exposure to the formulated products but not affected by pure Flubendiamide,

implying that toxicity effects are not necessarily attributable to the active constituent.

There is unlikely to be unacceptable aquatic risk as a result of spray drift from the proposed ground application as the proposed labels specify a spray drift buffer. The proposed labels contain drift warning statements, adherence to which is expected to result in acceptable aquatic risk.

The APVMA has considered the findings of the DEWHA assessment and accepts these conclusions.

- (v) The APVMA is considering whether the proposed use of Flubendiamide would not adversely affect trade between Australia and places outside Australia. Quantifiable residues of Flubendiamide are likely to occur in Brassicas when **BELT 480** and **BELT 240** Insecticides are used as directed. This creates a potential risk to trade as there are currently no established overseas MRLs for Flubendiamide. Comments are sought on the potential for **BELT 480** and **BELT 240** Insecticides to unduly prejudice Australian export trade when they are used on Brassica crops to control diamondback moth, cabbage white butterfly, cluster caterpillar, heliothis and soybean looper.
- (vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:
- It is satisfied the data from trials supporting the efficacy of **BELT 480** and **BELT 240** adequately demonstrates that under local conditions this product will be effective for the proposed uses.

Public Release Summary

A Public Release Summary of the evaluation is available by contacting Colin McCormack on telephone (02) 6210 4748. Written submissions on the APVMA's proposal to grant the application for registration should be addressed in writing to:

Pat Robinson
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4756
Fax: (02) 6210 4776
Email: pat.robinson@apvma.gov.au

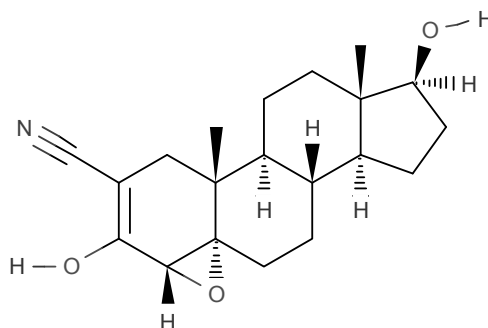
NOTICE**Trilostane****in the products: Vetoryl 20 mg Capsules, Vetoryl 60 mg Capsules and Vetoryl 30 mg Capsules**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it applications from Dermcare-Vet Pty Ltd for approval of the active constituent trilostane and registration of products containing the active constituent trilostane. The products are VETORYL 120 MG CAPSULES, VETORYL 60 MG CAPSULES and VETORYL 30 MG CAPSULES. The products are for use on dogs.

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 applications for active constituent approval and registration of the products should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Active Constituent

Chemical Name:	4 α ,5 α -epoxy-17 β -hydroxy-3-oxo-androstane-2 α -carbonitrile
Manufacturer's Code:	WIN 24540
CAS No:	13647-35-3
Molecular Formula:	C ₂₀ H ₂₇ NO ₃
Molecular Weight:	329.44
Structure:	



Chemical Family:	Steroid
Mode of Action:	Competitive inhibition of the enzyme 3-beta hydroxysteroid dehydrogenase at the level of the adrenal gland to block the normal steroidogenesis pathway of pregnenolone to progesterone to cortisol, aldosterone, and androstenedione.

Summary of the APVMA's Evaluation of Active Constituent Trilostane

The Chemistry Section of the APVMA has evaluated the chemistry aspects of the active constituent trilostane, (including the physico-chemical, spectral, manufacturing and quality control aspects, impurity formation, Specification/Declaration of Composition, batch analysis data, analytical methods and packAgeing information) and found them to be acceptable.

The Office of Chemical Safety in the Commonwealth Department of Health and Ageing has considered the toxicological aspects of trilostane and advised that there are no toxicological objections to the approval of this chemical.

Since trilostane is not intended for use in food production, an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) are not considered necessary.

The National Drugs and Poisons Schedule Committee (NDPSC) has included trilostane into Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

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

Particulars of Products

Proposed products' names:	VETORYL 120 MG CAPSULES VETORYL 60 MG CAPSULES VETORYL 30 MG CAPSULES
Applicant company:	Dermcare-Vet Pty Ltd
Name of active constituent:	Trilostane
Signal heading:	Schedule 4 Prescription Animal Remedy
Statement of claims:	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's syndrome) in dogs
Pack sizes:	30 capsules
Withholding period:	Not applicable

Summary of the APVMA's evaluation of VETORYL 120 MG CAPSULES, VETORYL 60 MG CAPSULES AND VETORYL 30 MG CAPSULES 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 applications 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 VETORYL 120 MG CAPSULES, VETORYL 60 MG CAPSULES and VETORYL 30 MG CAPSULES would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Commonwealth Department of Health and Ageing has conducted a risk assessment on the human toxicological aspects and occupational health and safety aspects of these applications.

The products will be formulated overseas and imported fully-packaged into Australia. Public exposure to trilostane would occur only when handling tablets for administration to dogs under veterinary prescription or accidental ingestion of capsules. Trilostane has low acute oral toxicity and expected to be of low acute inhalational and dermal toxicity. OCS advised the APVMA that there are no objections to the approval of trilostane and the registration of the products from a toxicological perspective. OCS advised the APVMA that use of the products would not be an undue hazard to the safety of people exposed to it during its handling and use and recommended no safety directions. The APVMA accepts the findings and recommendations of OCS on this criterion.

- (ii) The APVMA is satisfied that the proposed use of VETORYL 120 MG CAPSULES, VETORYL 60 MG CAPSULES and VETORYL 30 MG CAPSULES will not be an undue hazard to the safety of people using anything containing its residues. The products are for use in companion animals only, trilostane is unlikely to enter the food chain and therefore the determination of an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) are not considered necessary.
- (iv) The APVMA is satisfied that the proposed use of trilostane in the products VETORYL 120 MG CAPSULES, VETORYL 60 MG CAPSULES and VETORYL 30 MG CAPSULES 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, trilostane and finds that the chemistry and manufacturing details of the products are acceptable

The National Drugs and Poisons Scheduling Committee (NDPSC) has examined the active constituent and placed it in Schedule 4 Prescription Animal Remedy of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The appropriate Signal Heading is on the product label. First Aid for trilostane has been recommended by the Office of Chemical Safety in the Commonwealth Department of Health and Ageing and has been included on the label.

The APVMA accepts the findings and recommendations of its advisers on this criterion.

- (iv) The APVMA is satisfied that the proposed use of Vetoryl 120 mg Capsules, Vetoryl 60 mg Capsules and Vetoryl 30 mg Capsules is not likely to have an unintended effect that is harmful to animals, plants or the environment.

The Department of the Environment, Water, Heritage and the Arts (DEWHA) has assessed data in support of product registration. In considering the proposed use pattern and the relatively low amount proposed for use, DEWHA has advised that this will not result in a significant environmental hazard.

The APVMA accepts the findings and recommendations of its advisers on this criterion.

- (v) The APVMA is satisfied that the proposed use of trilostane in Vetoryl 120 mg Capsules, Vetoryl 60 mg Capsules and Vetoryl 30 mg Capsules would not adversely affect trade between Australia and places outside Australia as the products are for use in dogs only.

(vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that it is satisfied that the data from trials supporting the efficacy of the products demonstrate that the product is safe and effective for the proposed uses.

Written submissions on the APVMA's proposal to grant the applications for active constituent approval and product registrations should be addressed in writing to:

Karina Tyson
Acting Senior Product Evaluator
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Phone: (02) 6210 4729
Fax: (02) 6210 4741
Email: karina.tyson@apvma.gov.au

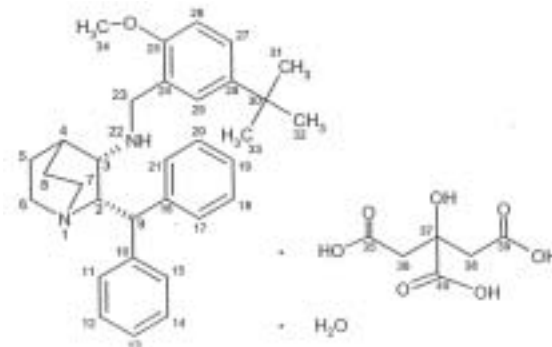
NOTICE**Maropitant citrate****in the products: Cerenia Injectable Solution, Cerenia 160mg Tablets for Dogs, Cerenia 60mg Tablets for Dogs, Cerenia 24mg Tablets for Dogs and Cerenia 16mg Tablets for Dogs**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it applications from Pfizer Animal Health, a Division of Pfizer Australia Pty Ltd for approval of the active constituent maropitant citrate and the registration products of containing the active constituent maropitant citrate. The products are CERENIA INJECTABLE SOLUTION, CERENIA 160MG TABLETS FOR DOGS, CERENIA 60MG TABLETS FOR DOGS, CERENIA 24MG TABLETS FOR DOGS and CERENIA 16MG TABLETS FOR DOGS. The products are for use in dogs.

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 applications for active constituent approval and registration of the products should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Active Constituent

Item	Description
Common name:	Maropitant citrate (manufacturer's code CJ-11,972-10)
IUPAC Name:	(2 <i>S</i> ,3 <i>S</i>)-2-benzhydryl- <i>N</i> -(5- <i>tert</i> -butyl-2-methoxybenzyl)quinuclidin-3-amine citrate monohydrate
Chemical Abstracts Name:	(2 <i>S</i> ,3 <i>S</i>)- <i>N</i> -[(5- <i>tert</i> -butyl-2-methoxybenzyl)]-2-(diphenylmethyl)-1-azabicyclo[2.2.2]octan-3-amine 2-hydroxy-1,2,3-propanetricarboxylate (1:1), monohydrate
CAS Number:	359875-09-5
Molecular Formula:	C ₃₂ H ₄₀ N ₂ O C ₆ H ₈ O ₇ ·H ₂ O
Molecular Weight:	678.81 (free base 468.67)
Structure:	



Mode of Action: Neurokinin 1 receptor inhibitor.

Summary of the APVMA's Evaluation of Active Constituent Trilostane

The Chemistry Section of the APVMA has evaluated the chemistry aspects of the active constituent maropitant citrate, (including the physico-chemical, spectral, manufacturing and quality control aspects, impurity formation, Specification/Declaration of Composition, batch analysis data, analytical methods and packAgeing information) and found them to be acceptable.

The Office of Chemical Safety (OCS) of the Australian Government Department of Health and Ageing has considered the toxicological aspects of maropitant citrate, and advised that there are no objections on human health grounds to the approval of this chemical.

Maropitant citrate is included in scheduled 4 in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). An Acceptable Daily Intake and Acute Reference Dose were not set for maropitant citrate as the products are proposed for use in non-food producing animals

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

Particulars of Application

Proposed products' names:	CERENIA INJECTABLE SOLUTION CERENIA 160MG TABLETS FOR DOGS CERENIA 60MG TABLETS FOR DOGS CERENIA 24MG TABLETS FOR DOGS CERENIA 16MG TABLETS FOR DOGS
Applicant company:	Pfizer Animal Health, a division of Pfizer Australia Pty Ltd
Name of active constituent:	Maropitant citrate
Signal heading:	Schedule 4 Prescription Animal Remedy
Statement of claims:	For the prevention and treatment of vomiting in dogs (injectable solution) and for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs (tablets).
Pack sizes:	20mL, 4 tablet blister packs
Withholding period:	Not applicable

Summary of the APVMA's evaluation of [product name u/c] 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 CERENIA INJECTABLE SOLUTION, CERENIA 160MG TABLETS FOR DOGS, CERENIA 60MG TABLETS FOR DOGS, CERENIA 24MG TABLETS FOR DOGS and CERENIA 16MG TABLETS FOR DOGS would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Commonwealth Department of Health and Ageing has conducted a risk assessment on the human toxicological aspects and occupational health and safety aspects of these applications.

The products will be formulated overseas and imported fully-packaged into Australia. Public exposure to maropitant would occur only when handling tablets for administration to dogs under veterinary prescription, accidental ingestion of tablets or accidental self-injection by professionals. Maropitant citrate has low acute oral toxicity and dermal toxicity and is expected to be of low acute inhalational toxicity. OCS advised the APVMA that there are no objections to the approval of maropitant citrate and the registration of the products from a toxicological perspective. OCS advised the APVMA that use of the products would not be an undue hazard to the safety of people exposed to it during its handling and use and recommended no safety directions.

The APVMA accepts the findings and recommendations of OCS on this criterion.

- (ii) The APVMA is satisfied that the proposed use of CERENIA INJECTABLE SOLUTION, CERENIA 160MG TABLETS FOR DOGS, CERENIA 60MG TABLETS FOR DOGS, CERENIA 24MG TABLETS FOR DOGS and CERENIA 16MG TABLETS FOR DOGS will not be an undue hazard to the safety of people using anything containing its residues. The products are for use in companion animals only, maropitant citrate is unlikely to enter the food chain and therefore the determination of an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) are not considered necessary.
- (v) The APVMA is satisfied that the proposed use of maropitant citrate in the products CERENIA INJECTABLE SOLUTION, CERENIA 160MG TABLETS FOR DOGS, CERENIA 60MG TABLETS FOR DOGS, CERENIA 24MG TABLETS FOR DOGS and CERENIA 16MG TABLETS FOR DOGS 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, maropitant citrate and finds that the chemistry and manufacturing details of the products are acceptable

The National Drugs and Poisons Scheduling Committee (NDPSC) has examined the active constituent and placed it in Schedule 4 Prescription Animal Remedy of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The appropriate Signal Heading is on the product label. First Aid for maropitant citrate has been recommended by the Office of Chemical Safety in the Commonwealth Department of Health and Ageing and has been included on the label.

The APVMA accepts the findings and recommendations of its advisers on this criterion.

- (iv) The APVMA is satisfied that the proposed use of CERENIA INJECTABLE SOLUTION, CERENIA 160MG TABLETS FOR DOGS, CERENIA 60MG TABLETS FOR DOGS, CERENIA 24MG TABLETS FOR DOGS and CERENIA 16MG TABLETS FOR DOGS is not likely to have an unintended effect that is harmful to animals, plants or the environment.

The Department of the Environment, Water, Heritage and the Arts (DEWHA) has assessed data in support of product registration. In considering the proposed use pattern and the relatively low amount proposed for use, DEWHA has advised that this will not result in a significant environmental hazard.

The APVMA accepts the findings and recommendations of its advisers on this criterion.

- (v) The APVMA is satisfied that the proposed use of maropitant citrate in the products CERENIA INJECTABLE SOLUTION, CERENIA 160MG TABLETS FOR DOGS, CERENIA 60MG TABLETS FOR DOGS, CERENIA 24MG TABLETS FOR DOGS and CERENIA 16MG TABLETS FOR DOGS would not adversely affect trade between Australia and places outside Australia as the products are for use in dogs only.

- (vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that it is satisfied that the data from trials supporting the efficacy of the products demonstrate that the product is safe and effective for the proposed uses.

Written submissions on the APVMA's proposal to grant the applications for active constituent approval and product registrations should be addressed in writing to:

Karina Tyson
Acting Senior Product Evaluator
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Phone: (02) 6210 4729
Fax: (02) 6210 4741
Email: karina.tyson@apvma.gov.au

Other Notices

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 issued, amended or cancelled the manufacturing licences in respect 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 web site: <http://www.apvma.gov.au>.

1. NEW LICENCES:

COSMETIC
MANUFACTURERS (AUST)
PTY. LTD.
ACN: 010 501 327
26 Steindl Street
BUNDABERG QLD 4670

Product Types:*
Category 2: Creams / lotions
Step(s) of Manufacture:
Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply.
Licence No: 2202
Full licence issued 16/12/08 with special conditions.

GMP PHARMACEUTICALS
PTY LIMITED
ACN: 063 353 006
7 to 9 Amax Avenue
GIRRAWEE NSW 2145

Product Types:*
Category 2: Tablets, pellets, capsules, creams / lotions, ointments, pastes, powders, spray and liquids
Step(s) of Manufacture:
Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister and sachet packaging, soft gelatine capsule manufacture, tableting, pellet extrusion, capsule filling from bulk, analysis and testing (physical), storage and release for supply.
Licence No: 2205
Full licence issued 16/12/08 with special conditions.

2. CHANGES TO EXISTING LICENCES:

DASCO PTY LTD
ACN: 004 581 113
24-26 Helen Street
HEIDELBERG HEIGHTS
VIC 3081

Product Types:*
Category 2: **Creams/lotions, ointments, pastes, powders and liquids**
Step(s) of Manufacture:
Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, storage and release for supply
Licence No: 2066
Amended licence issued 3/12/08, variation to licence conditions, extension of licence scope.

HESLOP CONTRACT
CASTERS PTY LTD
ACN: 116 308 233
8 Pitt Street
RESERVOIR VIC 3073

Product Types:*
Category 6: **Single Step**
Step(s) of Manufacture:
Quality assurance (QA) of raw materials, packaging, labelling, metallurgical die-casting (of intraruminal slow-release magnesium capsules)
Licence No: 6125
Amended licence issued 2/12/08, variation to licence conditions, change of key personnel.

LIENERT AUSTRALIA PTY
LTD
ACN: 008 293 007
Lot 1, Gartrel Street
ROSEWORTHY SA 5371

Product Types:*
Category 4: **Premixes, supplements and custom mixes**
Step(s) of Manufacture:
Formulation including blending, filling, packaging, labelling, storage and release for supply
Licence No: 4010
Amended licence issued 4/12/08, change of key personnel.

NEW HORIZONS
ENTERPRISES LIMITED
ACN: 002 066 604
15 Twin Road
NORTH RYDE NSW 2113

Product Types:*
Category 6: **Single step**
Step(s) of Manufacture:
Secondary packaging and secondary labelling
Licence No: 6076
Amended licence issued 8/12/08, change of key personnel.

NOVARTIS ANIMAL HEALTH
AUSTRALASIA PTY LIMITED
ACN: 076 745 198
Unit 1, 1 Dupas Street
SMITHFIELD NSW 2164

Product Types:*
Category 6: **Single step**
Step(s) of Manufacture:
Secondary packaging, secondary/supplementary labelling and release for supply
Licence No: 6126
Amended licence issued 10/12/08, licence format update.

PACKAGING
PROFESSIONALS PTY LTD
ACN: 096 824 850
**2-4 Wembley Place
KELSO NSW 2795**

Product Types:*
*Category 6: **Single step***
Step(s) of Manufacture:
Packaging, labelling, strip, blister or sachet packaging,
storage and release for supply
Licence No: 6111
*Amended licence issued 10/12/08, change of key
personnel.*

PHARMAPAK
TECHNOLOGIES PTY LTD
ACN: 093 794 104
**7 Inman Road
DEE WHY NSW 2099**

Product Types:*
*Category 6: **Single step***
Step(s) of Manufacture:
Quality assurance (QA) of raw materials, filling,
packaging, labelling, strip, blister and sachet packaging,
storage and release for supply
Licence No: 6107
*Amended licence issued 8/12/08, change of key
personnel.*

RTH SCIENTIFIC SERVICES
PTY LTD
ACN: 112 358 915
**47 Oak Place
MACKENZIE QLD 4156**

Product Types:*
*Category 2: **Liquids, suspensions, tablets***
Step(s) of Manufacture:
**Quality assurance (QA) of raw materials,
formulation including blending, filling, granulation,
tableting, packaging, labelling, analysis and testing
(physical, chemical), storage and release for supply.**
Licence No: 2185
*Amended licence issued 19/12/08, change of key
personnel.*

VIRBAC (AUSTRALIA) PTY
LIMITED
ACN: 003 268 871
**18-22 Denison Street
CROOKWELL NSW 2583**

Product Types:*
*Category 2: **Tablets, pastes, sprays, liquids,
suspensions, creams/lotions, ointments and powders.***
*Category 3: **Liquids, pastes and sprays.***
*Category 4: **Premixes and supplements.***
Step(s) of Manufacture:
**Formulation including blending, filling, wet milling
of powders, filling, packaging, labelling, tableting,
analysis and testing (physical) and storage.**
Licence No: 2188
*Amended licence issued 19/12/08, extension of licence
scope.*

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

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:
Rheannon McNeil
GMP Section
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Ph: (02) 6210 4805

Fax: (02) 6210 4813

Email: rheannon.mcneil@apvma.gov.au

Application Summaries

The APVMA publishes complete application summaries on the APVMA website (http://www.apvma.gov.au/data_protection/appl_summaries.shtml). 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 and list it separately in the APVMA Gazette Notice for Application Summaries.

As a requirement of Regulations 8C and E of the Agvet Code, some product names will appear as 'NOT AVAILABLE'.

A summary will be removed from the website 28 days after the application has been finalised. Therefore, some summaries published in this notice may have already been removed prior to the Gazette being published.

Application summaries published since those published in APVMA Gazette No. 13, 1st January 2009.

Application No.	Name
42748	TURFMASTER SELECTIVE HERBICIDE
42959	CHEMAG SUBJECT 240 HERBICIDE
43378	4FARMERS PROPYZAMIDE 500WDG SELECTIVE HERBICIDE
44215	AQUA PURE HEAVY DUTY BLACKSPOT REMOVER & ALGAE KILLER
44452	ACTARA INSECTICIDE
44513	NOT AVAILABLE
44846	SHARP SHOOTER COMPLETE LAWN GRUB & BEETLE KILLER HOSE ON IMIDACLOPRID SYSTEMIC INSECTICIDE
45543	IMTRADE TRIADIMEFON 500 WG FUNGICIDE
45628	SAFER PEST CONTROL BY 30 SECONDS MOSQUITO REPELLING GRANULES
45646	PATTOCHOICE MA HERBICIDE
45741	NOT AVAILABLE
45757	INDAR FUNGICIDE
45879	KENSO AGCARE HALOXYKEN 520 HERBICIDE
45891	CHEMFARM 2,4-D AMINE 300 HERBICIDE
46259	FARMOZ ESCALATE 500 SC COTTON DEFOLIANT
43381	BELT 240 WG INSECTICIDE
44878	IMAZAPIC
44892	COLLABORATE HERBICIDE
45786	AW DITCH 500 HERBICIDE
45852	RAID FLY & MOSQUITO INSECT KILLER NATURE SHIELD
45946	GULLF AG CLEARUP BIO BLUE MARKER GLYPHOSATE
46004	TURF CULTURE THUMPER MITICIDE
46142	NUFARM REVEAL LIQUID COTTON DEFOLIANT
46160	ARISTOPET AQUA RX ALGAE BUSTER
46262	IMTRADE CLETHODIM 240 EC HERBICIDE
46383	HUNTERS SETTLING DAY FAST KNOCKDOWN INSECT SPRAY
42472	POULVAC FLUFEND I AI H7NI
42897	4FARMERS TRITICONAZOLE 200 C SEED TREATMENT
44633	YATES ROSE GUN BLACK SPOT & INSECT PEST KILLER
44856	MOSQUITO-PATCH INSECT REPELLENT
45232	NOT AVAILABLE
45280	PINHEAD METHOMYL 225 INSECTICIDE
45333	ZOLIAR 800 DF HERBICIDE

45418	COUNTRY OXYFLUORFEN 240 HERBICIDE
45474	NOT AVAILABLE
45491	HOVEX HOME PROTECTION AUTOMATIC INSECT CONTROL SYSTEM FOR USE INDOORS AND OUTDOOR
45492	HOVEX AUTOMATIC INSECT CONTROL SYSTEM FOR USE INDOORS AND OUTDOOR
45616	TITAN LV ESTER 680 HERBICIDE
45629	GRASS VALLEY GLYPHOSATE CT 450 HERBICIDE
45636	GRASS VALLEY GLYPHOSATE 360 HERBICIDE
45695	GRASS VALLEY TRIFLURALIN 480 HERBICIDE
45696	GRASS VALLEY ALPHA-CYPERMETHRIN 100 INSECTICIDE
45697	GRASS VALLEY CHLORPYRIFOS 500 INSECTICIDE
45726	NOT AVAILABLE
45815	NOT AVAILABLE
45953	YATES MAVRIK CHEWING & SUCKING INSECT KILLER
45958	OZCROP BLOWOUT HERBICIDE
45969	COM 302 11 IAF AL INSECTICIDE/ACARICIDE/FUNGICIDE
46025	GENFARM SIMAGEN 900 WG HERBICIDE
46030	CHOICE DICAMBA 500 HERBICIDE
46089	AW GROWLER M HERBICIDE
46207	NOT AVAILABLE
46208	UNITED PHOSPHORUS ATRAPHOS 900 WG HERBICIDE
46221	ENVIROMAX DELTAMETHRIN 10SC RESIDUAL INSECTICIDE
46222	SUREFIRE FENITROTHION 1000EC INSECTICIDE
46321	SELECT MOSQUITO COILS
46322	SELECT OUTDOOR & INDOOR SURFACE SPRAY
46346	SACOA PREMIUM SPRAY GRADE AMMONIUM SULPHATE HERBICIDE ADJUVANT
46402	MORTEIN POWERGARD FLYING INSECT KILLER ODOURLESS
46438	SLAYER 450 HERBICIDE
46440	MACSPRED METMAC 600WG HERBICIDE
46446	MACSPRED SULFOMAC 750 WG HERBICIDE
46460	MORTEIN POWERGARD CRAWLING INSECT KILLER ODOURLESS
46468	NOT AVAILABLE

A change or correction has been made to the following summaries:

Application No.	Product/Active Constituent Name
42334	

Contact:

Application Management and Enquiries Team (AME)
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Ph: 6210 4701
Fax: 6210 4721

*AMENDMENT No. 8L***Amendments to the MRL Standard**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) sets maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. These 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. At the same time the APVMA is satisfied, from dietary exposure assessment, that the levels are not an undue hazard to human health.

The MRL Standard lists MRLs of substances which may arise from the approved use of those substances or other substances, and provides the relevant residue definitions to which these MRLs apply.

The evaluation process takes into account studies on chemistry, metabolism, analytical methodology, residues, good agricultural practice, toxicology and dietary exposure. From time to time the evaluation process results in amendments to the MRL Standard. It should be noted that relevant MRLs are referred to Food Standards Australia New Zealand for incorporation into Standard 1.4.2 of the Food Standards Code entitled "Maximum Residue Limits".

Note: ‘*’ denotes that the maximum residue limit (MRL) has been set at or about the limit of analytical quantitation (see: Residue Guideline No.4, *Maximum Residue Limit Proposals ‘At or about the Limit of Analytical Quantitation’*, published in NRA Gazette No.9, p44, 5/9/95).

‘T’ denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out in Australia or overseas, and will be reconsidered at some future date.

The MRL Standard is also accessible via the APVMA web page.

<http://www.apvma.gov.au/residues/mrl.shtml>

TABLE 1: MAXIMUM RESIDUE LIMITS OF PESTICIDES, AGRICULTURAL CHEMICALS, FEED ADDITIVES, VETERINARY MEDICINES AND ASSOCIATED SUBSTANCES IN FOOD COMMODITIES

Residues of substances which may occur in food commodities and for which the following maximum residue limits (MRLs) apply.

COMPOUND	FOOD	MRL (mg/kg)
Buprofezin		
ADD: VS 0624	Celery	T1
Indoxacarb		
DELETE: VL 0053	Leafy vegetables (except Lettuce, head)	5
ADD: HH 0092	Coriander (leaves, roots and stems)	T20
VL 0053	Herbs	T20
VL 0496	Leafy vegetables [except Lettuce, Head and Rucola (rocket)	5
	Mexican tarragon	T20
	Rucola (rocket)	T20
Pyraclostrobin		
ADD: VL 0054	Brassica leafy vegetables	T3
VB 0401	Broccoli, Chinese	T1

For further information please contact:

Dounia Houzaife
Residues Contact Officer
Australian Pesticides & Veterinary Medicines Authority
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KINGSTON ACT 2604

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Email dounia.houzaife@apvma.gov.au

Addendum list of Approved: Active Constituents

The current Record of Approved Active Constituents is also accessible via the APVMA web page on:
http://www.apvma.gov.au/actives/downloads/aa_AK.pdf and http://www.apvma.gov.au/actives/downloads/aa_LZ.pdf

Approved since Gazette No. 1, 6 January 2009

For Use in Agricultural Chemical Products:

DIFLUFENICAN	AGROGILL CHEMICALS PTY LTD	JIANGSU CHANGLONG CHEMICALS CO., LTD LONGHU TANG NEW DISTRICT OF CHANGZHOU JIANGSU 213031 PR CHINA	62920
IMIDACLOPRID	RALLIS INDIA LIMITED	RALLIS INDIA LIMITED IDA PHASE II PATANCHURU- 502319, MEDAK DISTRICT ANDHRA PRADESH INDIA	62654
IPRODIONE	SINON AUSTRALIA PTY LIMITED	SINON CORPORATION XINSHEN ROAD, XINSI TOWN FENGXIAN DISTRICT, SHANGHAI CHINA	62403
OXADIAZON	BAYER CROPSCIENCE PTY LTD	BAYER CROPSCIENCE COMPANY 1740 WHITEHALL ROAD NORTH MUSKEGON MICHIGAN 79445 USA	63071

For enquiries please contact:

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