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of Australia**

**Gazette**

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Published by The Australian Pesticides & Veterinary Medicines Authority

**AGRICULTURAL AND  
VETERINARY CHEMICALS**



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**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 10<sup>9</sup>/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 profoxydim.

**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:** Vibrat 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:  $\geq 500$  oocysts *Eimeria acervulina* HP,  $\geq 200$  oocysts *Eimeria maxima* CP,  $\geq 100$  oocysts *Eimeria maxima* MFP,  $\geq 1000$ . oocysts *Eimeria mitis* HP,  $\geq 500$  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

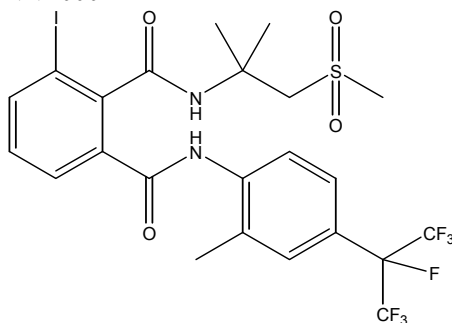
#### Flubendiamide

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-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> <sup>2</sup> -[1,1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo- <i>N</i> <sup>1</sup> -[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide
CAS Number:	272451-65-7
Molecular Formula:	C <sub>23</sub> H <sub>22</sub> F <sub>7</sub> IN <sub>2</sub> O <sub>4</sub> 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 <sup>2+</sup> 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:	<b>BELT 480 SC INSECTICIDE</b> <b>BELT 240 WG INSECTICIDE</b>
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](mailto:pat.robinson@apvma.gov.au)

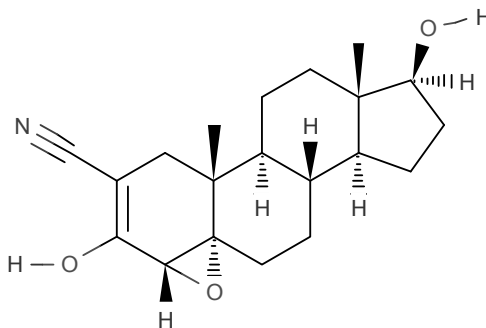
**NOTICE****Trilostane****in the products: Vetoryl 20 mg Capsules, Vetoryl 60 mg Capsules and Vetoryl 30 mg Capsules**

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 $\alpha$ ,5 $\alpha$ -epoxy-17 $\beta$ -hydroxy-3-oxo-androstane-2 $\alpha$ -carbonitrile
Manufacturer's Code:	WIN 24540
CAS No:	13647-35-3
Molecular Formula:	C <sub>20</sub> H <sub>27</sub> NO <sub>3</sub>
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](mailto:karina.tyson@apvma.gov.au)

## NOTICE

### Maropitant citrate

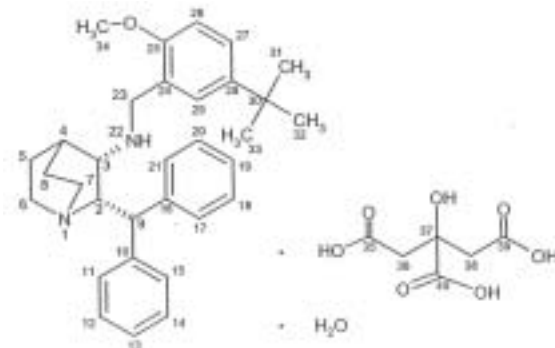
#### **in the products: Cerenia Injectable Solution, Cerenia 160mg Tablets for Dogs, Cerenia 60mg Tablets for Dogs, Cerenia 24mg Tablets for Dogs and Cerenia 16mg Tablets for Dogs**

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 <sub>32</sub> H <sub>40</sub> N <sub>2</sub> O C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ·H <sub>2</sub> 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](mailto:karina.tyson@apvma.gov.au)

## Other Notices

### Licensing of Veterinary Chemical Manufacturers

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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>.

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#### 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  
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## Application Summaries

The APVMA publishes complete application summaries on the APVMA website ([http://www.apvma.gov.au/data\\_protection/appl\\_summaries.shtml](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, 1<sup>st</sup> January 2009.**

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

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

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

<b>Application No.</b>	<b>Product/Active Constituent Name</b>
<b>42334</b>	

**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".

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**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)
<b>Buprofezin</b>		
ADD:		
VS 0624	Celery	T1
<b>Indoxacarb</b>		
DELETE:		
VL 0053	Leafy vegetables (except Lettuce, head)	5
ADD:	Coriander (leaves, roots and stems)	T20
HH 0092	Herbs	T20
VL 0053	Leafy vegetables [except Lettuce, Head and Rucola (rocket)	5
	Mexican tarragon	T20
VL 0496	Rucola (rocket)	T20
<b>Pyraclostrobin</b>		
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  
PO Box 6182  
KINGSTON ACT 2604

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Email [dounia.houzaife@apvma.gov.au](mailto: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](http://www.apvma.gov.au/actives/downloads/aa_AK.pdf) and [http://www.apvma.gov.au/actives/downloads/aa\\_LZ.pdf](http://www.apvma.gov.au/actives/downloads/aa_LZ.pdf)

Approved since Gazette No. 1, 6 January 2009

**For Use in Agricultural Chemical Products:**

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

For enquiries please contact:

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