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#### 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.

# $\frac{AGRICULTURAL\ CHEMICAL}{PRODUCTS}$

#### 1. RESTRICTED PRODUCT:

Product Name: B-Trade 100EC Insecticide Active Constituent/s: 100 g/L bifenthrin. Applicant Name: FMC Australasia Pty Ltd Applicant ACN: 095 326 891

Summary of Use: For the pre and post-construction protection of structures from damage by subterranean termites and the control of urban exterior insect pests.

Date of Registration: 30 July 2008

Label Approval No: 62834/20-1000L/0408, 62834/0408

Product Name: Homeguard Blue Corners

Termite Moisture Barrier

**Active Constituent/s:** 1 g/kg bifenthrin. **Applicant Name**: FMC Australasia Pty Ltd

Applicant ACN: 095 326 891 Summary of Use: For protection of structures from concealed termite entry. Date of Registration: 6 August 2008 Label Approval No: 63060/5c-50c/0508

**Product Name:** Homeguard DPC Corners

Termite Moisture Barrier

**Active Constituent/s:** 1 g/kg bifenthrin **Applicant Name:** FMC Australasia Pty Ltd

**Applicant ACN:** 095 326 891

Summary of Use: For the protection of structures from concealed termite entry.

Date of Registration: 7 August 2008

Label Approval No: 63059/5c-50c/05058

2. AGRICULTURAL 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. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS:

Product Name: Smart 2,4-D Ester 600 LV

Herbicide

Active Constituent/s: 600 g/L 2,4-D present as the ethyl hexyl ester Applicant Name: Crop Smart Pty Ltd Applicant ACN: 093 927 961

**Summary of Use:** For the selective control of various weeds in crops, pastures and non-

agricultural areas.

**Date of Registration:** 18 July 2008 **Label Approval No:** 62565/5L/0408, 62565/20L/0408, 62565/110L/0408, 62565/200L/0408, 62565/500L/0408, 62565/1000L/0408, 62565/0408

**Product Name:** Hovex Extra Strength

Crawling Insect Spray

Active Constituent/s: 1.40 g/kg imiprothrin, 2 g/kg cypermethrin. Applicant Name: Pascoe's Pty Ltd Applicant ACN: 055 220 463

Summary of Use: For the control of certain

crawling insects.

**Date of Registration:** 18 July 2008 **Label Approval No:** 62774/250g/0708,

62774/350g/0708

**Product Name:** Agcare Biotech 2,4-D Amine 625 Selective Herbicide **Active Constituent/s:** 625 g/L 2,4-D present as the dimethylamine &

diethanolamine salts

Applicant Name: Agcare Biotech Pty Ltd

Applicant ACN: 071 180 786

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

Date of Registration: 21 July 2008

Label Approval No: 61925/5-1000L/0907,

61925/110L/0907, 61925/0907

Product Name: Aqua Pure Pool Algaecide

Active Constituent/s: 150 g/L

benzalkonium chloride.

**Applicant Name:** Pool Products Of

Australia Pty Ltd

**Applicant ACN:** 085 385 511

**Summary of Use:** For the elimination and prevention of algae in swimming pools.

**Date of Registration:** 23 July 2008 **Label Approval No:** 62894/500mL/0408, 62894/1L/0408, 62894/5L/0408, 62894/25L/0408

Product Name: Ospray Barometer

Herbicide

Active Constituent/s: 200 g/L bromoxynil present as the n-octanoyl ester, 200 g/L MCPA present as the ethyl hexyl ester. Applicant Name: Ospray Pty Ltd Applicant ACN: 110 199 169

**Summary of Use:** For the control of weeds in wheat, oats, barley, cereal rye, triticale,

linseed, grass pastures and turf. **Date of Registration:** 24 July 2008 **Label Approval No:** 63239/5L/0608, 63239/20L/0608, 63239/110L/0608, 63239/1000L/0608, 63239/0608

**Product Name:** Off! Familycare Insect Repellent Spray Smooth & Dry Comfortable

Skin Feel Softly Scented **Active Constituent/s:** 150 g/kg

diethyltoluamide

**Applicant Name:** S.C. Johnson & Son Pty

Ltd

Applicant ACN: 000 021 009

**Summary of Use:** For the use as a personal insect repellent to repel mosquitoes,

sandflies and other biting insects. **Date of Registration:** 24 July 2008 **Label Approval No:** 62306/70/0408

Product Name: Ospray Pirimicarb WG

Aphicide

Active Constituent/s: 500 g/kg pirimicarb.

**Applicant Name:** Ospray Pty Ltd **Applicant ACN:** 110 199 169

**Summary of Use:** For control of certain aphids on various crops, pastures and ornamentals.

**Date of Registration:** 28 July 2008 **Label Approval No:** 63123/1kg/0608, 63123/5kg/0608, 63123/10kg/0608,

63123/0608

Product Name: Country Bifenthrin

Granular Insecticde

Active Constituent/s: 2 g/kg bifenthrin. Applicant Name: Accensi Pty Ltd Applicant ACN: 079 875 184

**Summary of Use:** For the control of a range of insect pests in turf; insect and anachnid pests of internal and external areas and surrounds of buildings and structures. **Date of Registration:** 29 July 2008

**Label Approval No:** 62233/2kg-15kg/0108,

62233/0108

**Product Name:** Spalding Penetrant **Active Constituent/s:** 1020 g/L polyether

modified polysiloxane

Applicant Name: Spalding Holdings Pty

Ltd

**Applicant ACN: 010 155 852** 

**Summary of Use:** For use, in combination with other agricultural chemicals as a nonionic wetter, spreader and penetrant. **Date of Registration:** 29 July 2008 **Label Approval No:** 62811/250ml/0308, 62811/1L/0308, 62811/5L/0308,

62811/20L/0308

**Product Name:** Country Metolachlor 720

Herbicide

Active Constituent/s: 720 g/L metolachlor

**Applicant Name:** Accensi Pty Ltd **Applicant ACN:** 079 875 184

**Summary of Use:** For control of certain annual grasses and broadleaf weeds in

certain crops.

Date of Registration: 29 July 2008 Label Approval No: 63171/1-1000/0608,

63171/1-1000L/0608

**Product Name:** Sylon 750 SG Herbicide **Active Constituent/s:** 750 g/kg clopyralid

present as the potassium salt

Applicant Name: Sipcam Pacific Australia

Pty Ltd

**Applicant ACN: 073 176 888** 

**Summary of Use:** For the control of a wide number of broadleaf weeds in wheat, barley, oats, triticale, canola, pastures and fallow land.

**Date of Registration:** 29 July 2008 **Label Approval No:** 62636/2kg/0308,

62636/0308

Product Name: Nufarm Amicide 720

Selective Herbicide

**Active Constituent/s:** 720 g/L 2,4-D present as the dimethyl amine salt.

Applicant Name: Nufarm Australia Limited

**Applicant ACN:** 004 377 780

**Summary of Use:** For control of a range of broadleaf weeds in fallow, cereal crops, pastures, sugar cane, peanuts and non

agricultural areas.

**Date of Registration:** 29 July 2008 **Label Approval No:** 62691/5L/0408, 62691/20L/0408, 62691/110L/0408, 62691/200L/0408, 62691/1000L/0408, 62691/0408

Product Name: Chameleon Jumbo

**Swimming Pool Tablets** 

**Active Constituent/s:** 890 g/kg chlorine present as trichloroisocyanuric acid.

Applicant Name: Stephen Clynch

Plumbing Pty Limited

**Applicant ACN: 079 775 992** 

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

Date of Registration: 30 July 2008

Label Approval No: 62237/1/0608

Product Name: Yates Zero Weedkiller

Rapid Works Twice As Fast

**Active Constituent/s:** 7.2 g/L glyphosate as

ammonium salt.

Applicant Name: Orica Australia Pty Ltd

**Applicant ACN:** 004 117 828

Summary of Use: For the control of various

weeds in the home garden.

**Date of Registration:** 31 July 2008 **Label Approval No:** 62561/750/0708, 62561/750R/0708, 62561/875R/0708, 62561/875R/0708, 62561/3/0708

**Product Name:** Yodimaspen Ester Of Benzyl Penicillin For Intramuscular

Injection

**Active Constituent/s:** 5000 mg

penethamate hydriodide

**Applicant Name:** Sykes Vet International

Pty Ltd

**Applicant ACN:** 085 158 434

**Summary of Use:** For the treatment of mastitis, foot rot, uterine and respiratory infections in cattle caused by gram positive bacteria susceptible to penethamate

hydriodide.

**Date of Registration:** 31 July 2008 **Label Approval No:** 61252/5g/0208, 61252/15mL/0208, 61252/2/0208, 61252/4/0208, 61252/12/0208, 61252/0208

Product Name: Nufarm L.V.E. Agritone

Selective Herbicide

**Active Constituent/s:** 570 g/L MCPA present as the 2-ethyl hexyl ester.

Applicant Name: Nufarm Australia Limited

**Applicant ACN: 004 377 780** 

**Summary of Use:** For the control of various broadleaf weeds in oats, barley, triticale, cereal rye, wheat, grass pastures and grass seed crops.

**Date of Registration:** 31 July 2008 **Label Approval No:** 62527/20L/0708, 62527/110L/0708, 62527/200L/0708, 62527/500L/0708, 62527/0708

**Product Name:** Flurox Termite Bait **Active Constituent/s:** 1 g/kg flufenoxuron. **Applicant Name:** Janssen-Cilag Pty Ltd

**Applicant ACN:** 000 129 975

Summary of Use: For use as part of a

termite interception and baiting system for the management of subterranean termites. **Date of Registration:** 1 August 2008 **Label Approval No:** 60037/1.8/0707,

60037/6/0707

**Product Name:** Country Alpha-Cypermethrin 100 Insecticide **Active Constituent/s:** 100 g/L alpha-

cypermethrin.

**Applicant Name:** Accensi Pty Ltd **Applicant ACN:** 079 875 184

Summary of Use: For the control of insect pests of cereals, cotton, grain legumes, oilseeds, pastures, pome, stone fruits, trees, ornamentals, tobacco and vegetables.

Date of Registration: 1 August 2008

Label Approval No: 62491/5-1000L/0208,

62491/0208

**Product Name:** Nufarm Trooper 75-D

Herbicide

**Active Constituent/s:** 75 g/L picloram present as the triisopropanolamine salt, 300 g/L 2,4-D present as the triisopropanolamine

salt

Applicant Name: Nufarm Australia Limited

**Applicant ACN:** 004 377 780

Summary of Use: For the control of a wide range of annual and perennial broadleaf weeds for cereals and sugarcane and in situations of agricultural non-crop areas, commercial and industrial areas, pastures and rights of way.

**Date of Registration:** 4 August 2008 **Label Approval No:** 62751/5L/0708, 62751/20L/0708, 62751/110L/0708, 62751/0708

**Product Name:** Titan Glyphosate 360

Herbicide

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

Applicant Name: Titan Ag Pty Ltd

Applicant ACN: 122 081 574

Summary of Use: For the non selective

control of many annual, aquatic and perennial weeds in various situations. **Date of Registration:** 4 August 2008 **Label Approval No:** 63078/1L/0508, 63078/5L/0508, 63078/20L/0508, 63078/110L/0508, 63078/1000L/0508, 63078/0508

**Product Name:** Chemforce Clopyralid 750SG Herbicide

Active Constituent/s: 750 g/kg clopyralid

present as the potassium salt.

Applicant Name: Frank Vanderkley & Paul

Richards T/A Chemforce Australia

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

**Date of Registration:** 5 August 2008 **Label Approval No:** 62583/2KG/0308,

62583/0308

**Product Name:** Sipcam LV Ester 680

Herbicide

**Active Constituent/s:** 680 g/L 2,4-D present as the ethyl hexyl ester

Applicant Name: Sipcam Pacific Australia

Pty Ltd

**Applicant ACN: 073 176 888** 

**Summary of Use:** For selective control of various weeds in crops, pastures and non-agricultural areas.

**Date of Registration:** 7 August 2008 **Label Approval No:** 62198/20L/0408, 62198/100L/0408, 62198/110L/0408, 62198/1000L/0408, 62198/0408

Product Name: Maxforce Prime Cockroach

Gel

Active Constituent/s: 21.5 g/kg

imidacloprid.

Applicant Name: Bayer Cropscience Pty

Ltd

Applicant ACN: 000 226 022 Summary of Use: For control of cockroaches in domestic, agricultural, industrial and commercial buildings. Date of Registration: 7 August 2008 Label Approval No: 61629/30/0508,

61629/30g/0508

Product Name: Nufarm Grunt 750WDG

Herbicide

Active Constituent/s: 750 g/kg hexazinone. Applicant Name: Nufarm Australia Limited

**Applicant ACN:** 004 377 780

**Summary of Use:** For the control of certain sedges, perennial grasses, broadleaf and woody weeds in *pinus radiata* forests, and industrial weed control situations.

**Date of Registration:** 7 August 2008 **Label Approval No:** 62549/10kg/0808,

62549/0808

Product Name: Brunnings Bindii Kill For

Lawns

Active Constituent/s: 2.3 g/L dicamba dimethylamine salt, 15 g/L MCPA present

as the dimethylamine salt.

Applicant Name: Brunnings Garden

Products Pty Ltd

**Applicant ACN:** 050 655 760 **Summary of Use:** For the control of

broadleaf weeds in lawns.

**Date of Registration:** 8 August 2008 **Label Approval No:** 63036/2/0608,

63036/3.5/0608

Product Name: Aristopet Aqua Master

Algae Buster

Active Constituent/s: 5 g/L Diuron. Applicant Name: Aristopet Pty Ltd Applicant ACN: 009 697 152

**Summary of Use:** For the control of algae and green water in large ponds in the home

garden.

**Date of Registration:** 11 August 2008 **Label Approval No:** 63113/250ml/0608, 63113/500ml/0608, 63113/1L/0608

**Product Name:** Hometeam Eco-Bor Timber

Preservative & Fungicide

**Active Constituent/s:** 52 g/L boron present as disodium octaborate tetrahydrate, 12 g/L

benzalkonium chloride.

Applicant Name: Hometeam Australia Pty

Ltd

**Applicant ACN:** 111 217 568 **Summary of Use:** For the

industrial/domestic use in pre-treatment and remedial treatment of timber against decay

and insects.

**Date of Registration:** 11 August 2008

Label Approval No:

62137/1L/0608,62137/5L/0608, 62137/10L/0608, 62137/20L/0608, 62137/200L/0608

**Product Name:** Token Herbicide **Active Constituent/s:** 100 g/L picloram present as the hexyloxypropylamine salt, 300 g/L triclopyr present as the butoxyethyl actor.

Applicant Name: Sipcam Pacific Australia

Pty Ltd

**Applicant ACN: 073 176 888** 

**Summary of Use:** For control of a range of environment and noxious woody and

herbaceous weeds.

**Date of Registration:** 12 August 2008 **Label Approval No:** 62035/20L/1007

62035/5L/1007, 62035/1007

Product Name: Country Bromoxynil 200

Selective Herbicide

Active Constituent/s: 200 g/L bromoxynil

present as the n-octanoyl ester. **Applicant Name:** Accensi Pty Ltd **Applicant ACN:** 079 875 184

**Summary of Use:** For the control of weeds in wheat, oats, barley, cereal rye and triticale

( alone or undersown ), linseed, clover and lucerne pastures, turf, fallow, non-crop, roadsides and rights-of-way.

**Date of Registration:** 12 August 2008 **Label Approval No:** 62747/5-1000L/0108

62747/0108

**Product Name:** Allfire MCPA 500 LVE

Herbicide

Active Constituent/s: 500 g/L MCPA present as the 2-ethyl hexyl ester.

Applicant Name: Agvantage Pty Ltd

**Applicant ACN:** 097 970 280

Summary of Use: For selective control of

certain weeds in agriculture crops. **Date of Registration:** 13 August 2008 **Label Approval No:** 63101/5L/0508, 63101/20L/0508, 63101/1000L/0508, 63101/200L/0508, 63101/1000L/0508,

63101/0508

**Product Name:** Suria 500 Herbicide **Active Constituent/s:** 500 g/L glyphosate present as the isopropylamine salt.

Applicant Name: Hextar Chemicals Pty Ltd

**Applicant ACN:** 114 525 709

**Summary of Use:** For non-selective control of many annual, perennial and aquatic

weeds in various situations.

**Date of Registration:** 14 August 2008 **Label Approval No:** 63225/5L/0608, 63225/10L/0608, 63225/20L/0608, 63225/110L/0608, 63225/120L/0608, 63225/1000L/0608, 63225/BULK/0608, 63225/1000L/0608, 63225/BULK/0608,

63225/0608

#### 4. VARIATIONS

Product Name: Nevweb Fenitrothion 1000

Insecticide

**Applicant Name:** Australian Pharmaceutical Partners Pty Limited **Applicant ACN:** 001 775 739

**Summary of Variation:** Change of product name from "Nevweb Fenitrothion 1000 Grain Protectant" to "Nevweb Fenitrothion

1000 Insecticide".

**Date of Variation:** 22 July 2008 **Label Approval No:** 52034/300/0608, 52034/2.4/0608, 52034/20/0608, 52034/300LL/0608, 52034/2.4LL/0608, 52034/20LL/0608

**Product Name:** Mortein Spider Control Outdoor Surface Spray Spider Control

**Household Protection** 

Applicant Name: Reckitt Benckiser

(Australia) Pty Limited
Applicant ACN: 003 274 655
Summary of Variation: Variation to

registered particulars and label approval to change the product name from "Mortein Spider Control Outdoor Surface Spray Household Protection" to "Mortein Spider Control Outdoor Surface Spray Spider Control Household Protection" and minor label updates.

**Date of Variation:** 23 July 2008 **Label Approval No:** 55099/350g/0508

Product Name: Bal Eulan Spa Moth

**Proofing Agent** 

**Applicant Name:** Lanxess Pty Ltd **Applicant ACN:** 071 919 116

**Summary of Variation:** Change of product name from "Bayer Eulan Spa Moth Proofing Agent" to "Bal Eulan Spa Moth

Proofing Agent".

Date of Variation: 28 July 2008

**Label Approval No:** 39228/25-1000L/0408

Product Name: Poolmart Your Local Pool

Professional Stabilised Chlorine **Applicant Name:** Poolmart

Summary of Variation: Change of product name from "Poolmart Your Local Pool Professional Stabilized Chlorine" To "Poolmart Your Local Pool Professional Stabilised Chlorine", minor formulation

change and label update.

**Date of Variation:** 31 July 2008 **Label Approval No:** 45458/2/1207, 45458/4/1207, 45458/10/1207

# 5. 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:** Convenia

Active Constituent/s: 80 mg/mL cefovecin as

sodium salt

**Applicant Name:** Pfizer Animal Health A Div

of Pfizer Australia Pty Ltd **Applicant ACN:** 008 422 348

**Summary of Use:** For the treatment of urinary tract, skin and soft tissue infections sensitive to

cefovecin in dogs and cats.

**Date of Registration:** 17 July 2008 **Label Approval No:** 60461/10/0508,

60461/0508

**Product Name:** Ibaflin 300mg Tablets For Dogs **Active Constituent/s:** Each tablet contains

300 mg ibafloxacin.

Applicant Name: Intervet Australia Pty Limited

**Applicant ACN: 008 467 034** 

**Summary of Use:** For use in dogs, for the treatment of urinary tract, respiratory tract, skin and soft tissue infections sensitive to ibafloxacin.

**Date of Registration:** 30 July 2008 **Label Approval No:** 59706/8T/0708,

59706/0708

Product Name: Ibaflin 3% Gel For Dogs And

Cats

**Active Constituent/s:** 30 mg/mL ibafloxacin. **Applicant Name:** Intervet Australia Pty Limited

**Applicant ACN:** 008 467 034

**Summary of Use:** For use in dogs and cats, for the treatment of urinary tract, respiratory tract, skin and soft tissue infections sensitive to ibafoxacin.

**Date of Registration:** 1 August 2008 **Label Approval No:** 59708/15M/0708

# 3. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS:

Product Name: Elanco AF0374 Surmax 200

Avilamycin Premix

**Active Constituent/s:** 200 g/kg avilamycin **Applicant Name:** Elanco Animal Health A Div

Of Eli Lilly Aust Pty Ltd **Applicant ACN:** 000 233 992

**Summary of Use:** An aid in the prevention of necrotic enteritis due to *Clostridium perfringens* 

in broiler chickens.

**Date of Registration:** 21 July 2008 **Label Approval No:** 62195/25kg/0508

**Product Name:** Rumevite 5 Year Sheep

Selenium Pills

Active Constituent/s: 50 g/kg selenium

(elemental).

Applicant Name: Ridley AgriProducts Pty Ltd

**Applicant ACN:** 006 544 145

**Summary of Use:** For the prevention and correction of selenium responsive conditions in

sheep for a period of 5 years. **Date of Registration:** 22 July 2008 **Label Approval No:** 62114/500/0807

**Product Name:** Rumevite Cattle Cobalt Pills **Active Constituent/s:** 300 g/kg cobalt oxide. **Applicant Name:** Ridley AgriProducts Pty Ltd

**Applicant ACN:** 006 544 145

**Summary of Use:** For the prevention and correction of cobalt responsive conditions in

cattle.

**Date of Registration:** 22 July 2008 **Label Approval No:** 62116/100/0807

**Product Name:** Rumevite Cattle Selenium Pills **Active Constituent/s:** 100 g/kg selenium

(elemental).

Applicant Name: Ridley AgriProducts Pty Ltd

**Applicant ACN:** 006 544 145

**Summary of Use:** For the prevention and correction of selenium responsive conditions in

**Date of Registration:** 24 July 2008 **Label Approval No:** 62118/100/0807

**Product Name:** Rumevite Sheep Cobalt Pills **Active Constituent/s:** 300 g/kg cobalt oxide. **Applicant Name:** Ridley Agriproducts Pty Ltd

**Applicant ACN:** 006 544 145

Summary of Use: For the prevention and correction of cobalt responsive conditions in

sheep.

Date of Registration: 25 July 2008 **Label Approval No:** 62120/500/0807

Product Name: Elanco AH0493 Extinosad

Pour-On For Sheep

Active Constituent/s: 20 g/L spinosad

**Applicant Name:** Elanco Animal Health A Div

Of Eli Lilly Aust Pty Ltd **Applicant ACN: 000 233 992** 

Summary of Use: For the control of lice (Bovicola ovis) on sheep with short wool and long wool, including strains resistant to synthetic

pyrethroids.

**Date of Registration:** 31 July 2008 **Label Approval No:** 60117/5L/0708, 60117/20L/0708, 60117/25L/0708

**Product Name:** Yodimaspen Ester Of Benzyl

Penicillin For Intramuscular Injection

Active Constituent/s: Each vial contains 5000

mg penethamate hydriodide

**Applicant Name:** Sykes Vet International Pty

Ltd

**Applicant ACN: 085 158 434** 

Summary of Use: For the treatment of mastitis, foot rot, uterine and respiratory infections in cattle caused by gram positive bacteria susceptible to penethamate hydriodide. Date of Registration: 31 July 2008 Label Approval No: 61252/5g/0208,

61252/15mL/0208, 61252/2/0208, 61252/4/0208, 61252/12/0208, 61252/0208

**Product Name:** Coopers Pinkeye Ointment Active Constituent/s: 833 mg per 5g tube of

cloxacillin as the benzathine salt

Applicant Name: Schering-Plough Pty Limited

**Applicant ACN: 000 235 245** 

**Summary of Use:** For the treatment of bovine keratoconjunctivitis caused by cloxacillinsusceptible bacteria including Moraxella bovis in cattle, sheep, horse, dogs and cats.

Date of Registration: 4 August 2008 Label Approval No: 63177/5G/0608, 63177/20X5g/0608, 63177/0608

**Product Name:** Avomec Triple Combination

Drench For Sheep

Active Constituent/s: 1 g/L abamectin, 33.9 g/L levamisole as levamisole hydrochloride, 2.2 g/L cobalt as cobalt disodium EDTA, 0.5 g/L selenium as sodium selenate, 22.7 g/L oxfendazole

Applicant Name: Merial Australia Pty Ltd

**Applicant ACN:** 071 187 285

Summary of Use: For the control and treatment

of internal parasites of sheep.

**Date of Registration:** 5 August 2008 **Label Approval No:** 62706/1L/0208, 62706/5L/0208, 62706/10L/0208

**Product Name:** NV Tranquil Paste

Active Constituent/s: 260 mg/g L-Tryptophan.

Applicant Name: Nature Vet Pty Limited

**Applicant ACN:** 002 692 426

Summary of Use: May assist in calming

nervous horses.

**Date of Registration:** 6 August 2008 Label Approval No: 60846/30G/0708,

60846/0708

Product Name: Rufus & Coco Flea Flee Shampoo With A Fresh Scent For Control Of Fleas, Lice And Aids Control Of Adult Brown Dog Ticks Suitable For Dogs, Cats, Puppies And

Kittens Natural Pyrethrins

Active Constituent/s: 10 g/L piperonyl

butoxide, 1 g/L pyrethrins.

Applicant Name: Rufus & Coco Pty Ltd

**Applicant ACN:** 123 213 070

Summary of Use: For the control of fleas (Ctenocephalides spp), lice (Trichodectes canis and *Heterodoxus spp*), aids in control of adult brown dog ticks (Rhipicephalus sanguineus). Does not control the paralysis tick (Ixodes holocyclus).

Date of Registration: 8 August 2008 **Label Approval No:** 62786/200ml/0808

Product Name: Rufus & Coco Itch Relief Medicated Shampoo With A Fresh Scent Helps Treat Non-Specific Dermatoses And Fungal Infections Suitable For Dogs And Cats

Active Constituent/s: 10 g/L selenium sulfide. Applicant Name: Rufus & Coco Pty Ltd

**Applicant ACN:** 123 213 070

Summary of Use: For aid in treatment of nonspecific dermatoses and fungal infections in dogs and cats.

**Date of Registration:** 11 August 2008 **Label Approval No:** 62754/200ml/0808

**Product Name:** Feliway Spray Analogue Of

Feline Facial Pheromones

Active Constituent/s: 100 mg/mL Synthetic analogue of F3 fraction feline facial pheromon in 89.2% ethanol.

**Applicant Name:** Virbac (Australia) Pty Ltd

**Applicant ACN:** 003 268 871

**Summary of Use:** Aids in alleviating signs associated with fear and stress in kittens and

Date of Registration: 14 August 2008 **Label Approval No:** 59464/60ml/0608

59464/0608

# 4. LISTED REGISTERED CHEMICAL PRODUCTS

Product Name: Vetafarm K9-Ezybones Joint

Health Chews For Dogs

**Active Constituent/s:** Each chew contains 200 mg chondroitin sulfate, 300 mg glucosamine

Applicant Name: Vetafarm Pty Ltd

**Summary of Use:** Listed registration of an oral chew product for use in dogs that may help

improve joint health and function. **Date of Registration:** 31 July 2008

**Product Number:** 62848

#### 5. VARIATIONS

**Product Name:** Moneco 200 Granular For Cattle, Goats And Poultry

**Applicant Name:** International Animal Health Products

Pty Ltd

**Applicant ACN: 003 185 699** 

**Summary of Variation:** To change the product name and presentation from "Moneco 200 Feed Additive Powder for Cattle, Goats and Poultry" to "Moneco 200 Granular for Cattle, Goats and Poultry".

**Date of Variation:** 22 July 2008 **Label Approval No:** 52208/20kg/0108,

52208/25kg/0108

**Product Name:** Carprieve 50 mg Tablets For

Dogs

**Applicant Name:** Norbrook Laboratories

Australia Pty Limited

**Applicant ACN:** 080 972 596

**Summary of Variation:** Change of product name from "Norocarp 50 mg Tablets For Dogs" to "Carprieve 50 mg Tablets For Dogs".

**Date of Variation:** 22 July 2008 **Label Approval No:** 54884/50B/0408, 54884/100B/0408, 54884/250B/0408, 54884/500B/0408, 54884/100T/0408, 54884/250T/0408, 54884/500T/0408, 54884/0408

**Product Name:** Carprieve 20 mg Tablets For

Dogs

**Applicant Name:** Norbrook Laboratories

Australia Pty Limited

**Applicant ACN:** 080 972 596

**Summary of Variation:** Change of product name from "Norocarp 20 mg Tablets For Dogs" to "Carprieve 20 mg Tablets For Dogs".

**Date of Variation:** 22 July 2008 **Label Approval No:** 54885/100B/0408, 54885/500B/0408, 54885/100T/0408, 54885/500T/0408, 54885/0408

**Product Name:** Deltamox 200 Broad Spectrum

Antibiotic

**Applicant Name:** Delvet Pty Ltd **Applicant ACN:** 072 484 167

Summary of Variation: Minor variation to the formulation, change of name from "Deltamox 200 Tabs Broad Spectrum Antibiotic" to "Deltamox 200 Broad Spectrum Antibiotic", confirmation of pack size, update of label to comply with current requirements and change of manufacturer site.

**Date of Variation:** 31 July 2008 **Label Approval No:** 36691/500/0108

Product Name: Mortein Ultra Low Allergenic Kills

Fast Fly Killer

Applicant Name: Reckitt Benckiser (Australia) Pty

Limited

**Applicant ACN:** 003 274 655

Summary of Variation: Variation to change product name from "Mortein Ultra Low Allergenic Fly Spray Kills Fast" to "Mortein Ultra Low Allergenic Kills Fast Fly Killer"

**Date of Variation:** 1 August 2008 **Label Approval No:** 54137/250g/0508,

54137/350g/0508

**Product Name:** Alamycin 10 Injection Oxytetracycline Hydrochloride 100mg/mL **Applicant Name:** Norbrook Laboratories

Australia Pty Limited

**Applicant ACN:** 080 972 596

Summary of Variation: Change of product

name from "Alamycin 10 Injection

Oxytetracycline 100 mg/mL" to "Alamycin 10 Injection Oxytetracycline Hydrochloride 100 mg/mL".

mg/ml.

**Date of Variation:** 8 August 2008 **Label Approval No:** 37040/100mL/0608,

37040/250mL/0608

**Product Name:** Metomide Anti-Emetic Sterile

Injection

**Applicant Name:** Delvet Pty Ltd **Applicant ACN:** 072 484 167

**Summary of Variation:** Change of product name from "Metomide Anti-Emetic Sterile Injection For Dogs And Cats" to "Metomide Anti-Emetic Sterile Injection".

Date of Variation: 8 August 2008 Label Approval No: 36700/20/0108

#### 6. RESTRICTED PRODUCT VARIATION

Product Name: Applicant Name: Applicant ACN: Summary of Variation: Date of Variation: Label Approval No:

"No entries"

#### **NOTICE**

## ethoxysulfuron

in the product: Hero Selective Herbicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Limited for registration of a new product containing the active constituent *ethoxysulfuron*. The product is *HERO SELECTIVE HERBICIDE*. The product is for post-harvest control of nutgrass in sugarcane.

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application 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 application. Comments must be received by the APVMA within 28 days of the date of this notice (i.e. by **30 September 2008**).

#### **Particulars of Application**

Proposed product name: HERO SELECTIVE HERBICIDE
Applicant company: Bayer CropScience Pty Limited

Name of active constituent: ethoxysulfuron

Formulation Type: water dispersible granule

Signal heading: Schedule 5

Statement of claims: For the post-emergent control of nutgrass in Sugarcane.

Pack sizes: 1, 1.5, 2 and 5 kg

Withholding period:

Harvest (sugarcane): Do not harvest for 19 weeks after application.

Grazing: Do not graze or cut for stockfood for 19 weeks after application.

The following Maximum Residue Limits (MRLs) are recommended in relation to the proposed use of *HERO SELECTIVE HERBICIDE*:

Table-1: Ethoxysulfuron Sugarcane and milks \*0.01 mg/kg

Edible offal\*\* and meat\*\* \*0.05 mg/kg

Table-4: Ethoxysulfuron Sugarcane fodder (fresh) and forage \*0.01 mg/kg

(\* : Limit of quantitation [LOQ] for active in the relevant commodity)

(\*\*: of mammalian origin only)

Summary of the APVMA's evaluation of *HERO SELECTIVE HERBICIDE* 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 Office of Chemical Safety (OCS) of the Australian Government Department of Health and Ageing has conducted an occupational health and safety (OHS) risk-assessment on HERO SELECTIVE HERBICIDE.

The OCS (OHS section) reports that *HERO SELECTIVE HERBICIDE* has low acute oral and dermal toxicity in rats. Based on the toxicity of ethoxysulfuron, the product is expected to have low inhalation toxicity. The product is a moderate eye irritant in rabbits, but is not a skin irritant in rabbits or a skin sensitiser in guinea pigs. The main hazards associated with repeat exposure to the product are systemic effects on liver and changes in haematology parameters.

Ethoxysulfuron is not listed on the NOHSC *List of Designated Hazardous Substances*. HERO SELECTIVE HERBICIDE is classified as hazardous according to NOHSC Approved Criteria for Classifying Hazardous Substances based on its eye irritation effects.

HERO SELECTIVE HERBICIDE will be formulated overseas and imported into Australia in sale packs. Transport workers, store persons and retailers will handle packaged product and could only become contaminated if packaging were breached. The product will be packed in 1, 1.5, 2 and 5 kg polyamide/HDPE containers with 63 mm diameter neck.

End-users may be exposed to the product when opening containers, preparing spray, applying spray, maintaining equipment and clearing up spills. In addition, workers reentering treated crops to carry out crop management practices can be exposed to product residues.

The risk assessment indicates that cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length PVC gloves and face shield or goggles should be worn when opening the container and preparing spray.

The Office of Chemical Safety (OCS) concluded that *HERO SELECTIVE HERBICIDE* can be used safely by workers, when handled in accordance with the control measures indicated in its assessment.

The APVMA accepts the findings and recommendations of the occupational health and safety evaluation by the OCS.

Hence the APVMA is satisfied that the proposed use of *HERO SELECTIVE HERBICIDE* would not be an undue hazard to the safety of people exposed to it during its handling and use.

(ii) Residue data was assessed by the APVMA and Maximum Residue Limits (MRLs) and Withholding Periods (WHPs) were set for *HERO SELECTIVE HERBICIDE* when used on sugarcane.

The chronic dietary exposure to ethoxysulfuron is estimated by the National Estimated Daily Intake (NEDI) calculation. The NEDI for ethoxysulfuron is equivalent to 0.3% of the ADI. It is concluded that the chronic dietary exposure is small and the risk is acceptable. .

The acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. The NESTIs for all relevant commodities (mammalian meat, edible mammalian offal, milks and sugarcane) are each less than 0.5% of the acute reference dose

(ArfD) for children of age 2 years and of age 2-6 years. It is concluded that the acute dietary exposure is small and the risk is acceptable.

.

Hence the APVMA is satisfied that the proposed use of *HERO SELECTIVE HERBICIDE* will not be an undue hazard to the safety of people using anything containing its residues.

(iii) The Office of Chemical Safety (OCS) of the Australian Government Department of Health and Ageing has conducted a toxicological (Tox) risk-assessment on *HERO SELECTIVE HERBICIDE*.

The OCS (Tox section) reports that ethoxysulfuron is a member of the sulfonylurea group of herbicides, which act by inhibiting acetolactate synthase, thereby blocking the biosynthesis of branched chain amino acids.

Ethoxysulfuron is readily absorbed through the gastrointestinal tract of rats and rapidly excreted in the faeces (through biliary excretion) and urine. The compound is extensively metabolised and has low concentrations in tissues.

Ethoxysulfuron has low acute oral, dermal and inhalation toxicity in rats. It is a slight eye irritant, but is not a skin irritant or a skin sensitiser.

HERO SELECTIVE HERBICIDE also has low oral, dermal and inhalation toxicity, and is a moderate eye irritant, but is not a skin irritant or a skin sensitiser.

The proposed use of ethoxysulfuron is not likely to cause any other significant effects, such as organ change, gland effects, cancer, genetic damage or reproductive anomalies.

Based on a risk assessment of the toxicology, OCS (Tox) considered that there should be no adverse effects on human health from the use of *HERO SELECTIVE HERBICIDE*, when it is used in accordance with the label directions.

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

The APVMA is satisfied that the proposed use of the *HERO SELECTIVE HERBICIDE* is not likely to be harmful to human beings, if used according to the product label directions

(iv) The Department of the Environment, Water, Heritage and the Arts (DEWHA) has assessed environmental fate and toxicity data in support of *HERO SELECTIVE HERBICIDE*. DEWHA has concluded that the risks to the environment from this use are acceptable, provided recommendations made by the DEWHA with respect to application methods and retention of irrigation waters on site are accepted.

Ethoxysulfuron is stable to hydrolysis at environmental pH values but undergoes indirect photolysis in the presence of photosensitisers. Ethoxysulfuron should readily degrade in aerobic soils. In river and lake water/sediment systems, ethoxysulfuron underwent extensive degradation. Ethoxysulfuron is not strongly bound to soils and has medium to high soil mobility. However, significant movement of ethoxysulfuron through the soil profile is not expected to occur.

Ethoxysulfuron is practically non-toxic to birds and mammals. At worst, it is slightly acutely toxic to representative fish species and practically non-toxic to freshwater and

marine invertebrates. Ethoxysulfuron is highly toxic to representative freshwater algae but only slightly toxic to a marine diatom. Ethoxysulfuron is very highly toxic to duckweed but recovery on cessation of exposure is expected.

Ethoxysulfuron exhibited very slight toxicity to honeybees and to earthworms. Substantial effects on non-target terrestrial invertebrates and soil micro-organisms are not expected.

Phytotoxic effects on seedling emergence, plant survival, biomass reduction on non-target terrestrial plants would be expected due to ethoxysulfuron's herbicidal nature.

There is likely to be acceptable aquatic and terrestrial risk as a result of spray drift from the proposed ground application, provided there is compliance with amendments of the label to specify:

- the use of a directed spray application only, and
- that runoff irrigation be retained on the farm.

The APVMA has considered the findings of the Department of the Environment, Water, Heritage and the Arts and accepts the findings, conclusions and recommendations of its advisers on these criteria.

Consequently the APVMA is satisfied that the proposed use of the new product *HERO SELECTIVE HERBICIDE*, containing the new active constituent ethoxysulfuron, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

(v) Export of treated produce containing finite residues of ethoxysulfuron may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Hence the APVMA conducted a risk assessment for ethoxysulfuron, with respect to possible adverse effects on trade between Australia and places outside Australia.

Sugar is a major export commodity for Australia, with a value of \$1.2 - \$1.6 billion dollars.

There are no CODEX tolerances for ethoxysulfuron, but no detectable residues are expected to occur in sugar cane or processed sugar commodities. Detectable residues are also not expected to occur in cane tops after the proposed grazing withholding period. It is expected that livestock dietary exposure will be negligible.

Therefore APVMA is satisfied that the proposed use of *HERO SELECTIVE HERBICIDE* would not adversely affect trade between Australia and places outside Australia.

In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:

(i) The APVMA is satisfied the data from trials supporting the efficacy of *HERO SELECTIVE HERBICIDE* adequately demonstrates that under local conditions this product is effective for the proposed uses.

### **Public Release Summary**

A Public Release Summary (PRS) of the evaluation is available on the APVMA website, <a href="https://www.apvma.gov.au">www.apvma.gov.au</a> or by contacting Colin McCormack on telephone (02) 6210 4748.

Submissions on the APVMA's proposal to grant the application for registration should be in writing and addressed to:

Ron Marks
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4772 Fax: (02) 6210 4776 Email: ron.marks@apvma.gov.au

#### NOTICE

# Nanomaterials In Agricultural or Veterinary Chemicals, or Agricultural or Veterinary Chemical Products - Call For Information

This notice is directed to all persons who have manufactured or imported, or intend to manufacture or import, agricultural or veterinary chemicals, or agricultural or veterinary chemical products, containing nanomaterials during 2008. This includes those persons who are involved in the formulation, fabrication and modification of agricultural or veterinary chemical products containing nanomaterials. This notice is also directed to those persons who are involved in the manufacturing of agricultural or veterinary chemicals, or agricultural or veterinary chemical products containing nanomaterials for research and development purposes.

Nanotechnology refers to the design, characterisation and application of materials engineered at the molecular (nanometre) level to take advantage of their small size and/or novel properties. Currently there is no agreed national or international definition of nanomaterials. For the purpose of this call for information, the current working definition of a nanomaterial will apply *viz* a material engineered to have at least one dimension of 100 nm or less. A nanometer is one one-billionth of a metre.

To date, little activity involving nanotechnology has occurred in the agricultural and animal health sectors; however, applications of nanotechnology are now beginning to emerge. The APVMA is responsible for the registration of agricultural and veterinary chemicals in Australia, and aims to ensure that nanomaterials are introduced safely and responsibly.

From a regulatory perspective, it is important to recognise that the Australian Office of Nanotechnology within the Department of Innovation, Industry, Science and Research is implementing the National Nanotechnology Strategy. A key priority of the National Nanotechnology Strategy is to review the impact of nanotechnology on regulatory frameworks. The release of a report entitled "A review of possible impacts of nanotechnology on Australia's regulatory framework" was an important milestone in meeting this goal. The report noted that some applications and products of nanotechnology may present health, safety and environmental (HSE) hazards and risks. It also identified some potential gaps in existing regulatory frameworks. The APVMA will address the findings of the report progressively over coming years. It is important and timely that the APVMA collects information on current and planned activities related to nanoscale agricultural and veterinary chemicals, gains an appreciation of their potential health and environmental impacts, and ensures that its regulatory framework is able to adequately assess the potential risks of nanomaterials.

The APVMA is seeking information on uses and quantities of nanomaterials imported or manufactured for use in agricultural or veterinary chemicals, or agricultural or veterinary chemical products, during 2008. This information will provide the APVMA with a better understanding of the nanomaterials available on the market, or close to commercialisation, for use in Australian agriculture. It will focus the efforts of the APVMA on ensuring the adequacy of the regulatory scheme as well as assist with future dialogue between the APVMA and industry in relation to the regulation of nanomaterials. Using the information received, the APVMA will prepare a report on the extent and scope of the use of nanomaterials in agricultural and veterinary chemicals in Australia. Material which is commercially confidential information, such as company details and chemical identity data will not be published or released.

The following specific information is sought for nanomaterials for 2008 (including estimated usage):

- Chemical names, trade name and formula (CAS number if available)
- Estimate of the total quantity (amount/year) of nanomaterials imported to Australia (in raw form or in products) and/or manufactured in Australia;
- Uses of nanomaterials in agricultural or veterinary chemicals, or in agricultural or veterinary chemical products, the concentration of nanomaterials in products and whether any nanomaterials are marketed in Australia.

Responses regarding the uses and quantities of nanomaterials are required on the attached form by 12 December 2008. A separate form should be completed for each nanomaterial. Respondents who prefer that specific information not be published or released based on a claim that the material is confidential commercial information should indicate this on the form.

This call for information applies only to nanomaterials used in agricultural or veterinary chemicals, or agricultural or veterinary chemical products.

If you would like any further information, please contact Dr Phil Reeves on 02 6210 4819.

Completed form(s) should be sent to:

Dr Phil Reeves Regulatory Strategy and Compliance APVMA PO Box 6182 Kingston ACT 2604

## **RESPONSE TO NANOMATERIALS** – Call for information

Please use a separate form for each Nanomaterial.

1. Company Name						
Type of Organisation						
Address						
Contact Name				Email		
Phone				Fax		
2. Chemical Name of Na						
Trade Name of Nanomat						
Chemical Formula of Na						
Chemical Abstract Service	ce Number (CA	S No)				
3. Do you manufacture						YES □ NO □
If yes, please provide an	estimate of the	quantity y	ou manufa	cture annua	ılly	
[milligrams (mg), grams	(g) or kilogram	s (kg)]				
4. Do you import the Na	anomaterial?					YES □ NO □
If yes, please provide an			of chemica	ıl you impo	ort annually	
[milligrams (mg), grams	(g) or kilogram	s (kg)]				
5 Do you import formu	lated products	s containi	ng thịc No	nomotorio	19	VES II NO II
5. Do you import formu						YES   NO
5. Do you import formu Name/Description of t		Conce	ntration	]	Form	Total Weight
		Conce		(solid	Form l, crystal,	Total Weight (weight/year)
		Conce	ntration	(solid	Form l, crystal, der, dust,	Total Weight (weight/year) (mg, g, kg)
		Conce	ntration	(solid power emulsion	Form l, crystal, der, dust, n, suspension	Total Weight (weight/year)
		Conce	ntration	(solid power emulsion or	Form I, crystal, der, dust, a, suspension other)	Total Weight (weight/year) (mg, g, kg)
		Conce	ntration	(solid power emulsion or	Form l, crystal, der, dust, n, suspension	Total Weight (weight/year) (mg, g, kg)
		Conce	ntration	(solid power emulsion or	Form I, crystal, der, dust, a, suspension other)	Total Weight (weight/year) (mg, g, kg)
		Conce	ntration	(solid power emulsion or	Form I, crystal, der, dust, a, suspension other)	Total Weight (weight/year) (mg, g, kg)
		Conce	ntration	(solid power emulsion or	Form I, crystal, der, dust, a, suspension other)	Total Weight (weight/year) (mg, g, kg)
		Conce	ntration	(solid power emulsion or	Form I, crystal, der, dust, a, suspension other)	Total Weight (weight/year) (mg, g, kg)
Name/Description of t	the Product	Conce (%	ntration w/w)	(solid power emulsion or [pleas	Form I, crystal, der, dust, a, suspension other)	Total Weight (weight/year) (mg, g, kg) [please specify]
Name/Description of to	the Product	Conce (%	ntration w/w) anomateri	(solid power emulsion or [pleas	Form I, crystal, Ider, dust, In, suspension Other) In specify	Total Weight (weight/year) (mg, g, kg) [please specify]
Name/Description of t	the Product	Conce (%)	ntration w/w) anomateri ntration	(solid power emulsion or [pleas	Form I, crystal, Ider, dust, In, suspension Other) In e specify  Form	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □ Total Weight
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri	al?	Form I, crystal, der, dust, I, suspension other) e specify]  Form I, crystal,	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year)
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri ntration	al?	Form I, crystal, der, dust, I, suspension other) e specify  Form I, crystal, der, dust,	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year) (mg, g, kg)
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri ntration	al?	Form I, crystal, der, dust, In, suspension other) In e specify  Form I, crystal, der, dust, In, suspension	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year)
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri ntration	al?	Form I, crystal, Ider, dust, In, suspension Other) Ider specify Ider specify Ider specify Ider, dust, In, suspension Other specify Ider	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year) (mg, g, kg)
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri ntration	al?	Form I, crystal, der, dust, In, suspension other) In e specify  Form I, crystal, der, dust, In, suspension	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year) (mg, g, kg)
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri ntration	al?	Form I, crystal, Ider, dust, In, suspension Other) Ider specify Ider specify Ider specify Ider, dust, In, suspension Other specify Ider	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year) (mg, g, kg)
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri ntration	al?	Form I, crystal, Ider, dust, In, suspension Other) Ider specify Ider specify Ider specify Ider, dust, In, suspension Other specify Ider	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year) (mg, g, kg)
Name/Description of to	the Product	Conce (%)	ntration w/w) anomateri ntration	al?	Form I, crystal, Ider, dust, In, suspension Other) Ider specify Ider specify Ider specify Ider, dust, In, suspension Other specify Ider	Total Weight (weight/year) (mg, g, kg) [please specify]  YES □ NO □  Total Weight (weight/year) (mg, g, kg)

#### AMENDMENT No. 3L

# 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.

COMPOUN	MPOUND FOOD		MRL (mg/kg)	
Abamectin DELETE: VO	0455	Peppers, Sweet [Capsicum]	0.02	
	0.00	1 opposit, a weet [ cupateum]	0.02	
ADD: VO	0051	Peppers	T0.02	
Amitraz DELETE:				
MO	0107	Edible offal of cattle, pigs and sheep	0.5	
MM	0097	Meat of cattle, pigs and sheep	0.1	
ADD:				
MO	0105	Edible offal (mammalian)	0.5	
MM	0095	Meat (mammalian)	0.1	
Clothianidin	ı			
ADD: GS	0659	Sugar cane	T0.2	
Oxamyl				
ADD: VR	0508	Sweet potato	T0.5	
Spinosad				
DELETE:	0105	T 121 66 1 / 12 12	TD0 4	
MO MM	0105 0095	Edible offal (mammalian) Meat (mammalian)[in the fat]	T0.2 T1	
141141	0075	mannanan/[m the fat]	11	
ADD:				
MO	0105	Edible offal (mammalian)	0.5	
MM	0095	Meat (mammalian)[in the fat]	2	

# TABLE 4: MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN ANIMAL FEED COMMODITIES

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

<b>COMPOUND</b>	ANIMAL FEED COMMODITY	MRL (mg/kg)
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#### Clothianidin

ADD:

$\mathbf{AM}$	0659	Sugar cane fodder	T0.5
$\mathbf{AV}$	0659	Sugar cane forage	T0.5

For further information please contact:
Michelle Hemming
Residues Contact Officer
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4837 Fax: (02) 6210 4840

Email: michelle.hemming@apvma.gov.au

## Notice Under Section 104 of the Agvet Codes No.0008 of 2008

On the 26 June 2008 4Farmers Pty Ltd voluntarily reported to the Australian Pesticides and Veterinary Medicines Authority (APVMA) that they were in possession of a quantity of unregistered agricultural chemical product. 4Farmers also advised that they had voluntarily quarantined this product from supply.

In the prudent discharge of its regulatory responsibilities the APVMA issued a Notice, on 14 July 2008, under s101 of the Agvet Codes in relation to 4Farmers Omethoate 290 Insecticide (all pack sizes).

The Notice requires the supplier to not supply the product, quarantine any stocks they hold and to report to the APVMA.

The product is an agricultural chemical product and the APVMA has not registered the product under the Agvet Codes.

#### **Supplier Details**

4Farmers Pty Ltd Unit 1/70 McDowell Street Welshpool WA 6106

For further information about this matter, please contact:

Drew Ward A/g Senior Compliance Analyst Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

Phone: 02 6210 4800

Email: drew.ward@apvma.gov.au

#### NOTICE

### The Adverse Experience Reporting Program for Veterinary Medicines and Agricultural Chemicals Request for Annual Summaries

Registrants are reminded that in accordance with the Guidelines for the Adverse Experience Reporting Program for veterinary medicines (AERP Vet) and agricultural chemicals (AERP Ag), they are requested to provide the APVMA with annual summary of all suspected adverse experiences by the close of business 30 September 2008.

These reports should be prepared in accordance with the Guidelines for Registrants for the AERP Vet and AERP Ag that can be found at:

http://www.apvma.gov.au/qa/vetaerp.shtml http://www.apvma.gov.au/qa/agaerp.shtml

or by contacting Elvira Currie on (02) 6210 4806.

APVMA contact

Dr Elvira Currie.
Senior Reviewer – Adverse Experience Reporting Program Australian Pesticides and Veterinary Medicines Authority PO Box 6182
KINGSTON ACT 2604
Telephone: (02) 6210 4806

Facsimile: (02) 6210 4810

Email: AERPCoordinator@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: <a href="http://www.apvma.gov.au/actives/downloads/aa\_LZ.pdf">http://www.apvma.gov.au/actives/downloads/aa\_LZ.pdf</a> and <a href="http://www.apvma.gov.au/actives/downloads/aa\_LZ.pdf">http://www.apvma.gov.au/actives/downloads/aa\_LZ.pdf</a>

## **Approved since Gazette No. 6, 1st December 2007**

For Use in Agricultural Chemical Products:

PROPICONAZOLE	ASTEC LIFESCIENCES LTD	PLOT NO B-18, MIDC INDUSTRIAL AREA MAHAD 402 301 DIST RAIGAD MAHARASHTRA INDIA	62402
TEBUCONAZOLE	JIANGSU AGROCHEM LABORATORY CO LTD	98 MINJIANG RD HI-TECH DEVELOPMENT ZONE CHANGZHOU JIANGSU 213022 PR CHINA	62859
DIMETHOMORPH	MAKHTESHIM CHEMICAL WORKS LTD	NORTHERN INDUSTRIAL ZONE HEBRON ROAD BEER SHEVA 84100 ISRAEL	62732

For enquiries please contact:

Chemistry & Residues

Pesticides Program

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

Phone: 02 6210 4818

Fax: 02 6210 4840

Email: apvma.chemistry@apvma.gov.au

#### **NOTICE**

#### **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:

ANIMAL CONSULTING ENTERPRISES PTY LTD

ACN: 115 191 056 Lot 3, Shed 2 Gildea Lane BENDIGO EAST VIC 3550 **Product Types:\*** 

Category 1: Immunobiologicals (bacterial vaccines)
Step(s) of Manufacture:

Quality assurance (QA) of raw materials, bacterial fermentation, formulation including blending, aseptic filling, sterilisation (heat), microbiological reduction treatment (heat, chemical), packaging, labelling, analysis and testing (physical, microbiological, sterility test), storage and release for supply

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Licence No: 1081

Licence issued 24/07/08, with special conditions.

#### 2. CHANGES TO EXISTING LICENCES:

**AGRICURE PTY LTD** 

**ACN:** 000 178 790 End Gantry Place

Braemar

Via MITTAGONG NSW 2575

**Product Types:\*** 

Category 2: Tablets, creams, lotions, ointments, pastes, powders, sprays, liquids

Category 3: Liquids

Category 4: Premixes, supplements

**Step(s) of Manufacture:** 

Formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, tableting, tablet coating, analysis and testing (physical and chemical), storage and release for supply.

Licence No: 2161

Amended licence issued 31/07/08, extension of licence scope and variation to conditions.

<sup>\*</sup> Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer

**BAYER CROPSCIENCE PTY** 

LTD

**ACN 000 226 022** 16 Lucca Road

WYONG NSW 2259

**Product Types:\*** 

Category 2: Powders and liquids Category 3: Powders and liquids

**Step(s) of Manufacture:** 

Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, filling, packaging, labelling, analysis and testing (physical,

chemical), storage, and release for supply

Licence No: 2171

Amended licence issued 31/07/08, variation to licence

conditions.

**GEORGE WESTON FOODS** 

LTD Trading As: JASOL AUSTRALIA

ACN: 008 429 632 131 Garling Street O'CONNOR WA 6163 Product Types:\*
Category 2: Liquids
Step(s) of Manufacture:

Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical & chemical), storage and

release for supply. **Licence No: 2129** 

Amended licence issued 28/07/08, extension of licence

scope, change of key personnel.

HY GAIN FEEDS PTY LTD

ACN: 006 198 821 10 Hickson Road OFFICER VIC 3809 **Product Types:\*** 

Category 6: Single Step Step(s) of Manufacture:

Packaging, labelling, storage, and release for supply

Licence No: 6088

Amended licence issued 11/07/08, extension of licence

scope, change of key personnel.

\* Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer

#### **JUROX PTY LIMITED**

ACN 000 932 230 85 Gardiners Road

**RUTHERFORD NSW 2320** 

#### **Product Types:\***

Category 1: Sterile products

Category 2: Tablets, creams/lotions, ointments,

pastes, powders, sprays and liquids

Category 3: Liquids, pastes, sprays and powders

**Step(s) of Manufacture:** 

Quality assurance (QA) of raw materials, chemical synthesis, formulation including blending, granulation, filling, aseptic filling, packaging, labelling, strip, blister or sachet packaging, tableting, tablet coating, sterilisation (heat & filtration), microbiological reduction treatment (heat & filtration), analysis and testing (physical, chemical, Limulus Amoebocyte Lysate (LAL) test, sterility testing and microbiological), storage and release for supply

Licence No: 1042

Amended licence issued 24/07/08, extension of licence scope.

#### **NATURE VET PTY LIMITED**

**ACN: 002 692 426** 11 Moores Road

**GLENORIE NSW 2157** 

## **Product Types:\***

Category 1: Sterile products

Category 2: Creams, lotions, pastes, powders, granules,

liquids

Category 4: Premixes and supplements

#### **Step(s) of Manufacture:**

Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, sterilisation (heat and filtration), analysis and testing (physical and chemical), storage and release for supply.

Licence No: 1070

Amended licence issued 30/07/08, extension of licence scope, change of key personnel and variation to conditions.

# TREND LABORATORIES PTY LTD

**ACN 001 627 103** 1 Corella Close

BERKELEY VALE NSW 2261

#### **Product Types:\***

Category 2: Liquids

Category 3: Liquids, sprays, powders

Category 4: Supplements

### **Step(s) of Manufacture:**

Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical, chemical,

microbiological), storage and release for supply

Licence No: 2169

Amended licence issued 24/07/08, change of key

personnel.

<sup>\*</sup> Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer

#### 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 Agyet Code']).

**NIL** 

#### **APVMA Contact:**

Kathryn Winterton **GMP Section** Veterinary Medicines Program Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

(02) 6210 4804 Ph: Fax: (02) 6210 4813

Email: <u>kathryn.winterton@apvma.gov.au</u>

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer

## **Notice of Appointment of Approved Analysts**

# Subsection 69G (2) of the Agricultural and Veterinary Chemicals (Administration) Act 1992

Notice is hereby given that the persons described in Schedule 1 below were duly appointed in accordance with subsection 69G (1) of the Agricultural and Veterinary Chemicals (Administration) Act 1992, as approved analysts for the purposes of the Agvet Codes. This notice is to advise of change of business addresses.

#### Schedule 1

Appointment No. AN084 Mr Vince Murone Analytical Consutling Services C/o Victoria Univesity (Footscray Campus) Building G, Level 6 Room 619 Appointment No. AN085 Mr Sandy Famulari Analytical Consutling Services C/o Victoria Univesity (Footscray Campus) Building G, Level 6 Room 619

APVMA Contact:
Joseph Morrall
Compliance Chemist
Quality Assurance and Compliance Section
Ph: 02 6272 3210

Ph: 02 6272 3210 Fax: 02 6271 6442

E-mail: joseph.morrall@apvma.gov.au