TABLE OF CONTENTS

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

Product Name: Titan Oxyfluorfen 240 EC Herbicide
Active Constituent/s: 240 g/L oxyfluorfen
Applicant Name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574
Summary of Use: For selective control of broadleaf weeds and grasses in fruit, nut trees, vines and vegetables.
Date of Registration: 24 April 2007
Label Approval No: 61537/5/0207, 61537/10/0207, 61537/0207

Product Name: Torpedo Herbicide
Active Constituent/s: 300 g/L clopyralid present as the monoethanolamine salt, 50 g/L florasulam
Applicant Name: Dow AgroSciences Australia Limited
Applicant ACN: 003 771 659
Summary of Use: A herbicide for the post-emergent control or suppression of broadleaf weeds in barley, triticale and wheat.
Date of Registration: 30 April 2007
Label Approval No: 59789/1/0307, 59789/5/0307, 59789/0307

3. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS:

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

Product Name: Regalis Plant Growth Regulator
Active Constituent/s: 100 g/kg prohexadione-calcium
Applicant Name: BASF Australia Ltd
Applicant ACN: 008 437 867
Summary of Use: Water dispersible granule product for the reduction of shoot growth in apples.
Date of Registration: 15 September 2006
Label Approval No: 59683/500g/0806, 59683/1kg/0806, 59683/3kg/0806, 59683/10kg/0806, 59683/0806

Product Name: Bushman Personal Insect Repellent
Active Constituent/s: 400g/kg diethyltoluamide.
Applicant Name: North Queensland Laboratories Pty Ltd
Applicant ACN: 010 700 311
Summary of Use: Registration of a personal repellent to repel sandflies, mosquitoes, ticks leeches and marchflies.
Date of Registration: 17 April 2007
Label Approval No: 60969/60g/0407, 60969/130g/0407, 60969/225g/0407

Product Name: Voodoo Guard Soil Insecticide
Active Constituent/s: 350 g/L imidacloprid.
Applicant Name: Sipcam Pacific Australia Pty Limited
Applicant ACN: 073 176 888
Summary of Use: For the control of greyback cane grub, childers cane grup, silver leaf whitefly in sugar cane and various vegetable crops.
Date of Registration: 17 April 2007
Label Approval No: 60883/1L/0906,

60883/5L/0906, 60883/10L/0906, 60883/20L/0906, 60883/60L/0906, 60883/0906

Product Name: Foliarflo C Seed Treatment
Active Constituent/s: 4 g/L cypermethrin, 150 g/L triadimenol.
Applicant Name: Chemtura Australia Pty Ltd
Applicant ACN: 005 225 507
Summary of Use: For use on wheat, barley and oats for the control of various diseases and pests of stored grain.
Date of Registration: 17 April 2007
Label Approval No: 60516/20L/0207, 60516/100L/0207, 60516/200L/0207

Product Name: Proleaf C Seed Treatment
Active Constituent/s: 4 g/L cypermethrin, 150 g/L triadimenol.
Applicant Name: Chemtura Australia Pty Ltd
Applicant ACN: 005 225 507
Summary of Use: For use on wheat, barley and oats for the control of various diseases and pests of stored grain.
Date of Registration: 17 April 2007
Label Approval No: 60515/20L/0207, 60515/100L/0207, 60515/200L/0207

Product Name: Rentokil Pest Control Rat Radar Rodenticide
Active Constituent/s: 1000 g/kg carbon dioxide
Applicant Name: Rentokil Initial Pty Ltd
Applicant ACN: 000 034 597
Summary of Use: A trap device with pressurised carbon dioxide to kill intruding rats.
Date of Registration: 17 April 2007
Label Approval No: 61201/33/0207

Product Name: Defender Maxguard Systemic, Contact & Residual Insecticide Kills & Controls
Active Constituent/s: 0.05 g/L acetamiprid
Applicant Name: Scotts Australia Pty Limited
Applicant ACN: 003 123 162
Summary of Use: For control of sucking pests on indoor and outdoor plants including roses, shrubs, palms, bedding plants and trees.
Date of Registration: 18 April 2007
Label Approval No: 60409/750mL/1106

Product Name: Dupont Velpar K4 Xtruded Herbicide
Active Constituent/s: 132 g/kg hexazinone, 468 g/kg diuron
Applicant Name: Du Pont (Australia) Ltd
Applicant ACN: 000 716 469
Summary of Use: For use in sugar cane for the control of various weeds.
Date of Registration: 19 April 2007
Label Approval No: 60843/0307, 60843/2/0307, 60843/10/0307, 60843/10P/0307, 60843/10b/0307, 60843/12P/0307

Product Name: Derby C Seed Treatment
Active Constituent/s: 150 g/L triadimenol, 4 g/L cypermethrin
Applicant Name: Chemtura Australia Pty Ltd
Applicant ACN: 005 225 507
Summary of Use: For use on wheat, barley and oats for the control of various diseases and pests of stored grain.
Date of Registration: 19 April 2007
Label Approval No: 60514/10L/0207

Product Name: IQ Maxi Chlor Platinum Granular Pool Chlorine
Active Constituent/s: 700 g/kg chlorine (Cl) present as calcium hypochlorite
Applicant Name: International Quadratics Pty Ltd
Applicant ACN: 091 533 167
Summary of Use: For the control of algae and bacteria in swimming pools.
Date of Registration: 20 April 2007
Label Approval No: 61320/500G/0906, 61320/2KG/0906, 61320/4KG/0906, 61320/10KG/0906, 61320/20KG/0906, 61320/40KG/0906

Product Name: 4farmers Clodinafop 240 EC Selective Herbicide
Active Constituent/s: 240g/L Clodinafop-propargyl, 60g/L Cloquintocet-mexyl
Applicant Name: 4 Farmers Pty Ltd
Applicant ACN: 067 443 485
Summary of Use: For the control of wild oats, paradoxa grass, canary grass and annual ryegrass in wheat.
Date of Registration: 24 April 2007
Label Approval No: 60849/0107, 60849/1-110L/0107

Product Name: Slugem Snail & Slug Killer Pellets
Active Constituent/s: 15g/kg metaldehyde
Applicant Name: Triox Pty Ltd
Applicant ACN: 068 066 446
Summary of Use: Snail and slug pellets for the control of snail and slugs.
Date of Registration: 24 April 2007
Label Approval No: 61764/25/0307, 61764/500/0307, 61764/1000/0307

Product Name: Hortico Bindii & Clover Killer Hose-On
Active Constituent/s: 15g/L MCPA present as the dimethylamine salt, 2.3gL dicamba present as the dimethylamine salt
Applicant Name: Yates Australia A Div of Orica Australia Pty Ltd
Applicant ACN: 004 117 828
Summary of Use: For the control of bindii,

clover and other broadleaf weeds in lawns.
Date of Registration: 24 April 2007
Label Approval No: 61376/2L/1106

Product Name: Farmoz Mandate Herbicide
Active Constituent/s: 240 g/L clodinafop-propargyl, 60 g/L cloquintocet-mexyl.
Applicant Name: Farmoz Pty Ltd
Applicant ACN: 050 328 973
Summary of Use: For the control of wild oats, paradoxa grass, canary grass and annual ryegrass in wheat.
Date of Registration: 27 April 2007
Label Approval No: 61451/1LAG/0407, 61451/1LLAG/0407, 61451/5AG/0407, 61451/5AGLL/0407, 61451/10AG/0407, 61451/10AGLL/0407, 61451/20AG/0407, 61451/20AGLL/0407, 61451/0407

Product Name: Farmoz Amplify Spray Tank Adjuvant
Applicant Name: Farmoz Pty Limited
Applicant ACN: 050 328 973
Summary of Use: For use as a spray tank adjuvant with Farmoz Pentagon Herbicide only.
Date of Registration: 27 April 2007
Label Approval No: 61180/5/0407, 61180/10/0407, 61180/20/0407

Product Name: Dupont Diuron Xtruded Herbicide
Active Constituent/s: 900 g/kg diuron
Applicant Name: Du Pont (Australia) Ltd
Applicant ACN: 000 716 469
Summary of Use: For selective weed control in various crops.
Date of Registration: 27 April 2007
Label Approval No: 60826/0207, 60826/10/0207, 60826/10b/0207

Product Name: Decoy 200 Herbicide
Active Constituent/s: 200 g/L fluroxypyr present as the methylheptyl ester
Applicant Name: Crop Care Australasia Pty Ltd
Applicant ACN: 061 362 347
Summary of Use: For the control of a range of broadleaf weeds in fallow, lucerne, maize, millets, pastures, poppies, sorghum, sugar cane, sweetcorn and winter cereals. Also for the control of woody weeds in agricultural non-crop areas, commercial and industrial areas, forests, pastures and rights-of-way.
Date of Registration: 27 April 2007
Label Approval No: 61676/1L/0207, 61676/5L/0207, 61676/20L/0207, 61676/110L/0207, 61676/200L/0207, 61676/1000L/0207, 61676/0207

Product Name: St.Marys Pool Shop Pro Chlor Sanitiser
Active Constituent/s: 100 g/kg sodium tetraborate pentahydrate, 810 g/kg chlorine present as trichloroisocyanuric acid.
Applicant Name: W Griffin & J Aronis T/A St Marys Pool Services
Summary of Use: For the control of algae and bacteria in outdoor swimming pools and to increase the longevity of chlorine in outdoor pools.
Date of Registration: 1 May 2007
Label Approval No: 61711/1KG/0207, 61711/4KG/0207, 61711/10KG/0207

Product Name: Mosquito-Band Anti-Insect Band
Active Constituent/s: 0.75 g citronella oil
Applicant Name: Franbar Glen Pty Ltd T/A Intelligent Health Systems
Applicant ACN: 109 292 284
Summary of Use: Personal insect repellent in a silicon band for helping to repel mosquitoes and other insects.
Date of Registration: 1 May 2007
Label Approval No: 60836/2/0407

Product Name: Farmoz Pentagon Herbicide
Active Constituent/s: 600 g/L tralkoxydim
Applicant Name: Farmoz Pty Limited
Applicant ACN: 050 328 973
Summary of Use: For the control of certain weeds in wheat, barley, rye and triticale.
Date of Registration: 1 May 2007
Label Approval No: 61183/1AG/0307, 61183/1AGLL/0307, 61183/5AG/0307, 61183/5AGLL/0307, 61183/10AG/0307, 61183/10AGLL/0307, 61183/20AG/0307, 61183/20AGLL/0307

Product Name: Raid 4 Seasons Moth Protection Gentle Fragrance
Active Constituent/s: 2.7 g/kg transfluthrin
Applicant Name: S.C. Johnson & Son Pty Ltd
Applicant ACN: 000 021 009
Summary of Use: Repels moths from clothes in drawers and wardrobes.
Date of Registration: 3 May 2007
Label Approval No: 60323/4/1206, 60323/8/1206

Product Name: Dow Agrosciences Amine 625 Herbicide
Active Constituent/s: 625g/L 2,4-D present as the dimethyl amine salt
Applicant Name: Dow Agrosciences Australia Limited
Applicant ACN: 003 771 659
Summary of Use: For the control of broadleaf weeds before sowing cereals and pastures; and

in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas.
Date of Registration: 4 May 2007
Label Approval No: 61117/0307, 61117/20/0307, 61117/100/0307, 61117/110/0307, 61117/1000/0307

Product Name: Choice Cleodim 240 Herbicide
Active Constituent/s: 240 g/L clethodim
Applicant Name: Grow Choice Pty Limited
Applicant ACN: 069 839 961
Summary of Use: For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans.
Date of Registration: 4 May 2007
Label Approval No: 61532/1L/1206, 61532/5L/1206, 61532/10L/1206, 61532/20L/1206, 61532/60L/1206, 61532/110L/1206, 61532/1206

Product Name: Innova Diflufenican 500 Herbicide
Active Constituent/s: 500 g/L diflufenican
Applicant Name: Syngenta Crop Protection Pty Limited
Applicant ACN: 002 933 717
Summary of Use: For the control of certain weeds in clover-based pasture, field peas, lentils, lupins and oilseed poppy.
Date of Registration: 7 May 2007
Label Approval No: 61647/5/0207

Product Name: Graslan Aerial Herbicide
Active Constituent/s: 200 g/kg tebuthiuron
Applicant Name: Dow Agrosciences Australia Limited
Applicant ACN: 003 771 659
Summary of Use: For the control of brigalow re-growth, tea tree re-growth, Mimosa pigra and certain woody weeds on grazing lands
Date of Registration: 9 May 2007
Label Approval No: 61214/25/0207, 61214/500-1000/0207, 61214/0207

Product Name: David Grays Imidacloprid 200 SC Termiticide
Active Constituent/s: 200 g/L imidacloprid
Applicant Name: Bayer Cropscience Pty Ltd
Applicant ACN: 000 226 022
Summary of Use: For management of subterranean termites in existing and new buildings, around service poles and fence posts.
Date of Registration: 9 May 2007
Label Approval No: 61097/1L/0906, 61097/2.5L/0906, 61097/5L/0906, 61097/10L/0906

Product Name: Woodcare Timber Preservative For Landscaping & Fencing Timbers Woodtreat LTF
Active Constituent/s: 20 g/L copper (Cu) present as copper naphthenate
Applicant Name: Preschem Pty Ltd
Applicant ACN: 006 867 929
Summary of Use: Timber preservative for landscaping & fencing timbers for protection against fungal decay and borers.
Date of Registration: 9 May 2007
Label Approval No: 60814/500mL/1206, 60814/2L/1206, 60814/4L/1206, 60814/10L/1206, 60814/20L/1206, 60814/200L/1206

Product Name: Timtech Azguard Losp Wood Preservative
Active Constituent/s: 3.2 g/L permethrin, 4.5 g/L propiconazole, 4.5 g/L tebuconazole
Applicant Name: Timtech Chemicals Pty Ltd
Applicant ACN: 096 245 108
Summary of Use: For the protection of softwood timber to be used for hazard level H3 (outside and above ground) situations against fungal decay, and timber insects, such as borers and termites.
Date of Registration: 9 May 2007
Label Approval No: 60859/BULK/0307, 60859/1000L/0307

Product Name: On Farm Quatsan
Active Constituent/s: 30 g/L decyl-octyl-dimethyl-ammonium chloride, 12 g/L dioctyl-dimethyl-ammonium chloride, 40 g/L benzalkonium chloride, 18 g/L didecyl dimethyl ammonium chloride.
Applicant Name: Applied Australia Pty Ltd
Applicant ACN: 082 810 973
Summary of Use: For sanitising poultry sheds, animal pens and farming equipment
Date of Registration: 10 May 2007
Label Approval No: 60990/25/0107, 60990/200/0107

Product Name: Intake Combi In-Furrow And Foliar Fungicide
Active Constituent/s: 250 g/L flutriafol
Applicant Name: Crop Care Australasia Pty Ltd
Applicant ACN: 061 362 347
Summary of Use: For the control of certain fungal diseases in wheat, barley and canola when mixed with fertiliser or applied as a foliar spray
Date of Registration: 10 May 2007
Label Approval No: 61702/10L/0107, 61702/110L/0107, 61702/200L/0107, 61702/1000L/0107

Product Name: Inquest Herbicide
Active Constituent/s: 520 g/L haloxyfop

(present as the haloxyfop-P-methyl ester)
Applicant Name: Sipcam Pacific Australia Pty Limited
Applicant ACN: 073 176 888
Summary of Use: For post emergent control of a wide range of annual and perennial grass weeds in a variety of situations.
Date of Registration: 10 May 2007
Label Approval No: 61752/5L/0107, 61752/10L/0107, 61752/20L/0107, 61752/0107

Product Name: Garrards Imidacloprid Termiticide
Active Constituent/s: 200g/L imidacloprid
Applicant Name: Bayer Cropscience Pty Ltd
Applicant ACN: 000 226 022
Summary of Use: For management of subterranean termites in existing and new buildings, around service poles and fence posts.
Date of Registration: 11 May 2007
Label Approval No: 61098/1L/0906, 61098/2.5L/0906, 61098/5L/0906, 61098/10L/0906

Product Name: Aerogard Family Protection Low Irritant Low Scent Personal Insect Repellent
Active Constituent/s: 11 g/kg n-octyl bicycloheptene dicarboximide, 52.2 g/kg diethyltoluamide
Applicant Name: Reckitt Benckiser (Australia) Pty Limited
Applicant ACN: 003 274 655
Summary of Use: For the control of mosquitos and biting insects.
Date of Registration: 11th May 2007
Label Approval No: 61739/100G/0307, 61739/150G/0307, 61739/250G/0307

Product Name: Ospray Respond Herbicide
Active Constituent/s: 400g/kg tralkoxydim
Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169
Summary of Use: For the control of wild oats, annual ryegrass and suppression of annual phalaris in wheat, barley, rye and triticale.
Date of Registration: 11 May 2007
Label Approval No: 61825/5KG/0307, 61825/50KG/0307, 61825/0307

Product Name: Fumigon Phosphine Fumigation Tablets
Active Constituent/s: 330 g/kg phosphone (PH_3) present as aluminium phosphine
Applicant Name: Proterra Pty Ltd
Applicant ACN: 120 507 182
Summary of Use: Aluminium phosphide tablets that release phosphine gas for pest control in stored food products.
Date of Registration: 11 May 2007
Label Approval No: 61630/300/0107, 61630/1/0107, 61630/1.5/0107, 61630/0107

Product Name: Ospray Salvation Herbicide
Active Constituent/s: 500g/L terbutryn
Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169
Summary of Use: For the control of certain early competing broadleaf weeds in wheat, barley, pastures, some varieties of oats and field peas.
Date of Registration: 14 May 2007
Label Approval No: 61800/10-20/0207, 61800/0207

Product Name: Echem Staroxy 200 Herbicide
Active Constituent/s: 200g/L fluroxypyr as the methyl heptyl ester
Applicant Name: Echem (Aust) Pty Limited
Applicant ACN: 089 133 095
Summary of Use: For the control of broadleaf weeds in fallow, lucerne, maize, millets, pastures, poppies, sorghum, sugarcane, sweet corn, winter cereals; and for the control of woody weeds in Agricultural Non-crop areas, Commercial and Industrial areas, Forests, Pastures and Rights-of-way.
Date of Registration: 14 May 2007
Label Approval No: 61136/5L/1206, 61136/20L/1206, 61136/200L/1206, 61136/1206

Product Name: Sipcam Agroxone 750 Herbicide
Active Constituent/s: 750 g/L MCPA present as the dimethylamine salt
Applicant Name: Sipcam Pacific Australia Pty Limited
Applicant ACN: 073 176 888
Summary of Use: For the control of broadleaf weeds in cereals, linseed, pastures, rice, sugar cane and turf.
Date of Registration: 14 May 2007
Label Approval No: 60733/20L/0307, 60733/110L/0307, 60733/0307

Product Name: Clark Rubber Filtrite Pool Ultra Shock Plus
Active Constituent/s: 504 g/kg chlorine present as sodium dichloroisocyanurate
Applicant Name: Clark Rubber Franchising Pty Ltd
Applicant ACN: 065 708 723
Summary of Use: For the control of algae and bacteria in outdoor swimming pools to increase the longevity of chlorine in outdoor pools.
Date of Registration: 16 May 2007
Label Approval No: 61645/500G/0207

Product Name: Titan Hermes 520 Herbicide
Active Constituent/s: 520 g/L haloxyfop present as haloxyfop-p methyl ester
Applicant Name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574
Summary of Use: For the post-emergence control of a wide range of annual and perennial grass weeds in grain legume and oil seed crops, lucerne, medic and clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops.
Date of Registration: 17 May 2007
Label Approval No: 61760/0307, 61760/5-20/0307

Product Name: Abound 400 Herbicide
Active Constituent/s: 400 g/L 2,4-D present as the isopropylamine salt
Applicant Name: Dow Agrosciences Australia Limited
Applicant ACN: 003 771 659
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: 18 May 2007
Label Approval No: 61182/20/0407, 61182/100/0407, 61182/110/0407, 61182/1000/0407, 61182/0407

4.VARIATIONS

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

Product Name: Talstar 100 EC Insecticide/Miticide
Applicant Name: FMC Australasia Pty Ltd
Applicant ACN: 095 326 891
Summary of Variation: Variation of the label approval to extend the use for control of *Helicoverpa armigera, Helicoverpa punctigera,* cucumber moth and silverleaf whitefly in cucurbits, redlegged earth mite in poppies and control of silverleaf whitefly in cotton and tomatoes.
Date of Variation: 01 May 2007
Label Approval No: 45704/1L/0307, 45704/5L/0307, 45704/20L/0307, 45704/50L/0307, 45704/110L/0307, 45704/200L/0307, 45704/1000L/0307, 45704/0307

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

Product Name: Euthalose Euthanasia Solution For Horses, Dogs And Cats
Active Constituent/s: 400 mg/mL quinalbarbitone sodium, 25 mg/mL cinchocaine hydrochloride
Applicant Name: Virbac (Australia) Pty Ltd
Applicant ACN: 003 268 871
Summary of Use: Intravenous euthanasia for cats, dogs and horses.
Date of Registration: 17 April 2007
Label Approval No: 59113/25ML/0107, 59113/50ML/0107, 59113/100ML/0107, 59113/1x50ML/0107, 59113/3x50ML/0107

Product Name: Metacam 1 mg Chewable Tablets For Dogs
Active Constituent/s: 1 mg per tablet meloxicam
Applicant Name: Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN: 000 452 308
Summary of Use: A tablet for use in dogs to alleviate inflammation and pain in acute and chronic musculo-skeletal disorders.
Date of Registration: 17 April 2007
Label Approval No: 60535/10B/0407, 60535/100B/0407, 60535/0407

Product Name: Purina Total Care Heartworm And Allwormer For Dogs
Each Tablet Contains: 0.1 mg abamectin, 50 mg praziquantel, 225 mg Toxibendazole.
Applicant Name: Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN: 000 011 316
Summary of Use: For the prevention of heartworm and the treatment of roundworm, hookworm, whipworm and tapeworm in dogs up to 10kg.
Date of Registration: 18 April 2007
Label Approval No: 61434/1/1206, 61434/2/1206, 61434/3/1206, 61434/4/1206, 61434/6/1206, 61434/10/1206, 61434/12/1206, 61434/10H/1206, 61434/500H/1206

Product Name: Metacam 2.5 mg Chewable Tablets For Dogs
Active Constituent/s: meloxicam 2.5 mg per tablet
Applicant Name: Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN: 000 452 308
Summary of Use: A tablet for use in dogs to alleviate inflammation and pain in acute and chronic musculo-skeletal disorders.
Date of Registration: 19 April 2007
Label Approval No: 60536/10B/0407, 60536/100B/0407, 60536/0407

Product Name: Switch With Selenium Double Combination Drench For Sheep
Active Constituent/s: 67.8 g/L levamisole as levamisole hydrochloride, 50 g/L fenbendazole, 1 g/L selenium as sodium selenate
Applicant Name: Ancare Australia Pty Limited
Applicant ACN: 076 252 241
Summary of Use: An oral drench for the control of round worm and as an aid in controlling

selenium deficiencies in sheep.
Date of Registration: 19 April 2007
Label Approval No: 61552/10L/0207

Product Name: Hill's Prescription Diet k/d Feline
Applicant Name: Hill's Pet Nutrition Pty Limited
Summary of Use: A complete diet which is intended to assist in the nutritional management of cats with chronic renal failure.
Date of Registration: 20 April 2007
Label Approval No: 59781/400g/0706, 59781/1.8kg/0706

Product Name: Purina Totalcare Flea Collar For Dogs
Active Constituent/s: 150 g/kg diazinon
Applicant Name: Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN: 000 011 316
Summary of Use: A pet collar product for the control of fleas in dogs for up to 5 months.
Date of Registration: 20 April 2007
Label Approval No: 61782/1/0307, 61782/2/0307

Product Name: Purina Totalcare Flea Collar For Cats
Active Constituent/s: 150 g/kg diazinon.
Applicant Name: Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN: 000 011 316
Summary of Use: A pet collar product for the control of fleas in cats for up to 5 months.
Date of Registration: 20 April 2007
Label Approval No: 61783/1/0307, 61783/2/0307

Product Name: Purina Totalcare Flea Eliminator Line-On For Small - Medium Dogs
Active Constituent/s: 3 g/L pyriproxyfen, 400 g/L permethrin 40:60.
Applicant Name: Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN: 000 011 316
Summary of Use: A spot-on product for flea and tick control on dogs.
Date of Registration: 20 April 2007
Label Approval No: 61427/0207, 61427/1/0207, 61427/2/0207, 61427/3/0207, 61427/4/0207, 61427/6/0207, 61427/24/0207

Product Name: Hill's Prescription Diet r/d Feline
Applicant Name: Hill's Pet Nutrition Pty Ltd
Summary of Use: A complete pet diet which is intended to assist in the nutritional management of fibre-responsive diseases in overweight cats.
Date of Registration: 23 April 2007
Label Approval No: 59816/400g/0706, 59816/1.8 kg/0706

Product Name: Hill's Prescription Diet u/d Canine
Applicant Name: Hill's Pet Nutrition Pty Ltd
Summary of Use: A complete pet diet which is intended to prevent the recurrence of urolithiasis in dogs.
Date of Registration: 23 April 2007
Label Approval No: 60087/4.5kg/0407, 60087/13.6kg/0407

Product Name: Hill's Prescription Diet z/d Low Allergen Canine
Applicant Name: Hill's Pet Nutrition Pty Ltd
Summary of Use: A dry therapeutic pet diet which is intended to assist in the nutritional management of dogs with dietary allergies.
Date of Registration: 23 April 2007
Label Approval No: 60088/3.6kg/0706, 60088/12.5kg/0706

Product Name: Hill's Prescription Diet z/d Ultra Allergen-Free Feline
Applicant Name: Hill's Pet Nutrition Pty Ltd
Summary of Use: A complete pet diet which is intended to assist in the nutritional management of cats with dietary allergies.
Date of Registration: 24 April 2007
Label Approval No: 60133/156g/0407

Product Name: Lice 'N' Simple Pour-On Equine Lousicide
Active Constituent/s: 25 g/L triflumuron
Applicant Name: Jurox Pty Limited
Applicant ACN: 000 932 230
Summary of Use: An insect growth regulator (IGR) for the control of biting lice "*Werneckiella (Bovicola) equi*" on horses.
Date of Registration: 26 April 2007
Label Approval No: 61009/100mL/0307

Product Name: Hill's Prescription Diet Canine l/d
Applicant Name: Hill's Pet Nutrition Pty Limited
Applicant ACN: 003 954 550
Summary of Use: A complete pet diet which is intended to assist in the nutritional management of dogs with liver disease.
Date of Registration: 26 April 2007
Label Approval No: 60072/4.5kg/0407

Product Name: Sylvet Capsules Blister Pack
Active Constituent/s: Each capsule contains 100mg calcium pentosan polysulfate
Applicant Name: Arthropharm Pty Ltd
Applicant ACN: 003 261 907
Summary of Use: An oral capsule to aid in the

treatment of osteoarthritis in dogs.
Date of Registration: 26 April 2007
Label Approval No: 61184/10capB (0307)

Product Name: Selovin LA Long Acting Selenium Injection For Cattle
Active Constituent/s: 50 mg/ml selenium as barium selenate
Applicant Name: Bomac Animal Health Pty Limited
Applicant ACN: 084 248 206
Summary of Use: For the treatment and prevention of selenium deficiency in cattle.
Date of Registration: 30 April 2007
Label Approval No: 59680/50mL/0307

Product Name: Purina Totalcare Flea Eliminator Line-On For Large Dogs
Active Constituent/s: 3 g/L pyriproxyfen, 400 g/L permethrin 40:60
Applicant Name: Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN: 000 011 316
Summary of Use: Registration of a spot-on product for flea and tick control on dogs.
Date of Registration: 4th May 2007
Label Approval No: 61435/0207, 61435/1/0207, 61435/3/0207, 61435/4/0207, 61435/6/0207, 61435/8/0207, 61435/24/0207

Product Name: Glyde Oral Powder For Dogs
Active Constituent/s: 95 mg/mL chondroitin sulfate, 190 mg/mL glucosamine hydrochloride, 253.3 mg/mL stabilised green-lipped mussel powder
Applicant Name: Parnell Laboratories (Aust) Pty Ltd
Applicant ACN: 003 087 367
Summary of Use: May improve joint structure and function.
Date of Registration: 14th May 2007
Label Approval No: 59885/360g/0507

Product Name: Hill's Prescription Diet I/D Feline
Applicant Name: Hill's Pet Nutrition Pty Limited
Summary of Use: A complete pet diet which is intended to assist in the nutritional management of dogs with liver disease.
Date of Registration: 14 May 2007
Label Approval No: 60083/1.8kg/0407

Product Name: Protrace Cobalt Pellets For Cattle
Active Constituent/s: 300 g/kg cobalt oxide
Applicant Name: Allfire Enterprises Pty Ltd
Applicant ACN: 097 970 280
Summary of Use: For the prevention and control of cobalt responsive conditions in cattle.
Date of Registration: 16 May 2007
Label Approval No: 61491/100/0307

Product Name: Clavubactin M 312.5 Mg Broad Spectrum Antibiotic Tablets
Active Constituent/s: Each tablet contains 250 mg amoxycillin (as the trihydrate), 62.5 mg clavulanic acid (as potassium clavulanate)
Applicant Name: Bomac Laboratories Limited (Nz)
Summary of Use: For treatment of bacterial infections sensitive to Clavulanic Acid and Amoxycillin in dogs and cats
Date of Registration: 17 May 2007
Label Approval No: 59839/4/0806, 59839/10/0806, 59839/100/0806, 59839/200/0806

4.VARIATIONS

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

"No Entries"

5. RESTRICTED PRODUCT VARIATION

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

"No Entries"

NOTICE

Cefovecin sodium

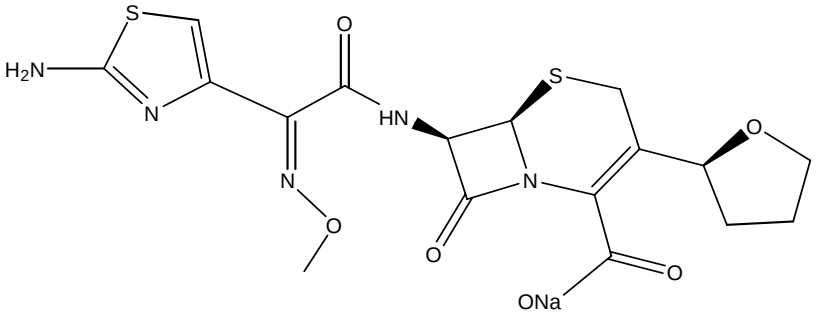
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent cefovecin sodium. Cefovecin sodium is a semi-synthetic broad-spectrum cephalosporin antibiotic.

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 approval of cefovecin sodium 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 the Active Constituent

Common Name:	Cefovecin sodium
IUPAC Name:	(6*R*, 7*R*) –7-[[2*Z*)-(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-3[(2*S*)-tetrahydro-2-furanyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2 carboxylic acid, monosodium salt.
CA Name	5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[(2*Z*)-2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-3-[(2*S*)-tetrahydrofuranyl]=monosodium salt , (6*R*,7*R*)-
CAS Number:	141195-77-9
Manufacturer's Codes:	UK-287-074-02
Minimum Purity:	950 g/kg
Molecular Formula:	$C_{17}H_{18}N_5NaO_6S_2$
Molecular Weight:	475.48

Structure:



Chemical Family:	β-Lactam antibiotic
Mode of Action:	Cefovecin sodium interferes with bacterial cell wall synthesis by covalently binding to the penicillin binding proteins

Summary of the APVMA's Evaluation Cefovecin sodium Active Constituent

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

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

On the basis of the data provided, it is proposed that the following APVMA Active Constituent Standard be established for cefovecin sodium active constituent:

Constituent	**Specification**	**Level**
Cefovecin sodium	Cefovecin sodium	Not less than 950 g/kg (anhydrous, solvent free basis)

The Office of Chemical Safety of the Therapeutic Goods Administration has considered the toxicological aspects of cefovecin sodium, and advised that there are no toxicological objections to the approval of this chemical.

As the product is intended to be used by veterinary professionals or under their supervision, in non-food producing animals, and establishment of an ADI or ARfD for cefovecin sodium was not considered necessary.

The National Drugs and Poisons Schedule Committee (NDPSC) has included cefovecin sodium 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 cefovecin sodium 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 cefovecin sodium should be addressed in writing to:

Dr Paul Sethi
Chemistry Manager
Chemistry and Residues Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6272 3987
Fax: (02) 6272 3551

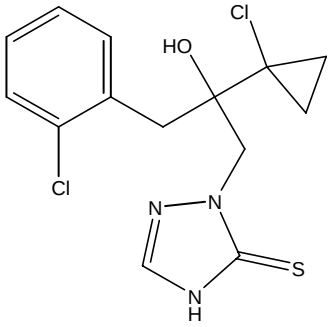
NOTICE

Prothioconazole

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, prothioconazole. Prothioconazole is a new class of fungicide which is proposed for use as a seed treatment to control common bunt in wheat 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 approval of prothioconazole 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 the Active Constituent

Common Name:	Prothioconazole
IUPAC Name:	(*RS*)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
CA Name:	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-trazole-3-thione
CAS Number:	178928-70-6
Manufacturer's Codes:	JAU 6476
Minimum Purity:	970 g/kg
Molecular Formula:	$C_{14}H_{15}Cl_2N_3OS$
Molecular Weight:	344.26
Structure:	
Chemical Family:	triazolinthione
Mode of Action:	inhibition of demethylation of lanosterol or 24-methylene-dihydrolanosterol, which are precursors of fungi sterols

Summary of the APVMA's Evaluation of Prothioconazole Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of prothioconazole 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, it is proposed that the following APVMA Active Constituent Standard be established for prothioconazole active constituent:

Constituent	Specification	Level
Prothioconazole	Prothioconazole	Not less than 970 g/kg

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

The Office of Chemical Safety of the Therapeutic Goods Administration has considered the toxicological aspects of prothioconazole, and advised that there are no toxicological objections to the approval of this chemical.

The group acceptable daily intake (ADI) for prothioconazole and prothioconazole-desthio (major metabolite) is 0.01 mg/kg bw/d based on no observed adverse effect level (NOAEL) of 1.1 mg/kg bw/d in a chronic/carcinogenicity study in rats with prothioconazole-desthio (major metabolite), using a safety factor of 100, and a group acute reference dose (ARfD) is 0.03 mg/kg bw, based on a NOAEL of 3 mg/kg bw/d in a rat developmental toxicity study on prothioconazole-desthio, using a safety factor of 100.

The National Drugs and Poisons Schedule Committee (NDPSC) has included prothioconazole into Appendix B (Substances Considered not to Require Control by Scheduling) 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 prothioconazole 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 prothioconazole should be addressed in writing to:

Dr Paul Sethi
Chemistry Manager
Chemistry and Residues Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

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

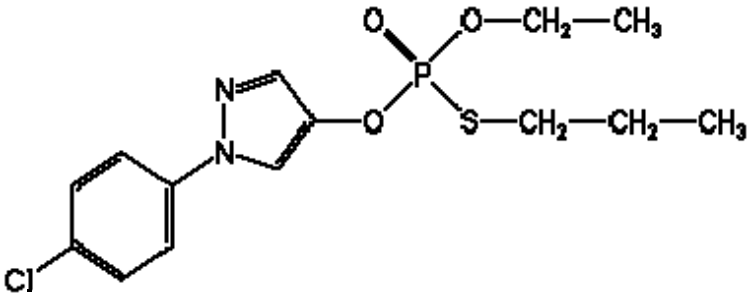
NOTICE

Pyraclofos

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, pyraclofos. Pyraclofos is an organophosphate insecticide developed for use as a broad spectrum anthelmintic in sheep.

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 approval of pyraclofos 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 the Active Constituent

Common Name:	Pyraclofos
IUPAC Name:	(*RS*)-[*O*-1-(4-chlorophenyl)pyrazol-4-yl *O*-ethyl *S*-propyl phosphorothioate]
CA Name:	*(±)*-*O*-[1-(4-chlorophenyl)-1*H*-pyrazol-4-yl] *O*-ethyl *S*-propyl phosphorothioate
CAS Number:	89784-60-1
Minimum Purity:	930 g/kg
Molecular Formula:	$C_{14}H_{18}ClN_2O_3PS$
Molecular Weight:	360.8
Structure:	
Chemical Family:	Organophosphate
Mode of Action:	Cholinesterase inhibitor

Summary of the APVMA's Evaluation of Pyraclofos Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of pyraclofos 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, it is proposed that the following APVMA Active Constituent Standard be established for pyraclofos active constituent:

Constituent	Specification	Level
Pyraclofos	Pyraclofos	Not less than 930 g/kg
	O,O-diethyl-S-n-propyl	Not more than 10 g/kg

	phosphorothioate	

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

The Office of Chemical Safety of the Therapeutic Goods Administration has considered the toxicological aspects of pyraclofos, and advised that there are no toxicological objections to the approval of this chemical.

An Acceptable Daily Intake (ADI) for pyraclofos is 0.001 mg/kg/day based on no observed adverse effect level (NOAEL) of 0.1 mg/kg/day using a safety factor of 100.

The National Drugs and Poisons Schedule Committee (NDPSC) has included pyraclofos into Appendix 6 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 pyraclofos 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 pyraclofos should be addressed in writing to:

Dr Paul Sethi
Chemistry Manager
Chemistry and Residues Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

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

NOTICE

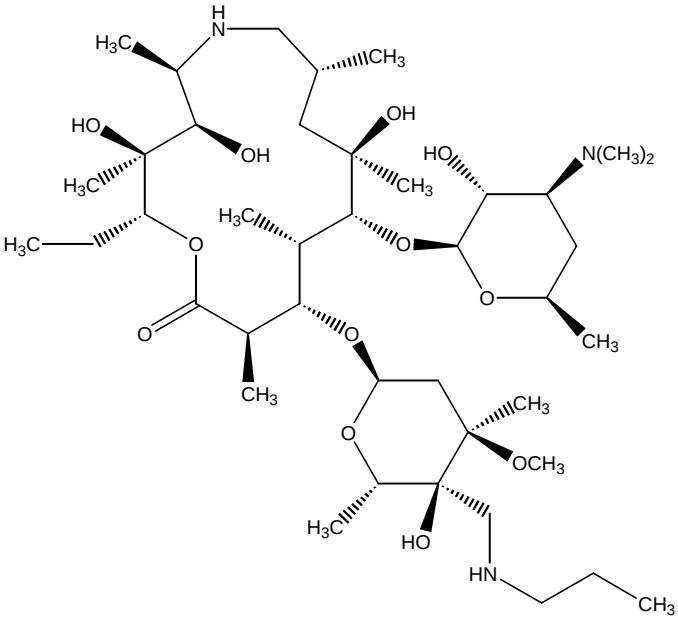
Tulathromycin

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, tulathromycin. Tulathromycin is a new semi-synthetic macrolide prepared by fermentation followed by organic synthesis which is proposed for use as a treatment of bacterial respiratory disease in cattle and pigs. It is a member of triamilide subclass of macrolide antibiotics. The technical tulathromycin active constituent consists of a ca. 99:1 ratio of two isomers which in the formulated product equilibrate to a ca. 9:1 ratio. The active constituent tulathromycin is optically active.

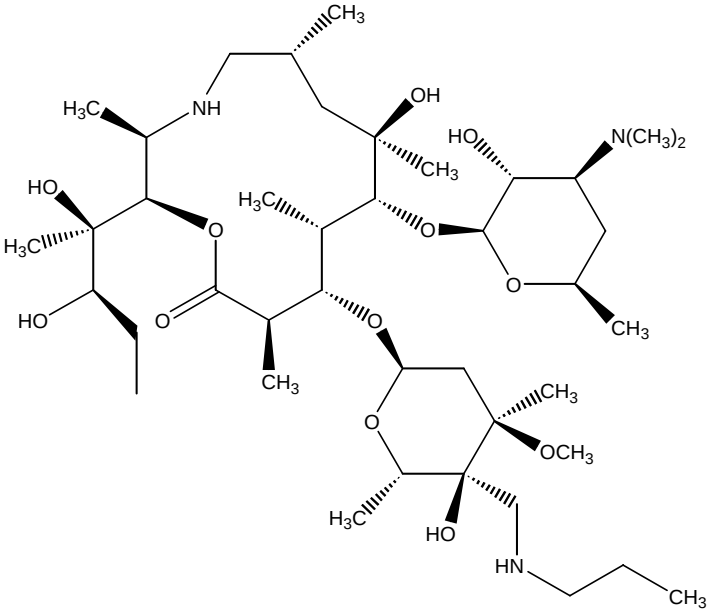
In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of tulathromycin should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to the matters 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 the Active Constituent

Common Name:	Tulathromycin
CA Names:	Major Isomer: (2*R*,3*S*,4*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-13-[[2,6-dideoxy-3-C-methyl-3-O-methyl-4-C[(propylamino)methyl-α-L-ribo-hexopyranosyl]oxy]-2-ethyl-3,4,10-trihydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one and Minor Isomer: (2*R*,3*R*,6*R*,8*R*,9*R*,10*S*,11*S*,12*R*)-11-[[2,6-dideoxy-3-C-methyl-3-O-methyl-4-C[(propylamino)methyl-α-L-ribo-hexopyranosyl]oxy]-2-[(1*R*,2*R*)-1,2-dihydroxy-1-methylbutyl]-8-hydroxy-3,6,8,10,12-pentamethyl-9-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa-4-azacyclopentadecan-13-one
CAS Number:	217500-96-4 (major isomer) and 280755-12-6 (minor isomer)
Manufacturer's Codes:	CP-472,295 (major isomer), CP-547,272 (minor isomer), CP-472,295(e) (equilibrated mixture), triamilide (mixture)
Minimum Purity:	94.0% w/w
Molecular Formula:	$C_{41}H_{79}N_3O_{12}$
Molecular Weight:	806.23
Structure:	Major Isomer:



and
Minor Isomer:



Chemical Family: Triamilide subclass of macrolide antibiotics
Mode of Action: Inhibition of essential protein biosynthesis by selective binding to bacterial 50S ribosomal subunits

Summary of the APVMA's Evaluation of Tulathromycin Active Constituent

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

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

Constituent	Specification	Level
Tulathromycin	Tulathromycin	Not less than 940 g/kg (anhydrous,

		solvent free basis)

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

The Office of Chemical Safety of the Therapeutic Goods Administration has considered the toxicological aspects of tulathromycin, and advised that there are no toxicological objections to the approval of this chemical.

A microbiological acceptable daily intake (ADI) of 0.005 mg/kg bw/d is recommended based on a MIC_{50} of 1 μg/mL in the most sensitive bacterial genus, *Bifidobacterium spp*, found in the human GI tract. The microbial ADI is supported by a toxicological ADI established at 0.005 mg/kg bw/d derived from a 12-month dog study and increased liver enzymes at the next highest dose and a 1000-fold safety factor. An Acute Reference Dose (ARfD) of 0.1 mg/kg bw, based on a lowest-observed-effect-level (LOEL) of 100 mg/kg bw in a dog oral acute study, using a safety factor of 1000, have been established.

The National Drugs and Poisons Schedule Committee (NDPSC) has included tulathromycin 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 tulathromycin 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 tulathromycin should be addressed in writing to:

Dr Paul Sethi
Chemistry Manager
Chemistry and Residues Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

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

NOTICE

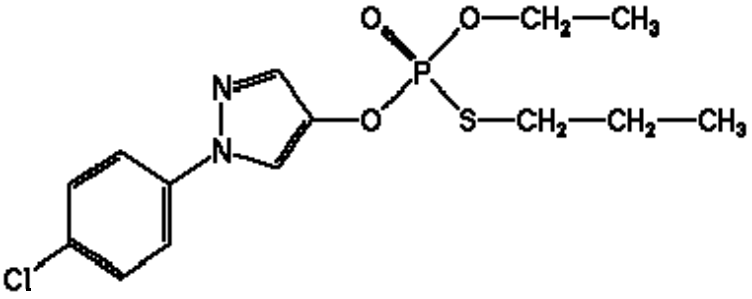
Pyraclofos, Albendazole

[in the product: COOPERS COLLEAGUE BROAD SPECTRUM SHEEP AND LAMB DRENCH]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Schering-Plough Animal Health for registration of a new product containing the new active constituent pyraclofos and the active constituent albendazole. The product is COOPERS COLLEAGUE BROAD SPECTRUM SHEEP AND LAMB DRENCH. The product is for use as an anthelmintic in sheep.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of the active constituent pyraclofos and registration of the product, 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. The APVMA must receive submissions within 28 days of the date of this notice.

Particulars of the Active Constituent

Common Name:	Pyraclofos
IUPAC Name:	(*RS*)-[*O*-1-(4-chlorophenyl)pyrazol-4-yl *O*-ethyl *S*-propyl phosphorothioate]
CA Name:	*(±)-O*-[1-(4-chlorophenyl)-1*H*-pyrazol-4-yl] *O*-ethyl *S*-propyl phosphorothioate
CAS Number:	89784-60-1
Minimum Purity:	930 g/kg
Molecular Formula:	$C_{14}H_{18}ClN_2O_3PS$
Molecular Weight:	360.8
Structure:	
Chemical Family:	Organophosphate
Mode of Action:	Cholinesterase inhibitor

Summary of the APVMA's Evaluation of Pyraclofos Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of pyraclofos 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, the APVMA proposes to establish the following Active Constituent Standard be established for pyraclofos active constituent:

Constituent	Specification	Level
Pyraclofos	Pyraclofos	Not less than 930 g/kg
	O,O-diethyl-S-n-propyl phosphorothioate	Not more than 10 g/kg

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

The Office of Chemical Safety (OCS) of the Therapeutic Goods Administration has considered the toxicological aspects of pyraclofos, and advised that there are no toxicological objections to the approval of this active constituent.

An acceptable daily intake (ADI) for pyraclofos is 0.001 mg/kg/day, based on a no observed adverse effect level (NOAEL) of 0.1 mg/kg/day and using a safety factor of 100.

The National Drugs and Poisons Schedule Committee (NDPSC) has included pyraclofos in Schedule 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

Particulars of the Product

Product Name:	COOPERS COLLEAGUE BROAD SPECTRUM SHEEP AND LAMB DRENCH
Applicant Company:	Schering-Plough Animal Health
Active Constituents:	Pyraclofos, albendazole
Signal Heading:	Schedule 6
Statement of Claim:	For the control of sensitive gastrointestinal roundworms, aids in the control of adult liver fluke and reduces the output of viable worm and fluke eggs in sheep.
Pack Sizes:	5L, 12L

Summary of the APVMA's evaluation of COOPERS COLLEAGUE BROAD SPECTRUM SHEEP AND LAMB DRENCH 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 the product would not be an undue hazard to the safety of people exposed to it during its handling and use.

OCS conducted a risk assessment on the product prior to the initial registration of the product in 1993. In 1994 the registrant voluntarily withdrew the product and the current product is identical to the original product. There were no new toxicological data requiring assessment and OCS advised that the original assessment, which concluded that the product can be used safely, remained valid.

The APVMA accepts the findings and recommendations of the OCS evaluation.

The product will be formulated in Australia or New Zealand. Pyraclofos is an organophosphate anticholinesterase compound which has moderate acute oral and inhalational toxicity, low dermal toxicity and has an ADI of 0.001 mg/kg/day. Albendazole is a benzimidazole compound which has low acute oral toxicity and an ADI of 0.7mg/kg/day. The product is determined to be of low toxicity by oral and dermal routes, it is considered to be a skin sensitiser and a slight skin and eye irritant.

(ii) The APVMA is satisfied that the proposed use of the product will not be an undue hazard to the safety of people using anything containing its residues. The APVMA assessed residue data and set maximum residue limits (MRLs) and withholding periods (WHPs) for pyraclofos and albendazole in the product when used in sheep.

(iii) The APVMA is satisfied that the proposed use of pyraclofos, albendazole in the product is not likely to be harmful to human beings if used according to the product label directions.

The active constituents albendazole and pyraclofos are listed in Schedule 6 of the SUSDP. The appropriate signal heading is on the label. First Aid and Safety Directions for pyraclofos and albendazole have been recommended by OCS and have 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 the product in sheep is not likely to have an unintended effect that is harmful to animals, plants or the environment.

The Department of Environment and Water (DEW) has assessed additional data provided by the applicant in support of registration of the product and has updated the original assessment conducted in 1993 to incorporate these additional data.

DEW's assessment is that the application contains adequate environmental fate and toxicity data to demonstrate that the use of the product according to the label is unlikely to result in primary poisonings of wildlife, fish etc. In the future if a wider use for pyraclofos as a foliar applied insecticide/acaricide is envisaged, the environmental risk

should be reassessed. Depending on the proposed use, additional environmental fate and ecotoxicity data may be required.

The product was originally registered in December 1993 and withdrawn in January 1994 due to death in large numbers of sheep. Very high death rates were observed in some individual mobs.

Data from new safety trials provided with the application to reregister the product demonstrated that when used according to the proposed label instructions, use of the product resulted in an overall mortality rate of less than 0.1%, with higher rates being observed in individual mobs. High mortality rates in sheep may be a consequence of gastrointestinal roundworm burdens and there is significant resistance present in gastrointestinal roundworms to many of the currently available anthelmintics. Pyraclofos is not contained in any other registered veterinary chemical product for this use.

The APVMA consulted with sheep industry and animal welfare representatives. In order to mitigate the risk to target animal safety, the APVMA proposes that the product be available only for use by, or under the direction of, registered veterinary surgeons.

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

(v) The APVMA is satisfied that the proposed use of pyraclofos, albendazole in the product would not adversely affect trade between Australia and places outside Australia.

In the absence of any Codex MRLs or overseas tolerances for pyraclofos, the presence of any pyraclofos residues above the method level of quantification (LOQ) in edible sheep commodities would constitute a risk to Australia's export sheep market. The applicant has proposed that an export slaughter interval (ESI) of 35 days be assigned to the product, because pyraclofos residues in all edible tissues from treated sheep are below the limit of detection (LOD) of the analytical method at this time. Consequently, the APVMA concludes that the risk to Australia's export trade in sheep meat and live sheep will be low when the proposed 35 day ESI is observed.

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 the product adequately demonstrate that this product is effective for the proposed uses.

Public Release Summary

A Public Release Summary of the evaluation of the product is available on the APVMA website at http://www.apvma.gov.au/new/public_consulation.shtml. A copy can also be requested by contacting Thea Reiman on (02) 6210 4726 or thea.reiman@apvma.gov.au.

Written submissions on the APVMA's proposal to grant the application for approval of the active constituent pyraclofos and registration of the product should be addressed in writing to:

Judith Platt
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4735
Fax: (02) 6210 4741
Email: judith.platt@apvma.gov.au

NOTICE

TULATHROMYCIN
[in the product: Draxxin Injectable Solution]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Pfizer Australia Pty Ltd for the registration of a new product, DRAXXIN INJECTABLE SOLUTION, which contains 100 mg/mL of tulathromycin. The product is an antibiotic for the treatment of bovine respiratory disease caused by *Mannheimia haemolytica* and *Pasteurella multocida* in cattle, and swine respiratory disease caused by *Mycoplasma hyopneumoniae* and *Pasteurella multocida* in pigs.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration should be granted. Submissions should state the grounds on which the submission is 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 Application

Product Name:	DRAXXIN INJECTABLE SOLUTION
Applicant Company:	Pfizer Australia Pty Ltd
Active Constituent:	Tulathromycin (100mg/mL)
Signal Heading:	S4
Statement of Claim:	For the treatment of tulathromycin sensitive bacterial respiratory diseases in cattle and pigs
Pack Sizes:	20mL, 50 mL, 100mL

Maximum Residues Limits: **Table 1**

MF 0812	Cattle fat	0.1 mg/kg
MO 1280	Cattle kidney	1.0 mg/kg
MO 1281	Cattle liver	3.0 mg/kg
MM 0812	Cattle meat	0.1 mg/kg
	Pig skin/fat	0.3 mg/kg
MO 1284	Pig kidney	3.0 mg/kg
MO 1285	Pig liver	2.0 mg/kg
MM 0818	Pig meat	0.5 mg/kg

Residue Definition: **Table 3**

Sum of tulathromycin and its metabolites that are converted by acid hydrolysis to (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-ß-D-xylohexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one, expressed as tulathromycin equivalents.

Withholding Periods: Cattle meat: **DO NOT USE** less than 35 days before slaughter for human consumption.

	Milk: **DO NOT USE** in cows which are producing or may in the future produce milk or milk products for human consumption. **DO NOT USE** in bobby calves. Pig meat: **DO NOT USE** less than 14 days before slaughter for human consumption.
Re-treatment Intervals:	Cattle: **DO NOT RE-TREAT** cattle for 12 weeks after last treatment. Pig: **DO NOT RE-TREAT** pigs for 8 weeks after last treatment.
Export Slaughter Interval:	Cattle: **DO NOT SLAUGHTER** for export for 35 days after treatment. Pig: **DO NOT SLAUGHTER** for export for 26 days after treatment.

Summary of the APVMA's assessment of DRAXXIN INJECTABLE SOLUTION in accordance with section 14(3)(e) 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 use of DRAXXIN INJECTABLE SOLUTION would not present an undue hazard to the safety of people exposed to it during its handling and use.

The Department of Health and Ageing, Office of Chemical Safety (OCS) conducted an evaluation of the toxicology aspects of tulathromycin. The active constituent displays low acute oral toxicity in rats and dogs, and low dermal acute toxicity in rabbits. It is a severe eye irritant and a skin sensitizer, but is not a skin irritant. There is no evidence that tulathromycin causes teratogenicity. Tulathromycin is not genotoxic and is considered unlikely to be carcinogenic. The product DRAXXIN INJECTABLE SOLUTION is a moderate eye irritant and is likely to be a skin sensitiser.

OCS has recommended a microbiological acceptable daily intake of 0.005 mg/kg bw/day, a toxicological acceptable daily intake of 0.005 mg/kg bw/day and an acute reference dose of 0.1 mg/kg bw for tulathromycin. As DRAXXIN INJECTABLE SOLUTION is to be administered under veterinary supervision, safety directions are not required. Since the product is a moderate eye irritant, OCS has recommended that a warning statement be included on the label.

The APVMA having considered the findings and recommendations of the OCS evaluation accepts these findings and recommendations.

(ii) The APVMA is satisfied that the proposed use of DRAXXIN INJECTABLE SOLUTION will not be an undue hazard to the safety of people using anything containing its residues. Residues data were assessed by the APVMA and Maximum Residue Limits are recommended for DRAXXIN INJECTABLE SOLUTION.

Withholding periods and re-treatment intervals have been established. The product is restricted from being used in bobby calves, dairy cows and heifers. The APVMA has conducted a dietary risk assessment and has found that the acute and chronic dietary exposures to tulathromycin residues are acceptable.

(iii) The APVMA is satisfied that the proposed use of tulathromycin in DRAXXIN INJECTABLE SOLUTION 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, tulathromycin, and finds that the chemistry and manufacturing details of the product are acceptable. The National Drugs and Poisons Scheduling Committee has assessed DRAXXIN INJECTABLE SOLUTION and has included it in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons. The signal heading that corresponds to Schedule 4 and the first aid instructions that OCS has recommended both appear on the label. Statements that warn users that tulathromycin is irritating to the eyes and may cause skin sensitisation, and the accompanying instructions are acceptable to the APVMA.

DRAXXIN INJECTABLE SOLUTION will be manufactured overseas and imported in self-contained vials. Tulathromycin is not classified as a hazardous substance, but DRAXXIN INJECTABLE SOLUTION is determined to be a hazardous substance, based on the NOHSC hazard classification of active and non-active constituents and the product toxicology information provided.

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

(iv) The APVMA is satisfied that the proposed use of DRAXXIN INJECTABLE SOLUTION is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The Department of the Environment and Water Resources (DEW) has evaluated the VICH Phase 1 Environment Impact Assessment of DRAXXIN INJECTABLE SOLUTION and agreed that that the Predicted Environmental $Concentration_{soil}$ values have met the criteria of VICH Phase 1. The Department of the Environment and Water Resources has concluded that the proposed use of DRAXXIN INJECTABLE SOLUTION on cattle and pigs will not pose an unacceptable aquatic risk and that the VICH trigger value of 100 μg/kg soil is unlikely to be exceeded.

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

(v) The APVMA is satisfied that the proposed use of DRAXXIN INJECTABLE SOLUTION would not adversely affect trade between Australia and places outside Australia.

Codex has not considered tulathromycin, but several countries have established MRLs/tolerances for tulathromycin. The EU MRLs for tulathromycin residues in pig liver and kidney are the same as, or higher than, the proposed Australian MRLs, but the

EU MRL for pig skin/fat (0.1 mg/kg) is significantly lower than the proposed Australia's MRL (0.3 mg/kg). The EU has not recommended an MRL for pig muscle. This implies that residues in muscle are lower than in skin/fat at any time.

The APVMA has assessed residues data and has determined that an export slaughter interval of 26 days for pigs would be required for tulathromycin residues in pig skin/fat and muscle to decline below the EU MRL of 0.1 mg/kg.

Australian MRLs for tulathromycin in edible cattle tissues are either the same as or lower than the corresponding MRLs/tolerances established by the main importers of Australian beef. Therefore observance of the domestic withholding period of 35 days will enable tulathromycin residues in edible cattle tissues to decline to below the standards of Australia's main export beef markets.

The APVMA has concluded that the overall risk to Australia's export trade in beef and pork products arising from the treatment of cattle and pigs with DRAXXIN INJECTABLE SOLUTION is considered to be low when the recommended export slaughter intervals are observed.

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

The APVMA is satisfied that data from trials supporting the efficacy of DRAXXIN INJECTABLE SOLUTION adequately demonstrate that the product would be safe and effective for the proposed use in cattle and pigs.

Public Release Summary

A Public Release Summary of the evaluation is available by contacting Thea Reiman on telephone (02) 6210 4726. Written submissions on the APVMA's proposal to grant the application for registration should be addressed in writing to:

Linden Moffatt
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4736
Fax: (02) 6210 4741

NOTICE

Halofuginone

[in the product: HALOCUR ORAL SOLUTION FOR TREATMENT OF CALVES]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Intervet Australia Pty Limited for the registration of a new product, HALOCUR ORAL SOLUTION FOR TREATMENT OF CALVES ('the product'), which contains 0.5 g/L of halofuginone as halofuginone lactate. The product is an oral solution that is will be administered to calves aged 1-21 days, as an aid in control and prevention of diarrhoea caused by *Cryptosporidium parvum*.

The application proposes to extend the use of halofuginone to cattle, and establish Australian maximum residue limits (MRLs) for halofuginone in meat and offal of cattle. In addition, the application requires the setting of a slaughter withholding period (WHP), an export slaughter interval (ESI), and approval of the proposed product label.

The APVMA invites any person to submit a relevant written submission as to whether the application to register the new product should be granted. Such submissions should state the grounds on which the submission is based. Such submissions should state the grounds on which the submission is based. Such grounds should relate only to the trade implications of the use of the product. The APVMA must receive submissions within 28 days of the date of this notice.

Particulars of the Application

Product Name:	HALOCUR ORAL SOLUTION FOR TREATMENT OF CALVES	
Applicant Company:	Intervet Australia Pty Limited	
Active Constituent:	Halofuginone (0.5 g/L; present as halofuginone lactate)	
Signal Heading:	Schedule 4	
Statement of Claim:	An oral solution that is to be administered to calves aged 1-21 days, as an aid in the control and prevention of diarrhoea caused by *Cryptosporidium parvum*.	
Pack Sizes:	490 mL, 980 mL	
Proposed MRLs:	Halofuginone	
	Cattle fat	0.025 mg/kg
	Cattle kidney	0.03 mg/kg
	Cattle liver	0.03 mg/kg
	Cattle meat	0.01 mg/kg

Withholding Period (WHP): MEAT: DO NOT USE less than 13 days before slaughter for human consumption.

Export Slaughter Interval (ESI): DO NOT slaughter for export for 17 days after last treatment.

Summary of the APVMA's assessment of the application in accordance with section 14(3)(e) 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:

The APVMA is satisfied that the use of this product would not present an undue hazard to the safety of people consuming produce from animals treated with this product.

The APVMA has completed an evaluation of the data and has supported the proposed MRLs and Withholding Periods for this product and use patterns.

Trade Evaluation

The APVMA has evaluated the residues aspects of the product. The APVMA has proposed MRLs for halofuginone which will cover the occurrence of residues if the product is used in calves in accordance with the proposed label instructions, and if the recommended meat WHP of 13 days is observed.

Australia's main export markets for beef/veal are Japan and the USA. Japan has established provisional MRLs for halofuginone residues in cattle commodities. The Japanese MRLs for cattle muscle and fat are the same as, or higher than, the proposed Australian MRLs. However, the Japanese MRLs for cattle kidney and liver (0.02 mg/kg) are lower than the proposed Australian MRLs of 0.03 mg/kg.

There are no halofuginone tolerances established for cattle commodities in the USA. Therefore, it is concluded that the USA is the most sensitive export market, and that the limits of quantification (LOQs) of the analytical method are the appropriate endpoints for the ESI determinations for the product. That is, 0.005 mg/kg for cattle muscle, and 0.01 mg/kg for cattle kidney, liver and fat.

Statistical analysis of the available residues trial data shows that a period of 17 days is required for halofuginone residues in muscle, liver, kidney and fat to decline to below the relevant method LOQ. Therefore, an export slaughter interval (ESI) of 17 days is recommended for the product.

Overall, the risk to Australia's export trade in cattle commodities, arising from the use of HALOCUR ORAL SOLUTION is considered to be low when an ESI of 17 days is observed.

The following trade advice statement is to be included on the product label.
EXPORT SLAUGHTER INTERVAL (ESI): DO NOT slaughter for export for 17 days after last treatment. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI from Intervet Australia on 1800 033 461 or the APVMA website (www.apvma.gov.au/residues/ESI.shtml).

Other Criteria for Registration and Label Approval

Additionally, during the evaluation of this application the APVMA addressed and is satisfied of the following criteria:

Chemistry and Manufacture
Toxicology
Occupational Health and Safety
Environmental Safety
Target Species Efficacy and Safety

Submissions

The APVMA welcomes comment from interested parties in relation to whether the proposed use of halofuginone in the product would not unduly prejudice to Australia's export trade in beef/veal.

The APVMA has circulated a trade advice notice (TAN) to peak bodies of industry groups to seek their comment on the trade aspects of the application, prior to the APVMA's determination of the application. The TAN is published on the APVMA's website at http://www.apvma.gov.au/new/public_consulation.shtml. A copy can also be requested by contacting Thea Reiman on (02) 6210 4726 or thea.reiman@apvma.gov.au.

Submissions relating to the trade implications of the proposal to grant this application for registration should be addressed in writing to:

Linden Moffatt
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4736
Fax: (02) 6210 4741
Email: linden.moffatt@apvma.gov.au

NOTICE

Prothioconazole

in the product: *REDIGO FUNGICIDAL SEED TREATMENT*

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd for registration of a new product containing the active constituent prothioconazole. The product is *REDIGO FUNGICIDAL SEED TREATMENT*. The product is for control of common bunt in wheat, when applied as a seed treatment.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for 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.

Particulars of Application

Proposed product name:	*REDIGO FUNGICIDAL SEED TREATMENT*
Applicant company:	Bayer CropScience Pty Ltd
Name of active constituent:	prothioconazole
Signal heading:	Exempt from scheduling
Concentration:	100 g/L
Formulation:	Flowable concentrate formulation for seed treatment
Statement of claims:	For the control of common bunt in wheat
Pack sizes:	10 L
Withholding period:	
Harvesting:	Not required when used as directed.
Grazing:	DO NOT graze plants from treated seed, or cut for stockfeed, for 5 weeks after sowing.

Summary of the APVMA's evaluation of *REDIGO FUNGICIDAL SEED TREATMENT* 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 *REDIGO FUNGICIDAL SEED TREATMENT* would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Department of Health and Ageing's Office of Chemical Safety (Occupational Health and Safety) [OCS (OHS)] section has conducted a risk assessment on *REDIGO FUNGICIDAL SEED TREATMENT* and concluded that it can be used safely.

The product will be formulated in Germany in 10 L fluorinated high-density polyethylene (HDPE) containers. Repackaging will not be required in Australia.

Personal protective equipment statements for the Safety Directions of *REDIGO FUNGICIDAL SEED TREATMENT* have been recommended by the OCS (OHS) section, and have been included on the draft label.

The APVMA has considered the OCS (OHS) assessment and accepts its findings and recommendations.

(ii) The APVMA is satisfied that the proposed use of *REDIGO FUNGICIDAL SEED TREATMENT* will not be an undue hazard to the safety of people using anything containing its residues.

Residue data were assessed by the APVMA and Maximum Residue Limits (MRLs) and Withholding Periods (WHPs) are recommended for prothioconazole in *REDIGO FUNGICIDAL SEED TREATMENT,* when used as a seed treatment in wheat.

MRLs established at the Limit(s) of Quantitation (LOQs) for prothioconazole in the relevant substrates, and for the respective food or feed commodities, are recommended for wheat (*0.05mg/kg), edible offal (mammalian) (*0.05mg/kg), eggs (*0.01mg/kg), meat (mammalian) (in the fat) (*0.01mg/kg), milks (*0.01mg/kg), poultry meat (*0.05mg/kg), poultry, edible offal of (*0.05mg/kg), wheat forage (fresh weight) (*0.05 mg/kg) and wheat straw and fodder (*0.05).

(iii) The APVMA is satisfied that the proposed use of the active constituent prothioconazole in *REDIGO FUNGICIDAL SEED TREATMENT* is not likely to be harmful to human beings if used according to the product label directions.

The active constituent, prothioconazole, has been evaluated and the chemistry and manufacturing details of the product have been found acceptable to the APVMA. *REDIGO FUNGICIDAL SEED TREATMENT* has been assessed by the National Drugs and Poisons Scheduling Committee (NDPSC) and has been exempted from inclusion in the Schedules of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

The Department of Health and Ageing's OCS (Toxicology) section have assessed the toxicology of prothioconazole in *REDIGO FUNGICIDAL SEED TREATMENT* and consider that there should be no adverse effects on human health from the product when used in accordance with the label directions.

Prothioconazole has displayed low acute oral, dermal and inhalation toxicity in rats and is not an eye or skin irritant in rabbits, however is expected to be a skin sensitiser. The product *REDIGO FUNGICIDAL SEED TREATMENT* has a similar acute toxicity and irritancy profile.

First Aid and Safety Directions (hazard statements) applicable to *REDIGO FUNGICIDAL SEED TREATMENT* have been recommended and have been included on the draft label.

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

(iv) The APVMA is satisfied that the proposed use of *REDIGO FUNGICIDAL SEED TREATMENT* as a seed treatment for wheat is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The Department of Environment and Water Resources (DEW) has assessed data in support of *REDIGO FUNGICIDAL SEED TREATMENT*. DEW considers that the application contains adequate environmental fate and toxicity data, to demonstrate that the use of *REDIGO FUNGICIDAL SEED TREATMENT* according to the label, is unlikely to result harmful environmental effects.

Laboratory and field fate-studies indicate that the active is readily degraded in soils, does not leach significantly and persistence in soils is not expected. The main metabolite is more persistent (field half-life approximately 72 days), but the use pattern of one application per year, does not lead to any concerns for environmental accumulation or long term impacts. The active is also not expected to persist in aquatic systems, being readily degraded and effectively removed from the system.

The proposed use of the product is not likely to present unacceptable risk to birds, aquatic organisms, sediment dwelling organisms, soil dwelling organisms, soil micro-organisms or terrestrial invertebrates. The chemical or its main metabolite are unlikely to bio-accumulate, and have been shown to rapidly depurate from fish following cessation of exposure.

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

(v) The APVMA is satisfied that the proposed use of prothioconazole in *REDIGO FUNGICIDAL SEED TREATMENT* would not adversely affect trade between Australia and places outside Australia.

Detectable residues of prothioconazole are not expected to occur in harvested wheat and its processed commodities, or in wheat straw or fodder, and therefore the proposed use of prothioconazole in wheat seed is unlikely to unduly prejudice trade in these commodities.

Harvested wheat and its processed commodities, as well as wheat forage, wheat straw and fodder, may be used as livestock feeds. Residues of prothioconazole in these commodities are expected to be below the LOQ. The feeding of these commodities to livestock is not expected to result in detectable residues in animal food commodities, and thus unlikely to prejudice trade in animal commodities.

The overall risk to export trade in wheat and its processed commodities, and animal food commodities derived from livestock fed on produce grown from treated seed, from the registration of *REDIGO FUNGICIDAL SEED TREATMENT*, is considered to be negligible.

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 *REDIGO FUNGICIDAL SEED TREATMENT* adequately demonstrate that under Australian conditions, this product will be effective for the proposed uses.

Public Release Summary

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

Veronia Elliott
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4757
Fax: (02) 6210 4776
email: veronica.elliott@apvma.gov.au

NOTICE

EQUINE ROTAVIRUS

[in the product: **Duvaxyn R Equine Rotavirus Vaccine (Inactivated)**]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Fort Dodge Australia P/L, for the approval of a new active constituent, *Equine rotavirus Strain H2 G2 Serotype*. The APVMA also has before it an application from the same applicant, for the registration of a new product, DUVAXYN R EQUINE ROTAVIRUS VACCINE (Inactivated) containing the above active constituent. The product is for the vaccination of pregnant mares to stimulate the production of antibodies in colostrum and milk against equine rotavirus as an aid in the management of rotavirus enteritis on equine studs.

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 approval of this active constituent and the application for the registration of the product DUVAXYN R EQUINE ROTAVIRUS VACCINE (Inactivated) 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 approval and registration. Comments must be received by the APVMA within 28 days of the date of this Gazette.

Particulars of the Active Constituent

Common name:	*Equine rotavirus*
Strain/serotype:	Strain H2 serotype G2
Identity and purity:	As per Federal Code of Regulation Title 9
Sterility:	As per Federal Code of Regulation Title 9
Extraneous agents:	As per Federal Code of Regulation Title 9
Mycoplasma:	As per Federal Code of Regulation Title 9
Mode of action:	Inducing immunological responses
Site of manufacture:	Recognised by the APVMA
Gene technology:	Not applicable
Applicant Name:	Fort Dodge Australia P/L P O Box 6024 Baulkham Hills B/C NSW 2153
Summary of Use:	This active is to be incorporated in a vaccine for the immunisation of pregnant mares to stimulate the production of antibodies in colostrum and milk against equine rotavirus as an aid in the management of rotavirus enteritis on equine studs.

Particulars of the Product

Proposed product name
Duvaxyn R Equine Rotavirus Vaccine (Inactivated)

Active Constituent
Equine rotavirus Strain H2 G2 Serotype

Adjuvant
Liquid light paraffin

Pharmaceutical form
Emulsion for injection

Target species
Pregnant mares

Indications for use
For the immunisation of pregnant mares to stimulate the production of antibodies in colostrum and milk against equine rotavirus as an aid in the management of rotavirus enteritis on equine studs.

Directions for use
Administer 1mL intramuscularly in the 8^{th}, 9^{th} and 10^{th} months of pregnancy. A booster dose should be given one month prior to foaling in each subsequent pregnancy.

Caution
For use in pregnant mares only.
Allergic reactions such as anaphylaxis occur rarely and may require parenteral treatment with an antihistamine, a corticosteroid or adrenalin as appropriate.

To the user
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling. Seek medical attention immediately,

Incompatibilities
Do not mix with any other medicinal product.

Withholding Period
Nil.

Shelf life
Stored at 2°C to 8°C). Do not freeze.

Label Approval No
56501/10/0607

Applicant Name
Fort Dodge Australia P/L
P O Box 6024 Baulkham Hills B/C NSW 2153

Summary of the APVMA's Evaluation of the Active Constituents and the Product

The chemistry and manufacturing aspects of *Equine rotavirus Strain H2 G2 Serotype* and the product, including starting materials, master seed organism (source, isolation, identification, testing), culture medium, vaccine production, storage, quality control and batch release analysis, have been evaluated and found to be acceptable.

The APVMA is satisfied that the proposed use of *Equine rotavirus Strain H2 G2 Serotype* in DUVAXYN R EQUINE ROTAVIRUS VACCINE (Inactivated) For the immunisation of pregnant mares to stimulate the production of antibodies in colostrum and milk against equine rotavirus as an aid in the management of rotavirus enteritis on equine studs would not be likely to have an effect that is harmful to human beings, environment or trade.

In relation to its assessment of efficacy and safety in target animals the APVMA is satisfied that the data supporting the efficacy and safety for the immunisation of pregnant mares to stimulate the production of antibodies in colostrum and milk against equine rotavirus as an aid in the management of rotavirus enteritis on equine studs, adequately demonstrates that this product is likely to be effective under Australian conditions when used as directed according to the label instructions.

Written submissions on the APVMA's proposal to grant the application for approval of the active constituents *Equine rotavirus Strain H2 G2 Serotype* and the registration of the product in DUVAXYN R EQUINE ROTAVIRUS VACCINE (Inactivated) should be addressed in writing to:

Dr. John Owusu
Manager Vaccines and Antibiotics
Veterinary Medicines Program
The Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4730
Fax: (02) 6210 4741
email: john.owusu@apvma.gov.au

NOTICE

Abamectin

[in the product: *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats*]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Virbac (Australia) Pty Ltd for the registration of a new product, CAPRIMEC BROAD SPECTRUM ORAL ANTIPARASITIC SOLUTION FOR GOATS ('the product'), which contains 0.8 mg/mL of abamectin. The product is an oral drench that is proposed to be used for the treatment and control of abamectin-sensitive strains of internal parasites of goats, including internal parasite strains resistant to benzimidazole, levamisole and morantel.

The application involves consideration of the extension of the use of abamectin to a new food-producing animal species (goats), and the establishment of Australian maximum residue limits (MRLs) for abamectin in goat commodities (meat, offal and milk). Additionally, the application requires the setting of meat and milk withholding periods (WHPs), establishment of an export slaughter interval (ESI), and approval of the proposed product label.

The APVMA invites any person to submit a relevant written submission as to whether the application to register the new product should be granted. Such submissions should state the grounds on which the submission is based. Such grounds should relate only to the trade implications of the use of the product. The APVMA must receive submissions within 28 days of the date of this notice.

Particulars of Application

Product Name:	CAPRIMEC BROAD SPECTRUM ORAL ANTIPARASITIC SOLUTION FOR GOATS	
Applicant Company:	Virbac (Australia) Pty Ltd	
Active Constituent:	Abamectin (0.8 mg/mL)	
Signal Heading:	CAUTION KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY	
Statement of Claim:	An oral drench that is to be used for the treatment and control of abamectin-sensitive strains of internal parasites of goats (including benzimidazole, levamisole and morantel-resistant strains).	
Pack Sizes:	1L, 3L, 5L, 20L	
Proposed MRLs:	Abamectin	
	Goat fat	0.1 mg/kg
	Goat kidney	0.01 mg/kg
	Goat liver	0.05 mg/kg
	Goat meat	0.01 mg/kg
	Goat milk	0.005 mg/kg

Withholding Period (WHP):	MEAT: DO NOT USE less than 14 days before slaughter for human consumption. MILK: Milk collected from does within 4 days (8 milkings) following treatment MUST NOT BE USED for human consumption or processing, or fed to bobby kids.
Export Slaughter Interval (ESI):	DO NOT slaughter for export for 28 days after last treatment.

Summary of the APVMA's assessment of the application in accordance with section 14(3)(e) 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 use of this product would not present an undue hazard to the safety of people consuming produce from animals treated with this product.

(ii) The APVMA has completed an evaluation of the data and supports the proposed MRLs and Withholding Periods for this product and use patterns.

Trade Evaluation

The APVMA has evaluated the residues aspects of the product. The APVMA has proposed appropriate MRLs for abamectin residues when the product is used in meat and dairy goats in accordance with the proposed label instructions, and when the recommended meat and milk WHPs are observed.

Goat meat exports: Australia's main export markets for goat meat are the USA and Taiwan. Taiwan is the most sensitive export market because there are no known Taiwanese MRLs for abamectin residues in edible goat tissues. The APVMA concludes that the appropriate 'endpoints' for the ESI determinations for the product are the limits of quantification (LOQs) of the analytical method, ie 0.001 mg/kg for all goat tissues.

The results from the tissue residues trial demonstrate that abamectin residues in all edible commodities have declined to levels below the method LOQ at 28 days after treatment. Therefore the APVMA recommends an export slaughter interval (ESI) of 28 days for the product.

Overall, the risk to Australia's export trade in goat meat arising from the use of the product is likely to be low when an ESI of 28 days is observed.

The following trade advice statement is proposed to be included on the product label.

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT slaughter for export for 28 days after last treatment.

The APVMA invites comment from interested parties in relation to whether the proposed use of abamectin in the product poses an undue prejudice to Australia's export trade in goat meat.

Trade advice notice
The APVMA has circulated a trade advice notice (TAN) to peak bodies of industry groups to seek their comment on the trade aspects of the application, prior to the APVMA's determination of the application. The TAN is published on the APVMA's website at http://www.apvma.gov.au/new/public_consultation.shtml. A copy can also be requested by contacting Thea Reiman on (02) 6210 4726 or thea.reiman@apvma.gov.au.

Other Criteria for Registration and Label Approval

Additionally, during the evaluation of this application the APVMA addressed and is satisfied of the following criteria for registration and label approval:

Chemistry and Manufacture
Toxicology
Occupational Health and Safety
Environmental Safety
Target Species Efficacy and Safety

Submissions

Submissions relating to the **trade implications** of the proposal to grant this application for registration should be addressed in writing to:

Zuzanna Rajczyk
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4733
Fax: (02) 6210 4741
Email: zuzanna.rajczyk@apvma.gov.au

AMENDMENT No.12J

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_standard.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)
Abamectin			
DELETE:			
VO	**0051**	**Peppers**	**0.02**
ADD:			
VO	**0455**	**Peppers, Sweet [Capsicum]**	**0.02**
Bifenthrin			
DELETE:			
VC	**0045**	**Fruiting vegetables, cucurbits**	**T*0.1**
ADD:			
VC	**0045**	**Fruiting vegetables, Cucurbits**	**0.1**
SO	**0698**	**Poppy seed**	***0.02**
Diazinon			
DELETE:			
HH	**0740**	**Parsley**	**T0.7**
ADD:			
		Coriander (leaves, stem and roots)	***0.05**
HS	**0779**	**Coriander, seed**	***0.05**
HH	**0740**	**Parsley**	***0.05**
Fipronil			
DELETE:			
VO	**0051**	**Peppers**	**T0.1**
ADD:			
VO	**0455**	**Peppers, Sweet [Capsicum]**	**T0.1**
Florasulam			
DELETE:			
GC	**0080**	**Cereal Grains**	**T*0.01**
ADD:			

GC	**0080**	**Cereal grains**	***0.01**
MO	**0105**	**Edible offal (mammalian)**	***0.01**
PE	**0112**	**Eggs**	***0.01**
MM	**0095**	**Meat (mammalian)**	***0.01**
ML	**0106**	**Milks**	***0.01**
PO	**0111**	**Poultry, Edible offal of**	***0.01**
PM	**0110**	**Poultry meat**	***0.01**

Oxytetracycline
DELETE:

		Salmonids	**T*0.2**

ADD:

		Fish muscle	**T0.2**

Triadimenol
DELETE:

VO	**0051**	**Peppers [Capsicums]**	**T1**

ADD:

VO	**0445**	**Peppers, Sweet [Capsicum]**	**T1**

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.

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
Florasulam			
DELETE:			
		Forage and fodder of cereal grains (dry)	**T*0.05**
ADD:			
AF	**0081**	**Forage of cereal grains [fresh weight]**	***0.05**
AS	**0081**	**Straw and fodder of cereal grains (dry)**	***0.05**

For further information please contact:
Joan Downing
Chemistry & Residues Program
Phone: (02) 6210 4820
Fax: (02) 6210 4840

Addendum list of Approved

ACTIVE CONSTITUENTS

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

Approved since Gazette No. 5, 1 May 2007

For Use in Agricultural Chemical Products:

Abamectin	SYNGENTA CROP PROTECTION PTY LIMITED	NORTH CHINA PHARMACEUTICAL CORPORATION GROUP AINO LTD XINGYE ROAD SHIJIAZHUANG ECONOMIC & TECHNICAL DEVELOPMENT ZONE SHIJIAZHUANG CITY HEBEI PROVINCE CHINA	61373
Florasulam	DOW AGROSCIENCES AUSTRALIA LIMITED	DOW AGROSCIENCES LLC DOW TEXAS OPERATIONS 2301 BRAZOSPORT BLVD APB BUILDING FREEPORT TEXAS USA	59826

For enquiries please contact:
Chemistry & Residues Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604
Phone: 02 6210 4818
Fax: 02 6210 4840
Email: apvma.chemistry@apvma.gov.au

NOTICE

Suspension of label approvals of products containing carbendazim

The APVMA has suspended the label approvals of the following products containing carbendazim:

Product Number	Product Name	Registrant	Label Approval Number/s
30399	BASF Bavistin FL Systemic Fungicide	BASF Australia Ltd	30399/02 30399/1100
30740	Hylite Timber Preservative	Osmose Australia Pty Ltd	30740/0799 30740/0500 30740/1100
47708	Hylite 80 Anti-Sapstain	Osmose Australia Pty Ltd	47708/0799
50528	4Farmers Carbendazim 500 Fungicide WP	4Farmers Pty Ltd	50528/0599
51514	Antiblu CC Concentrate Timber Fungicide	Koppers Arch Wood Protection (Aust) Pty Limited	51514/0299
52878	Farmoz Howzat SC Systemic Fungicide	Farmoz Pty Limited	52878/0600 52878/0202
53061	Boomer Systemic Fungicide	Sipcam Pacific Australia Pty Ltd	53061/0600
53390	Chemag Carbendazim 500 SC Fungicide	Imtrade Australia Pty Ltd	53390/0101 53390/0203
53587	Campbell Goldazim 500 SC Systemic Fungicide	Colin Campbell (Chemicals) Pty Ltd	53587/1200
54167	Kendon Carbendazim SC Systemic Fungicide	Kendon Chemicals & MNFG Co Pty Ltd	54167/1201
54269	Nufarm Carbend Fungicide	Nufarm Australia Limited	54269/0701 54269/0402 54269/0502
55949	Rotate SC Systemic Fungicide	Kendon Plant Care Pty Ltd	55949/0602
56497	Sava 500 Fungicide	Allfire Enterprises Pty Ltd	56497/1102
56692	Superway Carbendazim 500 Systemic Fungicide	Superway Garden Products Pty Ltd	56692/0703
56783	Halley Carbendazim 500 Systemic Fungicide	Halley International Enterprise (Australia) Pty Ltd	56783/0103
58452	Kenso Agcare Carbendazim 500 SC Systemic Fungicide	Kenso Corporation (M) SDN BHD	58452/0105
58832	Conquest Commodore 500 Fungicide	Conquest Agrochemicals Pty Ltd	58832/0604
58886	Crop Care Bavistin FL Systemic Fungicide	Crop Care Australasia Pty Ltd	58886/1105 58886/0705 58886/0804
59434	Shincar 500 SC Fungicide	Sinon Australia Pty Limited	59434/0905
59815	Nufarm Spin Flo Systemic Fungicide	Nufarm Australia Limited	59815/0705 59815/1105
60942	Ospray Carbendazim 500 Fungicide	Ospray Pty Ltd	60942/0906

The suspensions are in effect from 4 May 2007 until 4 May 2009.

Reasons

The reason for the suspension is that instructions on currently approved labels for carbendazim products might no longer be adequate. They do not contain instructions advising of the potential birth defect risks for pregnant women and women of childbearing age who may come into contact with carbendazim products.

In view of the identified health and safety concerns, the APVMA has determined that:

- label approvals be suspended; and
- new instructions be issued for the continued supply and use of carbendazim (for product supplied from the manufacturer after 4 May 2007).

The APVMA has also placed all approvals and registrations of carbendazim under reconsideration on the basis of the potential for an undue hazard to human health and to those exposed to carbendazim during its handling, as well as concerns over the adequacy of labelling *(APVMA April 2007 Gazette).*

The APVMA has issued the following instructions that allows for the continued supply and use of carbendazim during the period of suspension.

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR OTHERWISE DEALING WITH PRODUCTS CONTAINING THE SUSPENDED LABEL

For product supplied from the manufacturer BEFORE 4 May 2007

Possession and custody
A person may possess, have custody of, use or otherwise deal with the product containing a suspended label in accordance with the instructions on the suspended label.

Supply
Product can continue to be supplied without a copy of the new instructions.

Use
Product already in the possession of the user should be used in accordance with the suspended label.

For product supplied from the manufacturer AFTER 4 May 2007

Possession and custody
A person may possess, have custody of, use or otherwise deal with the product containing a suspended label only in accordance with these instructions.

Supply
Product may only be supplied if a copy of the instructions contained in this notice are securely affixed to the container.

Use

Product can only be used in accordance with the instructions contained in this notice during the period of suspension.

READ THESE INSTRUCTIONS before using or otherwise handling the product.
When using or otherwise handling the product, follow these instructions.
Other than as specified below, the products must be used in accordance with the instructions on the label attached to the container. Where the instructions below are inconsistent with the label instructions, the instructions on this notice (below) must be followed.
In all states and territories the following are new instructions for products containing carbendazim.

Warning statement (all products)
WARNING: Contains carbendazim which causes birth defects in laboratory animals. Women of childbearing age should avoid contact with carbendazim.

SAFETY DIRECTIONS (wettable powder formulations (all strengths) and soluble concentrates 500 g/L or less, greater than 80 g/L only)

HARMFUL IF INHALED OR SWALLOWED. WILL IRRITATE THE EYES AND SKIN. DO NOT INHALE VAPOUR OR SPRAY MIST. WHEN OPENING THE CONTAINER, PREPARING SPRAY AND USING THE PREPARED SPRAY WEAR COTTON OVERALLS BUTTONED TO THE NECK AND WRIST, A WASHABLE HAT, ELBOW-LENGTH PVC GLOVES AND *A HALF FACEPIECE RESPIRATOR.* AFTER USE AND BEFORE EATING, DRINKING OR SMOKING, WASH HANDS, ARMS AND FACE THOROUGHLY WITH SOAP AND WATER. AFTER EACH DAY'S USE, WASH GLOVES AND CONTAMINATED CLOTHING

Warning
This label is currently suspended. A person must not possess with the intent to supply or deal with any of these products during this period except in accordance with the instructions contained in this notice. A failure to comply with them will result in an offence against the Agvet Codes and the APVMA will take appropriate compliance action.

For any queries or further information about this matter, please contact:

Sharon Pike
Senior Evaluator
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Ph. 02-6210-4773

NOTICE

Suspension of Label Approvals of Selected Products Which Contain Diazinon

The APVMA has suspended the label approvals of five products which contain diazinon, and which have label instructions for dipping and/or jetting sheep. The products are listed in Table 1.

Table 1: Products which contain diazinon, and which have label instructions for dipping and/or jetting sheep

Product number	Product name	Registrant	Label approval numbers
Products with dipping/jetting instructions only			
46295	Coopers 4-in-1 Dip	Schering-Plough Pty Limited	Transitional label, 46295/01, 46295/1202
50544	Diprite Constant Concentration Dipping For Sheep	Argenta Manufacturing Limited	50544/0200
Products with uses in addition to dipping/jetting			
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	Schering-Plough Pty Limited	Transitional label, 33475/01
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Virbac (Australia) Pty Ltd	Transitional label, 38874/0499
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	Rebop Holdings Pty Ltd T/A Western Stock Distributors	Transitional label, 39572/1100

The suspensions are in effect from 4 May 2007 until 4 November 2008.

Existing stocks of the five products already on retail shelves or purchased prior to the suspension may be used according to current label instructions, for a period of two years. However, users should check that any such use complies with state OH&S legislation.

Reasons for suspension

The reasons for suspension are set out in the June 2006 publication titled: *'The reconsideration of approvals of the active constituent diazinon, registration of products containing diazinon and approval of their associated labels, Part 2, Preliminary Review Findings'* (the PRF).

In the PRF the APVMA proposed to find amongst other things, that it is not satisfied that the labels of certain products, including those currently approved for traditional dipping and jetting of sheep, contain adequate instructions in relation to the criteria set out in section 14(3)(g) of the Agvet codes as well as those referred to in Regulations 11 and 12. Additional information on the basis for the findings and the proposed

regulatory outcomes can be found in the PRF on the APVMA website at http://www.apvma.gov.au/chemrev/diazinon.shtml.

The APVMA has completed its consideration of responses relevant to the use of diazinon for dipping and jetting sheep, and has concluded that the responses do not alter its preliminary findings reported in the PRF. The key finding continues to be that there is an occupational health and safety risk to workers when they dip or jet sheep by traditional methods in accordance with existing label instructions.

Further, the APVMA has concluded that there is currently no practical way to vary the existing label instructions on the five registered products listed in Table 1 in order for the APVMA to be satisfied that the use of diazinon for dipping and jetting sheep would not be likely to be harmful to workers.

However, the APVMA is currently evaluating additional information related to the 'Richards System Submersible Cage Dipper'. In due course the APVMA may be able to vary existing label instructions to enable this or other methods of 'cage dipping' to continue, provided that sufficient information is available to enable the AVPMA to conclude that any 'cage dipping' system that is approved for continued use, does not leave workers at risk of harm due to chemical exposure. The APVMA has called for additional data to support alternative 'cage dipping' systems.

In the interim, the APVMA has concluded that it will address the existing OHS concerns related to traditional dipping and jetting practices.

Instructions for possessing, having custody of, supplying, using or dealing with products containing the suspended labels

1. Possession and custody

A person may possess, have custody of, use, or otherwise deal with the product containing a suspended label only in accordance with these instructions.

2. Supply of products with sheep dipping/jetting instructions only

Products listed in Table 2 may not be supplied **from the manufacturer** after the date of this suspension.

For existing stocks already supplied to the wholesale/retail supply chain, supply to the user may continue.

Table 2: Products with sheep dipping/jetting instructions only

Product number	Product name	Registrant	Label approval numbers
46295	Coopers 4-in-1 Dip	Schering-Plough Pty Limited	Transitional label, 46295/01, 46295/1202
50544	Diprite Constant Concentration Dipping For Sheep	Argenta Manufacturing Limited	50544/0200

3. Use of products with sheep dipping/jetting instructions only

Products listed in Table 2 which have been supplied to the user, or which are already in the possession of the user, may be used in accordance with existing label instructions.

4. Supply of products which have label instructions additional to those for sheep dipping and/or jetting

The following label instructions apply to the supply of products listed in Table 3 which are manufactured after the date of this suspension and for the duration of the suspension, but do NOT apply to products which have already been supplied to the wholesale/retail supply chain before the date of this suspension.

Stocks of products listed in Table 3, which are manufactured after the date of suspension, may only be supplied if a copy of these instructions is securely affixed to the container, or if labels of these products have been amended to be consistent with these instructions.

Label instructions

READ THESE INSTRUCTIONS before using or otherwise handling the product.
When using or otherwise handling the product, follow these instructions.
Other than as specified below, the products must be used in accordance with the instructions on the label attached to the container.

If the instructions below are inconsistent with the label instructions, the instructions in this notice must be followed.

In all states and territories the following DIRECTIONS FOR USE apply:

DO NOT use this product for dipping or jetting sheep.

Warning: These labels are not approved during the period of suspension. A person must not possess with the intent to supply, or deal with any product containing this label during this period except in accordance with the instructions contained in this notice. A failure to comply with them will result in an offence against the Agvet Codes and the APVMA will take appropriate compliance action.

For products listed in Table 3, the label instructions set out above apply to products which are supplied from the manufacturer to wholesalers/retailers after the date of suspension.

Products which have already been supplied to the wholesale/retail supply chain prior to 4 May 2007 may be supplied to the end-user without a copy of these instructions.

Table 3: Products which have label instructions additional to those for sheep dipping and/or jetting

Product number	Product name	Registrant	Label approval numbers
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	Schering-Plough Pty Limited	Transitional label, 33475/01
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Virbac (Australia) Pty Ltd	Transitional label, 38874/0499
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	Rebop Holdings Pty Ltd T/A Western Stock Distributors	Transitional label, 39572/1100

5. Use of products which have label instructions additional to those for sheep dipping and/or jetting

Products listed in Table 3 which have been supplied from the manufacturer before 4 May 2007, or which are already in the possession of the user before 4 May 2007, may be used in accordance with existing label instructions for a period of 2 years. Table 4 specifies the last batch of products which were manufactured before 4 May 2007.

Table 4: Batch details of products in Table 3 which were manufactured before 4 May 2007.

Product number	Product name	Batch numbers
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle And Pig Spray	011WS7003, 011WS7004, 011WS7005
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	004VB7001 – 4, 004VB7002 – 3
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	05-233

Products listed in Table 3 which are supplied from the manufacturer after 4 May 2007 may only be used in accordance with the label instructions in this notice.

For any queries or further information about this matter, please contact:

Joan Ashton
Senior Evaluator
Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box E 240
KINGSTON ACT 2604
Phone: 02-6210 4774
Email: joan.ashton@apvma.gov.au

NOTICE

Cancellation of old labels on products containing methomyl and instructions for users of products that may bear these labels

This notice is published under section 45A of the *Agricultural and Veterinary Chemicals Code Act, 1994* (Agvet Codes).

Background

Methomyl is a carbamate insecticide. It is registered for use in a range of vegetable crops including brassicas, legumes, peppers, potatoes, sweet corn and tomatoes. It was previously registered for use on lettuce to control *Helicoverpa* and Cluster caterpillar.

In 2006, a new set of methomyl residue data for hydroponic lettuce became available to the APVMA. The data indicated that methomyl residues in hydroponic lettuce were in excess of the Maximum Residue Limit (MRL), possibly leading to unacceptable dietary intake by consumers.

While the data to hand raised APVMA's concerns, no data were available to examine if a with-holding period longer than the then current period of one day would mitigate the potential dietary intake risks. Although the data that raised concerns were collected from hydroponically grown lettuce, the APVMA considered that, in the absence of relevant data, the dietary exposure concerns were also applicable to field grown lettuce, and food crops grown in covered or protected situations such as glasshouses, greenhouses or plastic tunnels. Furthermore, the concerns were also applicable to the use of methomyl on leafy vegetables as the residue profile for lettuce was considered an indicator of the likely residue profile in other leafy vegetables.

Accordingly, the APVMA wrote to the registrants of methomyl products asking them to remove the use of the chemical on all lettuce, leafy vegetables and all food crops grown in covered or protected situations. The registrants modified their labels instructions to remove those uses. The registrants also applied to cancel all previously approved labels bearing these crops and situations. They put warning stickers on the product containers in the supply chain, and disseminated information to alert end users not to use methomyl in situations mentioned above. All the new product containers supplied carried the new labels.

Regulatory actions

The APVMA is satisfied that there are no valid reasons why it should not agree to the requests of the registrants to cancel the old labels. Accordingly, effective from 21 March 2007, the APVMA cancelled the old labels (shown in Table 1), under s42(1) of the Agvet Codes. Through this Gazette notice, the APVMA declares that subsection s45A(5)(a) of the Agvet Codes ceases to apply in respect of the products bearing the labels shown in Table 1. The usual two-year period is not applicable for the supply of product containers with old labels. Methomyl products containing the cancelled labels can be used, in accordance with the label instructions, on all crops listed on those labels except on hydroponically grown lettuce, leafy vegetables and on any food crops grown in protected situations.

Table 1. Old labels of methomyl products that do not contain adequate instructions and hence are cancelled.

Product registration number	**Product Name**	**Label approval number**
48910	Electra 225 Insecticide	48910/01 48910/0306 48910/20/0505 48910/200/0505 48910/0505
60658	Dupont Lannate L Insecticide	60658/5/0206 60658/10/0206 60658/20/0206 60658/200/0206 60658//0206
32032	Marlin Insecticide	32032/0102 32032/0103 32032/02 32032/03 32032/0499 32032/0600
47336	Lannate L Insecticide	47336/01 47336/0100 47336/0199 47336/0302 47336/0498 47336/0599 47336/0800 47336/1199 47336/3635
47469	Nudrin Insecticide	47469/03 47469/0400 47469/1199
47470	Nudrin 225 Insecticide	47470/02 47470/03 47470/0500 47470/0899 47470/1202

Related information

Note that all methomyl products which bear a currently approved label (modified as above to remove certains uses; see Table 2) can be used in accordance with those label instructions. Further, they can also be used in accordance with permit PER-9932 which was issued in March 2007 based on new data submitted to the APVMA. As noted above, the data which supported the issuing of the permit were not available in late 2006 when the APVMA was liaising with the registrants in relation to the deletion of uses on lettuce. The new data indicated that methomyl can be used on field-grown head and leafy lettuce without causing unacceptable dietary

exposure, provided the crop is not harvested until three days after application of the chemical; there were no new data on hydroponic lettuce. Based on the new data, the APVMA has raised the methomyl MRL in lettuce from 1 to 2 mg/kg. This revised MRL is a temporary MRL valid until 30 June 2008, pending the submission of a full residue data package to the APVMA. For further details of the permit uses, visit http://www.apvma.gov.au/permits/permits.shtml.

Table 2. Currently approved labels for methomyl products.

Product registration number	**Product Name**	**Label approval number**
48910	Electra 225 Insecticide	48910/20/0906 48910/200/0906 48910/0906
60658	Dupont Lannate L Insecticide	60658/5/1006 60658/10/1006 60658/20/1006 60658/200/1006 60658/1006
32032	Marlin Insecticide	32032/20/1006 32032/1006
47336	Lannate L Insecticide	47336/5L/0906 47336/20L/0906 47336/110L/0906 47336/200L/0906 47336/1000L/0906 47336/BULK/0906 47336/0906
47469	Nudrin Insecticide	47469/5L/0906 47469/20L/0906 47469/200L/0906 47469/BULK/0906 47469/0906
47470	Nudrin 225 Insecticide	47470/20L/0906 47470/200L/0906 47470/BULK/0906 47470/0906

NOTICE

New Manufacturing Principles and
Australian Code of Good Manufacturing Practice
for Veterinary Chemical Products

The APVMA has made the *Agricultural and Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007* for the purposes of subsection 23(1) of the *Agricultural and Veterinary Chemicals Act 1994.* The instrument sets out the written principles to be observed in the manufacture of veterinary chemical products. The instrument commences on 1 May 2007 and replaces the *Agricultural and Veterinary Chemicals (Manufacturing Principles) Determination No. 1 of 1997.*

Following consultation with the veterinary chemicals industry and the wider community, the APVMA released the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products on 29 March 2007. Compliance with the Code is a requirement of the new manufacturing principles.

A copy of the *Agricultural and Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007* and the associated Explanatory Statement are available on the APVMA website.

Details of the APVMA's considerations regarding the new manufacturing principles and the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products, including the process of industry consultation, are described in the Regulation Impact Statement (RIS). A copy of the RIS is attached to the Explanatory Statement, which is available on the APVMA website.

For further information, contact:

Dr Bruce Johnson
Manager, Quality Assurance
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
Kingston ACT 2604
Phone: (02) 6272 4924
Fax: (02) 6271 6442
Email: **bruce.johnson@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.

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1. NEW LICENCES:

MILESTONE CHEMICALS AUSTRALIA PTY. LTD. ***ACN: 115 166 357*** 13-19 Percy Street WEST HEIDELBERG VIC 3081	**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 and chemical), storage and release for supply. **Licence No: 2189** ***Full licence issued 30/04/2007***

2. CHANGES TO EXISTING LICENCES:

COSMETIC MANUFACTURERS (AUST) PTY. LTD. ***ACN: 010 501 327*** Unit 3, 10 Kingston Drive GAVEN QLD 4211	**Product Types:*** ***Category 2:*** Creams/lotions, sprays, liquids. **Step(s) of Manufacture:** Formulation including blending, filling, packaging, labelling, and release for supply. **Licence No: 2176** ***Amended licence issued 30/04/2007, with special conditions - change of key personnel and extension of licence scope.***

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* *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

FORT DODGE AUSTRALIA PTY LIMITED
ACN: 000 074 902
2152 Castlereagh Road
PENRITH NSW 2750

Product Types:*
Category 1: Immunobiologicals and sterile products.
Category 2: Liquids.
Step(s) of Manufacture:
Quality assurance (QA) of raw materials, bacterial fermentation, formulation including blending, filling, aseptic filling, sterilisation (heat, filtration), microbiological reduction treatment (heat, filtration, chemical), packaging, labelling, analysis and testing (physical, chemical, Limulus Amoebocyte Lysate [LAL] test, microbiological, sterility test, serological, immunological), storage and release for supply.
Licence No: 1005
Amended licence issued 10/04/2007, with special conditions, change of key personnel and changes to licence scope.

GOODWALE PTY LTD
T/As: Allied Animal Health
ACN: 003 939 339
Unit 15/11 Bowmans Road
KINGS PARK NSW 2148

Product Types:*
Category 2: Pastes and powders.
Category 4: Premixes.
Step(s) of Manufacture:
Quality assurance (QA) of raw materials, formulation including blending, filling, analysis and testing (physical), packaging, labelling, storage and release for supply.
Licence No: 2044
Amended licence issued 02/04/2007, change to key personnel and extension of licence scope.

3. LICENCE CANCELLATIONS:

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

ALL FOOD SYSTEMS PTY LTD
ACN: 078 013 644
2 / 41 Steel Place
MORNINGSIDE QLD 4170

Licence No: 4062
Cancelled: 04/04/07
Reason for cancellation: s127(1)(f)

4. LICENCE SUSPENSIONS:

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

NIL

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* *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

APVMA Contact:
Kathryn Winterton
Quality Assurance and Compliance
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Ph: (02) 6210 4804
Fax: (02) 6210 4813
Email: kathryn.winterton@apvma.gov.au

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* *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

NOTICE

Agricultural Chemical Product Sales
Financial Year 05/06

Agricultural Product Types	No. of Prods	$ Value of disposals
ADJUVANT/SURFACTANTS	271	53,208,148.65
ANTIFOULING - BOAT	52	11,492,586.05
DAIRY CLEANSER	197	10,759,204.50
DISINFECTANT/SANITISER	74	4,647,323.54
FUNGICIDE	526	154,680,139.33
GROWTH PROMOTER/REGULATOR	164	24,856,132.53
HERBICIDE	1442	960,750,963.83
HOUSEHOLD INSECTICIDE	482	115,582,317.37
INSECTICIDE	995	277,075,077.41
MITICIDE	71	13,919,121.81
MIXED FUNCTION PESTICIDE	106	25,279,900.35
MOLLUSCICIDE	40	7,751,678.02
NEMATICIDE	9	2,709,213.67
POOL PRODUCTS/ALGICIDE	627	56,113,105.82
REPELLENT - DOGS/BIRDS ETC	19	1,078,069.94
SEED TREATMENTS	129	37,100,682.20
VERTEBRATE POISON	117	19,003,352.59
WOOD PRESERVATIVE	102	43,074,474.14
MISC-(E.G. SEED SAFENERS,MARKERS ETC).	37	5,299,920.49
TOTALS	**5460**	**$ 1,824,381,412.24**

NOTICE

Veterinary Chemical Product Sales
Financial Year 05/06

Veterinary Product Types		No. of Products	$ Value of disposals
ALIMENTARY SYSTEM	ANTIBLOAT	18	$ 3,567,771.75
ALIMENTARY SYSTEM	ANTIDIARRHOEALS & SCOUR TREATMENTS	21	$ 1,387,910.10
ALIMENTARY SYSTEM	LAXATIVES, PURGATIVES, LUBICANTS, ANTISPASMODICS	12	$ 1,551,241.89
ANAESTHETICS/ANALGESICS	ANAESTHETICS - LOCAL AND GENERAL	49	$ 6,470,634.57
ANAESTHETICS/ANALGESICS	ANALGESICS	13	$ 3,618,104.52
ANTIBIOTIC & RELATED	ANTIBIOTIC - INTRAMAMMARY	30	$ 8,702,795.00
ANTIBIOTIC & RELATED	ANTIBIOTIC - ORAL	183	$ 25,843,705.00
ANTIBIOTIC & RELATED	ANTIBIOTIC - PARENTERAL	93	$ 12,875,361.42
ANTIBIOTIC & RELATED	OTHER ANTI-INFECTIVE AGENTS	52	$ 2,223,692.24
ANTIBIOTIC & RELATED	SULFONAMIDES	43	$ 2,438,730.26
ANTIDOTES	ANTIDOTES	11	$ 1,158,688.27
BRANDING SUBSTANCE	BRANDING SUBSTANCE	8	$ 573,030.80
CARDIOVASCULAR SYSTEM	CARDIAC REACTANTS, CLOTTING AGENTS	29	$ 4,780,748.81
CENTRAL NERVOUS SYSTEM	HYPNOTICS, TRANQUILIZERS, EMETICS, ANTIEMETICS	31	$ 1,908,476.09
DERMATOLOGICAL PREPS.	ANTIBIOTICS, ANTIFUNGALS, CORTICOSTEROID COMBINATIONS	38	$ 1,481,667.36
DERMATOLOGICAL PREPS.	ANTISEPTICS (DERMATOLOGICAL AND GENERAL)	175	$ 15,534,634.93
DERMATOLOGICAL PREPS.	GROOMING AIDS	9	$ 189,662.51
DERMATOLOGICAL PREPS.	NONSTEROIDAL ANTIPRURITICS, KERATOLYICS	42	$ 4,655,711.44

EAR,NOSE,THROAT PREPS.	AURAL	31	$ 2,640,714.69
ENDOCRINE SYSTEM	ANABOLIC STERIODS	29	$ 1,373,042.51
ENDOCRINE SYSTEM	CORTICOSTEROIDS AND ADRENAL COMPOUNDS	32	$ 1,765,893.20
ENDOCRINE SYSTEM	TROPIC HORMONES (PITUITARY) & INSULIN PREPARTIONS	29	$ 4,291,251.57
ENDOCRINE SYSTEM	SEX HORMONES	59	$ 7,525,155.62
EUTHANASIATES	EUTHANASIATES	5	$ 770,249.99
GENITOURINARY SYSTEM	UTERINE OR VAGINAL ACTING AGENTS	10	$ 608,262.85
GENITOURINARY SYSTEM	DIURETICS, ACIDIFIERS, ALKANISERS	30	$ 1,314,136.71
IMMUNOTHERAPY	ANTISERA, ANTIVENOM	10	$ 1,961,701.50
IMMUNOTHERAPY	IMMUNOMODIFYING AGENTS	11	$ 1,036,565.30
IMMUNOTHERAPY	INJECTABLE VACCINES	173	$ 77,959,380.83
IMMUNOTHERAPY	NASAL,ORAL,OPTHALMIC VACCINES	26	$ 12,694,041.00
MUSCULOSKELETAL SYSTEM	ANTI-INFLAMMATORY AGENTS	121	$ 18,094,965.70
MUSCULOSKELETAL SYSTEM	COUNTER-IRRITANTS, RUBEFACIENTS, POULTICES	27	$ 1,121,298.77
MUSCULOSKELETAL SYSTEM	MUSCLE RELAXANTS	6	$ 167,881.12
NUTRITION & METABOLISM	ANTIBIOTIC AND ANTI-INFECTIVE SUPPLEMENTS	42	$ 7,482,921.67
NUTRITION & METABOLISM	DIETARY/THERAPEUTIC PET FOODS	57	$ 13,945,333.29
NUTRITION & METABOLISM	DIGESTIVE ENZYME SUPPLEMENTS	71	$ 9,884,223.67
NUTRITION & METABOLISM	ELECTROLYTES	73	$ 4,481,231.14
NUTRITION & METABOLISM	GROWTH PROMOTANTS	65	$ 32,624,508.64
NUTRITION & METABOLISM	IRON AND HAEMOPOIETIC AGENTS	33	$ 1,771,915.46
NUTRITION & METABOLISM	PROBIOTIC AND PREBIOTIC	11	$ 78,419.48
NUTRITION & METABOLISM	TONICS, STIMULANTS	9	$ 489,348.57
NUTRITION & METABOLISM	VITAMIN, MINERAL, & NUTRITIONAL SUPPLEMENTS	268	$ 27,988,937.04
OPHTHALMIC PREPARATIONS	OPHTHALMIC PREPARATIONS	25	$ 1,939,185.26
PARASITICIDES	BIRDS - EXTERNAL	17	$ 269,573.16

PARASITICIDES	BIRDS - INTERNAL	36	$ 3,687,287.03
PARASITICIDES	BIRDS & LARGE ANIMALS - INTERNAL	6	$ 148,770.16
PARASITICIDES	LARGE & SMALL ANIMALS - EXTERNAL	16	$ 1,305,996.80
PARASITICIDES	LARGE ANIMALS - EXTERNAL	145	$ 68,780,132.08
PARASITICIDES	LARGE ANIMALS - INTERNAL	256	$ 58,322,647.36
PARASITICIDES	LARGE ANIMALS - INTERNAL & EXTERNAL	48	$ 49,060,633.46
PARASITICIDES	SMALL ANIMALS - EXTERNAL	272	$ 74,886,494.69
PARASITICIDES	SMALL ANIMALS - INTERNAL	250	$ 55,120,565.92
PARASITICIDES	SMALL ANIMALS - INTERNAL AND EXTERNAL	20	$ 9,017,504.00
PARASITICIDES	SMALL ANIMALS & BIRDS - EXTERNAL	8	$ 13,606,223.87
RESPIRATORY SYSTEM	EXPECTORANTS,MUCOLYTICS,DECONGESTANTS,BRONCHODILATORS,RESP,STIM	26	$ 912,725.59
MISCELLANEOUS	E.G: DISINFECTANTS,,BEHAVIOUR MODIFIERS,GENERAL DERMATOLOGICAL PREPARATIONS, ANTIHISTAMINES, MISCELLANEOUS ETC	49	$ 6,429,679.20
TOTALS		**3259**	**$ 674,521,365.86**