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Notice – New Agricultural & Veterinary Chemical Products

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**NOTICE OF REGISTRATION OF
AGRICULTURAL AND VETERINARY
CHEMICAL PRODUCTS**

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the registration in respect of the following products, with effect from the dates shown.

**AGRICULTURAL CHEMICAL
PRODUCTS**

1. RESTRICTED PRODUCT:

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

**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:

**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: Innova Picloram + MCPA 242 Herbicide
Active Constituent/s: 26 g/L picloram present as the potassium salt, 420 g/L MCPA present as the potassium salt
Applicant Name: Syngenta Crop Protection

Pty Limited

Applicant ACN: 002 933 717

Summary of Use: For the control of climbing buckwheat, common sowthistle, skeleton weed, capeweed, doublegee and other broadleaf weeds in winter cereals and linseed crops.

Date of Registration: 18 June 2007

Label Approval No: 61620/20/0307,
61620/0307

Product Name: Allfire Triadimefon 500WG Fungicide

Active Constituent/s: 500 g/kg triadimefon

Applicant Name: Allfire Enterprises Pty Ltd

Applicant ACN: 097 970 280

Summary of Use: For the control of fungal diseases in wheat and barley.

Date of Registration: 18 June 2007

Label Approval No: 61753/1KG/0307,
61753/10KG/0307

Product Name: 30 Seconds Roof Treatment Lichen, Moss & Algae Killer Concentrate Spray & Walk Away

Active Constituent/s: 99g/L benzalkonium chloride

Applicant Name: 30 Seconds Limited (NZ)

Summary of Use: For the control of lichen, moss & algae on roofing surfaces.

Date of Registration: 19 June 2007

Label Approval No: 61692/1L/0107,
61692/2L/0107, 61692/5L/0107,
61692/10L/0107, 61692/20L/0107,
61692/100L/0107, 61692/200L/0107

Product Name: Searles White Oil Insect Control Spray

Active Constituent/s: 820 g/L petroleum oil

Applicant Name: J C & A T Searle Pty Ltd

Applicant ACN: 002 898 893

Summary of Use: For the control of various insects on citrus, roses and ornamentals.

Date of Registration: 19 June 2007

Label Approval No: 61781/200ML/0507,
61781/500ML/0507, 61781/1L/0507

Product Name: Low Toxic For You & Your Garden Yates Nature's Way Fruit Fly Control

Active Constituent/s: 0.24 g/L spinosad

Applicant Name: Yates Australia A Div Of Orica Australia Pty Ltd

Applicant ACN: 004 117 828

Summary of Use: Insecticidal lure to control fruit flies on fruit trees, vines, nuts, trees, vegetables and ornamentals in the home garden.

Date of Registration: 19 June 2007

Label Approval No: 60907/200/1206

Product Name: Ospray Unleash Herbicide
Active Constituent/s: 26 g/L picloram present as the potassium salt, 420 g/L MCPA present as the potassium salt
Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169
Summary of Use: For the control of climbing buckwheat, common sowthistle, skeleton weed, capeweed, doublegee and other broadleaf weeds in winter cereals and linseed crops.
Date of Registration: 20 June 2007
Label Approval No: 61894/20L/0407, 61894/0407

Product Name: Innova Picloram + Triclopyr 400 Herbicide
Active Constituent/s: 100 g/L picloram present as the hexyloxypropylamine salt, 300 g/L triclopyr present as the butoxyethyl ester
Applicant Name: Syngenta Crop Protection Pty Limited
Applicant ACN: 002 933 717
Summary of Use: For the control of environmental and noxious woody and herbaceous weeds.
Date of Registration: 25 June 2007
Label Approval No: 61648/20/0507, 61648/0507

Product Name: Mortein Naturgard Fly Control Spray
Active Constituent/s: 16.1 g/kg piperonyl butoxide, 3.5 g/kg pyrethrins
Applicant Name: Reckitt Benckiser (Australia) Pty Limited
Applicant ACN: 003 274 655
Summary of Use: An aerosol product for use as a fly spray.
Date of Registration: 25 June 2007
Label Approval No: 61747/235g/0107, 61747/320g/0107

Product Name: Ospray Firefighter Herbicide
Active Constituent/s: 200 g/L bromoxynil present as the n-octanoyl ester
Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169
Summary of Use: For the control of weeds in wheat, oats, barley, cereal rye, triticale, linseed, clover, Lucerne, turf, fallow, non-crop roadsides and rights-of-way.
Date of Registration: 27 June 2007
Label Approval No: 61945/5L/0507, 61945/20L/0507, 61945/110L/0507, 61945/200L/0507, 61945/1000L/0507, 61945/05/07

Product Name: Chemforce Tebuconazole 430 SC Fungicide
Active Constituent/s: 430 g/L tebuconazole
Applicant Name: Frank Vanderkley & Paul Richards T/A Chemforce Australia
Summary of Use: For the control of leaf spot and leaf speckle on bananas, rust, leaf spot, and net blotch of peanuts; foliar diseases on cereal crops; and other diseases on beans, peas, onions, pawpaw, pyrethrum and ryegrass and fescue seed crops.
Date of Registration: 28 June 2007
Label Approval No: 61936/10L/0507, 61936/20L/0507, 61936/110L/0507, 61936/200L/0507, 61936/0507

Product Name: Genero 600 Flowable Seed Dressing Insecticide
Active Constituent/s: 600 g/L imidacloprid
Applicant Name: Echem (Aust) Pty Limited
Applicant ACN: 089 133 095
Summary of Use: Seed treatment product for the control of thrips, aphids, brown flea beetle and wireworms on cotton; protection of canola, pastures and lupins from damage by redlegged earth mite and blue oat mite; control of aphids and prevention of spread of barley yellow dwarf virus in cereal crops; and control of some soil pests of summer crops.
Date of Registration: 29 June 2007
Label Approval No: 62019/5L/0507, 62019/20L/0507, 62019/200L/0507, 62019/1000L/0507, 62019/0507

Product Name: Farmoz Chief 250 Liquid Fungicide
Active Constituent/s: 250 g/L iprodione
Applicant Name: Farmoz Pty Limited
Applicant ACN: 050 328 973
Summary of Use: For the control of certain fungal diseases in various crops and situations as specified in the directions for use table.
Date of Registration: 2 July 2007
Label Approval No: 61083/5R/0407, 61083/10R/0407, 61083/20R/0407, 61083/0407

Product Name: Innova Glyphosate Trimesium 480 Herbicide
Active Constituent/s: 480 g/L glyphosate-trimesium
Applicant Name: Syngenta Crop Protection Pty Limited
Applicant ACN: 002 933 717
Summary of Use: For the control of a wide range of annual and perennial weeds.
Date of Registration: 02 July 2007
Label Approval No: 62011/20/0607

Product Name: Forward Paraquat 250 Herbicide
Active Constituent/s: 250 g/L paraquat present as paraquat dichloride
Applicant Name: Forward Australia Pty Ltd
Applicant ACN: 112 532 395
Summary of Use: For the control of annual and perennial weeds in certain situations.
Date of Registration: 2 July 2007
Label Approval No: 60444/20L/0107, 60444/100L/0107, 60444/110L/0107, 60444/200L/0107, 60444/1000L/0107, 60444/0107

Product Name: Dupont Cimarron Herbicide
Active Constituent/s: 200 g/kg metsulfuron-methyl
Applicant Name: Du Pont (Australia) Ltd
Applicant ACN: 000 716 469
Summary of Use: For use to control broadleaf weeds in forestry, pastures, rights of way, commercial and industrial areas.
Date of Registration: 2 July 2007
Label Approval No: 60844/500/0307, 60844/500a/0307, 60844/3/0307, 60844/3a/0307

Product Name: Tradelands Fluazifop-P 212 EC Selective Herbicide
Active Constituent/s: 212g/L fluazifop-p present as the butyl ester
Applicant Name: Tradelands Pty Ltd
Applicant ACN: 115 285 679
Summary of Use: For the control of certain grasses in a variety of agricultural and horticultural situations.
Date of Registration: 3 July 2007
Label Approval No: 61355/1/0307, 61355/5L/0307, 61355/5R/0307, 61355/20L/0307, 61355/leaf/0307

Product Name: Richgro Ant, Spider & Cockroach Insecticide
Active Constituent/s: 3 g/L permethrin (25:75)
Applicant Name: A Richards Pty Ltd T/A Richgro Garden Products
Applicant ACN: 008 734 852
Summary of Use: For contact and residual control of ants, bedbugs, cockroaches, fleas, silverfish and spiders in domestic and commercial premises.
Date of Registration: 3 July 2007
Label Approval No: 61618/750ML/0507

Product Name: Baygon Do-It-Yourself (DIY) Indoor Expert Home Surface Spray
Active Constituent/s: 1 g/kg imiprothrin, 1 g/kg cypermethrin
Applicant Name: S.C. Johnson & Son Pty Ltd
Applicant ACN: 000 021 009

Summary of Use: For the control of indoor crawling insect pests.
Date of Registration: 3 July 2007
Label Approval No: 61833/250G/0407, 61833/350G/0407

Product Name: Genfarm Optex 240EC Herbicide
Active Constituent/s: 240 g/L oxyfluorfen
Applicant Name: Genfarm Crop Protection Pty Ltd
Applicant ACN: 115 327 378
Summary of Use: For selective weed control of broadleaf weeds and some grasses.
Date of Registration: 03 July 2007
Label Approval No: 61576/1L/0407, 61576/5L/0407, 61576/10L/0407, 61576/20L/0407, 61576/0407

Product Name: Kenso Agcare Dicamba 500 Selective Herbicide
Active Constituent/s: 500 g/L dicamba present as the dimethylamine salt
Applicant Name: Kenso Corporation (M) Sdn Bhd
Summary of Use: For the control of certain broadleaf weeds in winter cereals, pastures, conservation tillage, sugar cane, turf, rice and non-crop areas.
Date of Registration: 04 July 2007
Label Approval No: 61369/5/0507, 61369/20/0507, 61369/110/0507, 61369/0507

Product Name: Richgro Pyrethrum Insect Killer
Active Constituent/s: 1.2 g/L piperonyl butoxide, 0.3 g/L pyrethrins
Applicant Name: A Richards Pty Ltd T/A Richgro Garden Products
Applicant ACN: 008 734 852
Summary of Use: For the control of ants, aphids, caterpillars, thrips and other insects on garden plants.
Date of Registration: 4 July 2007
Label Approval No: 61617/750ML/0407

Product Name: Summit Ecopar 20 SC Herbicide
Active Constituent/s: 20g/L pyraflufen-ethyl
Applicant Name: Summit Agro Australia Pty Ltd
Applicant ACN: 105 302 298
Summary of Use: For the control of annual broadleaf weeds in wheat, barley and triticale.
Date of Registration: 5 July 2007
Label Approval No: 60493/20L/0607

Product Name: Castrate Selective Herbicide
Active Constituent/s: 60 g/L cloquintocet-mexyl, 240 g/L clodinafop-propargyl
Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169
Summary of Use: For the control of wild oats, paradoxa grass, annual ryegrass, canary grass and annual ryegrass in wheat.
Date of Registration: 5 July 2007
Label Approval No: 61510/1L/0707, 61510/5L/0707, 61510/0707

Product Name: David Grays Antex Insecticide Granules
Active Constituent/s: 2 g/kg bifenthrin
Applicant Name: David Gray & Co. Pty Limited
Applicant ACN: 008 671 127
Summary of Use: For the control of ants around the home.
Date of Registration: 6 July 2007
Label Approval No: 60398/500G/0207

Product Name: Sorex Pro Rodenticide Blocks
Active Constituent/s: 0.05 g/kg difenacoum
Applicant Name: Sorex Ltd
Summary of Use: For the control of brown or norway rat (*rattus norvegicus*) and mice, including those resistant to other anticoagulants.
Date of Registration: 9 July 2007
Label Approval No: 61842/5KG/0407, 61842/10KG/0407

Product Name: Sorex Pro Rodenticide Paste
Active Constituent/s: 0.05 g/kg difenacoum
Applicant Name: Sorex Ltd
Summary of Use: For the control of brown or norway rat (*rattus norvegicus*) and mice, including those resistant to other anticoagulants.
Date of Registration: 9 July 2007
Label Approval No: 61910/5KG/0407

Product Name: Sorex Pro Rodenticide Pellets
Active Constituent/s: 0.05 g/kg difenacoum
Applicant Name: Sorex Ltd
Summary of Use: For the control of brown or norway rat (*rattus norvegicus*) and mice, including those resistant to other anticoagulants.
Date of Registration: 9 July 2007
Label Approval No: 61847/5KG/0407

Product Name: Sorex Pro Rodenticide Gel
Active Constituent/s: 0.05 g/kg difenacoum
Applicant Name: Sorex Ltd
Summary of Use: For the control of brown or norway rat (*rattus norvegicus*) and mice, including those resistant to other anticoagulants.
Date of Registration: 9 July 2007
Label Approval No: 61848/300g/0407

Product Name: Diehard 240 EC Herbicide
Active Constituent/s: 240g/L clethodim
Applicant Name: Allfire Enterprises Pty Ltd
Applicant ACN: 097 970 280
Summary of Use: For the control of certain grasses in a range of horticultural crops, cereal crops, forestry, pulse crops and ornamentals.
Date of Registration: 10 July 2007
Label Approval No: 60661/1L/0307, 60661/5L/0307, 60661/0307

Product Name: Black Flag Rapid Kill Blowfly Strength Fly & Insect Killer Household Protection
Active Constituent/s: 1.26 g/kg esbiothrin, 0.50 g/kg permethrin
Applicant Name: Reckitt Benckiser (Australia) Pty Limited
Applicant ACN: 003 274 655
Summary of Use: An aerosol product for control of flies, mosquitoes, cockroaches and other insects in the home.
Date of Registration: 11 July 2007
Label Approval No: 60628/200g/0107, 60628/300g/0107

Product Name: Nufarm Preface 200SC Termiticide
Active Constituent/s: 200g/L imidacloprid
Applicant Name: Nufarm Australia Limited
Applicant ACN: 004 377 780
Summary of Use: For the control of termites in buildings and other situations.
Date of Registration: 10 July 2007
Label Approval No: 61597/1A/1206, 61597/2.5A/1206, 61597/5A/1206, 61597/1B/1206, 61597/2.5B/1206, 61597/5B/1206

Product Name: Brigade T & O Multi-Insecticide
Active Constituent/s: 100 g/L bifenthrin
Applicant Name: FMC Australasia Pty Ltd
Applicant ACN: 095 326 891
Summary of Use: For the control of a range of pests in turf and ornamental plants, as well as control of a range of urban interior and exterior pests.
Date of Registration: 11 July 2007
Label Approval No: 61928/1L/0507, 61928/5L/0507, 61928/10L/0507, 61928/0507

Product Name: Voodoo 200 Insecticide
Active Constituent/s: 200 g/L imidacloprid
Applicant Name: Sipcam Pacific Australia Pty Ltd
Applicant ACN: 073 176 888
Summary of Use: Control of insect pests of cotton, fruit, vegetables, ornamentals and turf.

Date of Registration: 12 July 2007
Label Approval No: 60848/1L/1206,
60848/5L/1206, 60848/10L/1206,
60848/20L/1206

Product Name: Titan Paraquat 250 Herbicide
Active Constituent/s: 250 g/L paraquat present
as paraquat dichloride
Applicant Name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574
Summary of Use: For the control of a wide
range of grasses and broadleaf weeds.
Date of Registration: 12 July 2007
Label Approval No: 61869/20-1000/0507,
61869/0507

Product Name: Foxtrot Selective Herbicide
Active Constituent/s: 34.5g/L cloquintocet-
mexyl and 69g/L fenoxaprop-p-ethyl.
Applicant Name: Ospray Pty Ltd
Applicant ACN: 110 199 169
Summary of Use: Herbicide for the selective
weed control of wild oats and annual phalaris in
wheat, barley, triticale and cereal rye crops.
Date of Registration: 12 July 2007
Label Approval No: 61410/10L/0607,
61410/20L/0607

Product Name: Innova Fluroxypyr 200
Herbicide
Active Constituent/s: 200 g/L fluroxypyr as the
methyl heptyl ester
Applicant Name: Syngenta Crop Protection Pty
Limited
Applicant ACN: 002 933 717
Summary of Use: For the control of a wide
range of broadleaf weeds in fallow, lucerne,
maize, millets, pastures, poppies, sorghum,
sugar cane, sweet corn 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: 13 July 2007
Label Approval No: 61651/20/0507

Product Name: Family Protection Aerogard
Odourless Low Irritant* Great For Kids 12
Months & Over Insect Repellent Roll On
Active Constituent/s: 99.6 g/L picaridin
Applicant Name: Reckitt Benckiser (Australia)
Pty Limited
Applicant ACN: 003 274 655
Summary of Use: For repelling mosquitoes,
flies, sandflies and other annoying and biting
insects.
Date of Registration: 13 July 2007
Label Approval No: 61363/50mL/0607,
61363/100mL/0607

Product Name: Crop Care Stomp 440
Herbicide
Active Constituent/s: 440 g/L pendimethalin
Applicant Name: Crop Care Australasia Pty
Ltd
Applicant ACN: 061 362 347
Summary of Use: For the control of
wireweed, annual grasses (including annual
ryegrass) and certain broadleaf weeds in various
crops.
Date of Registration: 13 July 2007
Label Approval No: 61322/20L/0906,
61322/110L/0906, 61322/1000L/0906,
61322/0906

Product Name: Colorfast Red Spray Marker
Active Constituent/s: 355g/L rhodamine b
Applicant Name: Becker Underwood Pty Ltd
Applicant ACN: 107 914 563
Summary of Use: For use as a spray marker
and as a foam marking colourant.
Date of Registration: 13 July 2007
Label Approval No: 61185/1L/0407,
61185/5L/0407

Product Name: 4Farmers Turbooil Adjuvant
Active Constituent/s: 426g/L mineral oil
Applicant Name: 4 Farmers Pty Ltd
Applicant ACN: 067 443 485
Summary of Use: For use as a spray adjuvant.
Date of Registration: 13 July 2007
Label Approval No: 61933/10L/0507,
61933/20L/0507

Product Name: Crop Care Cobber 475
Herbicide
Active Constituent/s: 475 g/L 2,4-d present as
the dimethylamine and diethanolamine salts
Applicant Name: Crop Care Australasia Pty
Ltd
Applicant ACN: 061 362 347
Summary of Use: For the control of emerged
broadleaf weeds prior to sowing crops and
pastures, in conservative tillage situations and
for selective weed control of crops.
Date of Registration: 16 July 2007
Label Approval No: 61565/20L/0507,
61565/110L/0507, 61565/200L/0507,
61565/500L/0507, 61565/1000L/0507,
61565/0507

Product Name: Titan Amine 300 Herbicide
Active Constituent/s: 300g/L 2,4-D present as
the isopropylamine salt.
Applicant Name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574
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 various crops and

situations.

Date of Registration: 16 July 2007
Label Approval No: 61568/20/0107,
61568/110/0107, 61568/200/0107,
61568/1000/0107, 61568/0107

Product Name: Family Protection Aerogard
Odourless Low Irritant* Great For Kids 12
Months & Over Insect Repellent Spray
Active Constituent/s: 92.8 g/L picaridin
Applicant Name: Reckitt Benckiser
(Australia) Pty Limited
Applicant ACN: 003 274 655
Summary of Use: For repelling mosquitoes,
flies, sandflies and other annoying and biting
insects.
Date of Registration: 16 July 2007
Label Approval No: 61365/135mL/0607,
61365/175mL/0607

Product Name: Iodogard Cleaner Sanitiser
Active Constituent/s: 15g/L iodine, 99g/L
phosphoric acid.
Applicant Name: Chemetall (Australasia) Pty
Ltd
Applicant ACN: 074 869 015
Summary of Use: For sanitising poultry sheds,
animal pens and farming equipment.
Date of Registration: 18 July 2007
Label Approval No: 61659/25-200/0207

4.VARIATIONS

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

Product Name: Farnoz Diuron 900 WDG
Herbicide
Applicant Name: Farnoz Pty Limited
Applicant ACN: 050 328 973
Summary of Variation: To add field peas, faba
beans, lentils, narbon beans, chickpeas, vetch
and non-crop areas. Changes to rates and weeds
controlled of the following uses: apples and
pear, banana, citrus, coffee, cotton, gladioli,
grass and seed crops, lucerne, lupins, paw paw,
pineapple, sugar cane, summer fallows, winter
cereals and vineyards. Variation of states for
irrigation channel use and additional statements
under 'general instructions'
Date of Variation: 22 June 2007
Label Approval No: 46812/10/0207,
46812/15/0207, 46812/LL/0207, 46812/0207

Product Name: Nufarm Opus 125 Fungicide
Applicant Name: Nufarm Australia Limited
Applicant ACN: 004 377 780
Summary of Variation: Extension of use for
the control of certain fungal diseases in wheat
and barley.

Date of Variation: 10 July 2007
Label Approval No: 60135/5L/0607,
60135/10L/0607, 60135/20L/0607,
60135/10LL/0607, 60135/0607

Product Name: Tordon 75-D Herbicide
Applicant Name: Dow Agrosciences Australia
Limited
Applicant ACN: 003 771 659
Summary of Variation: To extend the use to
include the control of Fleabane (*Conyza*
Bonariensis).
Date of Variation: 11 July 2007
Label Approval No: 40487/5/0507,
40487/20/0507

Product Name: Certified Organics
Concentrate Organic Interceptor Contact Weed
Control
Applicant Name: Certified Organics (Aust)
Pty Ltd
Applicant ACN: 099 114 413
Summary of Variation: Extension of use as a
non-systemic contact herbicide for general weed
control in home-garden/domestic situations, to a
non-selective, non-systemic contact herbicide
for control of specific broadleaf and grass weeds
in commercial orchards and vineyards.
Date of Variation: 11 July 2007
Label Approval No: 56204/15-942L/1006

Product Name: Calypso 480 SC Insecticide
Applicant Name: Bayer Cropscience Pty Ltd
Applicant ACN: 000 226 022
Summary of Variation: Extend the use to
include control of dimpling bug in apples and
oriental fruit moth in pome fruit.
Date of Variation: 11 July 2007
Label Approval No: 53203/5/0507,
53203/0507

5. RESTRICTED PRODUCT VARIATION

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

**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: Vetmec Pour-On For Cattle
Active Constituent/s: 10mg/mL ivermectin
Applicant Name: Chemvet Australia Pty Ltd
Applicant ACN: 059 380 068
Summary of Use: For the treatment and control of internal and external parasites of beef and dairy cattle.
Date of Registration: 20 June 2007

Label Approval No: 61813/2.5L/207,
61813/10L/0207

Product Name: Nutritional Physiology Corporation NPC Beef Culture
Active Constituent/s: 4×10^7 *Lactobacillus acidophilus* (strains 25 and 51), 2×10^{10} *propionibacterium freudenreichii*
Applicant Name: Nutrition Physiology Corporation
Summary of Use: Microbial feed additive for beef cattle for the maintenance of healthy animals during normal husbandry practice.
Date of Registration: 26 June 2007
Label Approval No: 61530/500G/0207

Product Name: Hill's Prescription Diet Canine Z/D Ultra Allergen-Free
Applicant Name: Hill's Pet Nutrition Inc
Summary of Use: A complete pet diet which is intended to assist in the nutritional management of dogs with dietary allergies.
Date of Registration: 2 July 2007
Label Approval No: 59791/1.0kg/0706,
59791/3.6kg/0706, 59791/8.1kg/0706

Product Name: Troy Vitamin ADE Injection For Cattle, Sheep & Pigs
Active Constituent/s: Each mL contains 294 mg retinol palmitate (vitamin A), 1.25 mg cholecalciferol (vitamin D3), 50 mg alpha tocopherol acetate (vitamin E).
Applicant Name: Troy Laboratories Pty Ltd
Applicant ACN: 000 283 769
Summary of Use: An injectable formulation of vitamins A, D3 and E for the treatment of deficiencies in cattle, sheep and pigs.
Date of Registration: 2 July 2007
Label Approval No: 61154/100ML/0507

Product Name: Elanco Nicarbazine Granular
Active Constituent/s: not less than 270 g/kg nicarbazine
Applicant Name: Elanco Animal Health A Div of Eli Lilly Aust Pty Ltd
Applicant ACN: 000 233 992
Summary of Use: An aid in the prevention and control of coccidiosis caused by *Eimeria spp.*
Date of Registration: 02 July 2007
Label Approval No: 61635/25kg/0107

Product Name: Elanco Narasin Granular
Active Constituent/s: not less than 105 g/kg narasin
Applicant Name: Elanco Animal Health A Div of Eli Lilly Aust Pty Ltd
Applicant ACN: 000 233 992
Summary of Use: For improved feed conversion efficiency in lotfed cattle and as an aid in the prevention of *coccidiosis* caused by

Eimeria acervulina, *E. brunette*, *E. maxima*, *E. mivati*, *E. necatrix* and *E. tenella* in broiler chickens.

Date of Registration: 2 July 2007

Label Approval No: 61637/25kg/0107

Product Name: Hill's Prescription Diet Feline 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 cats with liver disease.

Date of Registration: 2 July 2007

Label Approval No: 60068/1.8kg/0407

Product Name: Procure Combinator Plus Selenium

Active Constituent/s: 82.5 g/L levamisole hydrochloride (equivalent to 70.0 g/L levamisole), 36 g/L albendazole oxide (equivalent to 34.0 g/L albendazole), 1 g/L selenium as sodium selenate

Applicant Name: Allfire Enterprises Pty Ltd

Applicant ACN: 097 970 280

Summary of Use: For the control of gastrointestinal roundworms, lungworms and tapeworm and aids in the control of selenium deficiencies in sheep.

Date of Registration: 2 July 2007

Label Approval No: 61718/10L/0407, 61718/20L/0407

Product Name: Vetsense Permetrol Insecticidal Spray And Rinse Concentrate For Dogs And Horses

Active Constituent/s: 40g/L permethrin 25:75(cis:trans)

Applicant Name: C M Laboratories Pty Ltd

Applicant ACN: 098 897 637

Summary of Use: For the control of buffalo fly, stable fly and biting insects on horses, control of fleas and ticks on dogs and as an aid in the treatment of Flea Allergy Dermatitis on dogs and Queensland Itch on horses. Does not control paralysis ticks on dogs.

Date of Registration: 2 July 2007

Label Approval No: 60919/250mLC/0107, 60919/250mL/0107, 60919/500mL/0107, 60919/1L/0107

Product Name: Purina Total Care Tasty Allwormer For Dogs

Active Constituent/s: Each tablet contains 50 mg praziquantel, 225 mg oxiabendazole

Applicant Name: Nestle Purina Petcare A Div Of Nestle Australia Ltd

Applicant ACN: 000 011 316

Summary of Use: For the treatment and control

of roundworm, hookworm, whipworm and tapeworm including hydatids in dogs.

Date of Registration: 3 July 2007

Label Approval No: 61428/1/0407, 61428/2/0407, 61428/3/0407, 61428/4/0407, 61428/6/0407, 61428/10/0407, 61428/10B/0407, 61428/50/0407, 61428/100/0407, 61428/250/0407, 61428/500/0407

Product Name: Fort Dodge Fortaclav Injection

Active Constituent/s: 140 mg/mL amoxicillin (as trihydrate), 35 mg/mL clavulanic acid (as potassium clavulanate)

Applicant Name: Norbrook Laboratories Australia Pty Limited

Applicant ACN: 080 972 596

Summary of Use: For the treatment of infections caused by organisms sensitive to amoxicillin and clavulanic acid in dogs and cats.

Date of Registration: 3 July 2007

Label Approval No: 61512/10/0207, 61512/50/0207, 61512/10ML/0207, 61512/50ML/0207, 61512/0207

Product Name: Hill's Prescription Diet s/d Feline

Applicant Name: Hill's Pet Nutrition Inc

Summary of Use: A complete pet diet which is intended to assist in the nutritional management of cats with struvite urolithiasis.

Date of Registration: 3 July 2007

Label Approval No: 60082/1.8kg/0407

Product Name: Ilium Frontera Spray

Active Constituent/s: 2.5 g/L fipronil

Applicant Name: Troy Laboratories Pty Ltd

Applicant ACN: 000 283 769

Summary of Use: For the treatment and prevention of flea infestations, control of flea allergy dermatitis, control of ticks (including paralysis tick) and control of biting lice on dogs and cats.

Date of Registration: 3 July 2007

Label Approval No: 60887/100ML/0307, 60887/200ML/0307, 60887/500ML/0307, 60887(0307)

Product Name: Purina Total Care Tasty Allwormer For Small Dogs And Puppies

Active Constituent/s: Each tablet contains 25 mg praziquantel, 112.50 mg oxiabendazole.

Applicant Name: Nestle Purina Petcare A Div Of Nestle Australia Ltd

Applicant ACN: 000 011 316

Summary of Use: For the treatment and control of roundworm, hookworm, whipworm and tapeworm including hydatids in small dogs and puppies.

Date of Registration: 03 July 2007

Label Approval No: 61439/4/0307,

61439/1/0407, 61439/2/0407, 61439/3/0407,
61439/4/0407, 61439/6/0407, 61439/10B/0407,
61439/10H/0407, 61439/50/0407,
61439/100/0407, 61439/250/0407,
61439/500H/0407

Product Name: Hill's Prescription Diet t/d
Feline

Applicant Name: Hill's Pet Nutrition Inc

Summary of Use: A complete diet which is
intended to treat and prevent a range of dental
conditions in cats.

Date of Registration: 4 July 2007

Label Approval No: 59788/1.8kg/0706,
59788/4.5kg/0706

Product Name: Fort Dodge Carprogesic 20mg
Tablets For Dogs

Active Constituent/s: 20 mg/Tb carprofen

Applicant Name: Norbrook Laboratories
Australia Pty Limited

Applicant ACN: 080 972 596

Summary of Use: For oral use to relieve pain
and inflammation in dogs.

Date of Registration: 5 July 2007

Label Approval No: 61026/100C/0806,
61026/500C/0806, 61026/100T/0806,
61026/500T/0806, 61026/0806

Product Name: Petpep Up For Dogs Probiotic
Food Supplement For Dogs

Active Constituent/s: 1 mg/g Calcium
ascorbate, 10,000,000 cfu/g Lactobacillus
acidophilus, <500 cfu/g Saccharomyces
boulardii, <500 cfu/g Saccharomyces cerevisiae

Applicant Name: J.V.P Foods A Div of
A.G.M. Foods Pty Ltd

Applicant ACN: 080 343 513

Summary of Use: Probiotic food supplement
for improving digestion and enhancing general
health in dogs.

Date of Registration: 6 July 2007

Label Approval No: 59754/150g/0106,
59754/300g/0106, 59754/1kg/0106

Product Name: Coopers Piliguard Pinkeye-1
Trivalent Vaccine for Cattle

Active Constituent/s: Contains chemically-
inactivated cultures of *Moraxella bovis* isolates
(≥ 1.0 RP per antigen per 2mL dose) in an oil
emulsion adjuvant.

Applicant Name: Schering-Plough Pty Limited
Applicant ACN: 000 235 245

Summary of Use: As an aid in the prevention
of pinkeye in cattle associated with infection by
moraxella bovis expressing pili similar to those
expressed by isolates Schering-Plough refers to
as strains EPP63, FLA64 and SAH3.

Date of Registration: 6 July 2007

Label Approval No: 60802/20/0407,
60802/100/0407

Product Name: Fort Dodge Carprogesic 50 mg
Tablets For Dogs

Active Constituent/s: Each tablet contains 50
mg carprofen

Applicant Name: Norbrook Laboratories
Australia Pty Limited

Applicant ACN: 080 972 596

Summary of Use: A non-steroidal, anti-
inflammatory for oral use to relive pain and
inflammation in dogs.

Date of Registration: 11 July 2007

Label Approval No: 61027/50C/0806,
61027/100C/0806, 61027/250C/0806,
61027/500C/0806, 61027/100T/0806,
61027/250T/0806, 61027/500T/0806,
61027/0806

Product Name: Caprimec Broad Spectrum Oral
Anthelmintic Solution For Goats

Active Constituent/s: 0.8 g/L abamectin

Applicant Name: Virbac (Australia) Pty Ltd

Applicant ACN: 003 268 871

Summary of Use: For the treatment of
abamectin-sensitive strains of internal parasites
of goats.

Date of Registration: 18 July 2007

Label Approval No: 60420/1L/0707,
60420/3L/0707, 60420/5L/0707,
60420/20L/0707

4.VARIATIONS

Product Name:

Applicant Name:

Applicant ACN:

Summary of Variation:

Date of Variation:

Label Approval No:

Product Name: Elanco AF0250 Tylan 250
Tylosin Phosphate Premix

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

Applicant ACN: 000 233 992

Summary of Variation: Extension of use to
include poultry as an aid in the control of
necrotic enteritis associated with susceptible
strains of *Clostridium perfringens*.

Date of Variation: 13 July 2007

Label Approval No: 36806/25AUS/1106

5. RESTRICTED PRODUCT VARIATION
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Product Name:

Applicant Name:

Applicant ACN:

Summary of Variation:

Date of Variation:

Label Approval No:

“ No Entries”

NOTICE

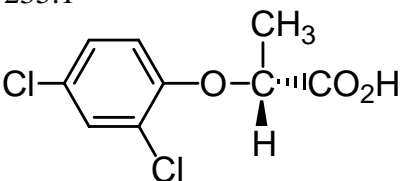
Dichlorprop-P Dichlorprop-P 2-Ethylhexyl Ester

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of two new active constituents, Dichlorprop-P and Dichlorprop-P 2-ethylhexyl ester. Dichlorprop-P is an aryloxyalkanoic acid (phenoxy propionic acid) herbicide. It is a selective hormone type herbicide absorbed through leaves with translocation to the roots. It acts as an auxin growth regulator. Dichlorprop-P 2-Ethylhexyl Ester is the (R,S)-2-Ethylhexyl Ester of Dichlorprop-P.

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 Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester approval should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to the matters that the APVMA is required to take into account in deciding whether to grant the approval. Comments must be received by the APVMA within 28 days of the date of this Gazette.

Particulars of Active Constituents

Dichlorprop-P

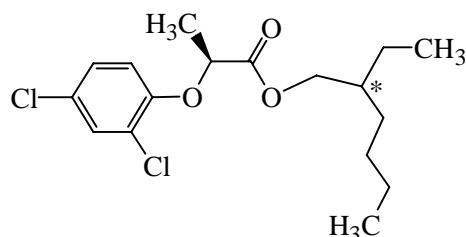
IUPAC Name:	(R)-2-(2,4-dichlorophenoxy)propionic acid
Chemical Abstracts Name:	(+)-2-(2,4-dichlorophenoxy)propanoic acid
CAS Number:	15165-67-0
Molecular Formula:	C ₉ H ₈ Cl ₂ O ₃
Minimum Purity:	900 g/kg
Molecular Weight:	235.1
Structure:	

Chemical Family:	Aryloxyalkanoic acid (phenoxy propionic acid)
Mode of Action:	Absorbed through leaves with translocation to the roots. It acts as an auxin growth regulator.

Dichlorpro-P 2-Ethylhexyl ester

IUPAC Name:	R-2-(2,4-dichlorophenoxy)propionic acid, 2-ethylhexyl ester
Chemical Abstracts Name:	(+)-2-(2,4-dichlorophenoxy)propanoic acid, 2-ethylhexyl ester
CAS Number:	865363-39-9
Minimum Purity:	850 g/kg
Molecular Formula:	C ₁₇ H ₂₄ Cl ₂ O ₃
Molecular Weight:	347.28

Structure:



Chemical Family:

Aryloxyalkanoic acid (phenoxy propionic acid)

Mode of Action:

Absorbed through leaves with translocation to the roots. It acts as an auxin growth regulator.

Summary of the APVMA's Evaluation of Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester active constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester active constituents:

Dichlorprop-P

Constituent	Specification	Level
Dichlorprop-P	Dichlorprop-P	Not less than 900 g/kg
Free phenols	Free phenols calculated as 2,4-dichlorophenol	Not higher than 3 g/kg

Dichlorprop-P 2-Ethylhexyl Ester

Constituent	Specification	Level
Dichlorprop-P 2-Ethylhexyl Ester	(+)-(R)-2-(2,4-dichlorophenoxy) propionic acid, 2-ethylhexyl ester	Not less than 850 g/kg
Free phenols	Free phenols calculated as 2,4-dichlorophenol	Not higher than 3 g/kg

Other compounds of toxicological significance are not expected to occur in Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester as a result of the raw materials and the synthetic route used.

The Office of Chemical Safety of the Department of Health and Ageing has considered the toxicological aspects of Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester, and advised that there are no toxicological objections to the approval of this chemical.

An Acceptable Daily Intake (ADI) was established at 0.03 mg/kg bw/day, based on a No Observed Effect Level (NOEL) of 6 mg/kg bw/day in a 18-month mouse study and using a 200-fold safety factor for dichlorprop-P. An Acute Reference Dose (ARfD) was established at

0.20 mg/kg bw, based on a NOEL of 20 mg/kg bw/day in a rat developmental rat study and using a 100-fold safety factor for dichlorprop-P.

The National Drugs and Poisons Schedule Committee (NDPSC) has included Dichlorprop-P in Schedule 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 APMVA is satisfied that the proposed importation and use of Dichlorprop-P and Dichlorprop-P 2-ethylhexyl ester 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 Dichlorprop-P and Dichlorprop-P 2-ethylhexyl ester 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

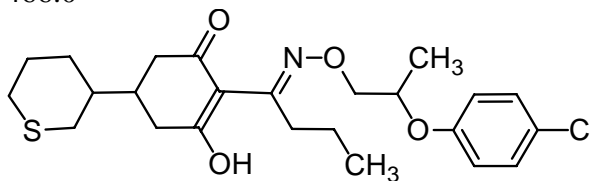
Profoxydim Manufacturing Concentrate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, profoxydim. Profoxydim is a new herbicidal active ingredient belonging to the chemical family of cyclohexenone herbicide. The mode of action is inhibition of the acetyl Co-enzyme A carboxylase (ACCase) in the lipid biosynthetic pathway of sensitive plant species. It is intended to be used as a systemic herbicide for the post-emergence control of *Echinochloa crus-galli* and other grass-weeds in rice.

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 Profoxydim Manufacturing Concentrate approval should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to the matters that the APVMA is required to take into account in deciding whether to grant the approval. Comments must be received by the APVMA within 28 days of the date of this Gazette.

Particulars of Active Constituent

Common Name:	Profoxydim
IUPAC Name:	(<i>EZ</i>)-2-{1-[(2 <i>RS</i>)-2-(4-chlorophenoxy)propoxyimino]butyl}-3-hydroxy-5-(<i>cis</i> -thian-3-yl)cyclohex-2-en-1-one
CAS Number:	139001-49-3
Manufacturer's Code:	Clefoxydim
Minimum Purity:	930 g/kg (dry, solvent free basis)
Molecular Formula:	C ₂₄ H ₃₂ ClNO ₄ S
Molecular Weight:	466.0
Structure:	



Chemical Family:	Cyclohexenone
Mode of Action:	Inhibition of the acetyl Co-enzyme A carboxylase (ACCase) in the lipid biosynthetic pathway of sensitive plant species

Summary of the APVMA's Evaluation of Profoxydim Manufacturing Concentrate active constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of Profoxydim Manufacturing Concentrate active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. Profoxydim is not isolated during the production process and a 30% solution is produced as a manufacturing concentrate.

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

Constituent	Specification	Level
Profoxydim	Profoxydim	Not less than 930 g/kg (dry, solvent free basis)

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

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

An Acceptable Daily Intake (ADI) was established at 0.05 mg/kg bw/day, based on a No Observed Effect Level (NOEL) of 5 mg/kg bw/day in a 24-month rat study and using a 100-fold safety factor. An Acute Reference Dose (ARfD) was not established for profoxydim.

The National Drugs and Poisons Schedule Committee (NDPSC) has included Profoxydim in Schedule 5 (except in preparations containing 20 percent or less of profoxydim) of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

The APMVA is satisfied that the proposed importation and use of Profoxydim 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 Profoxydim 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

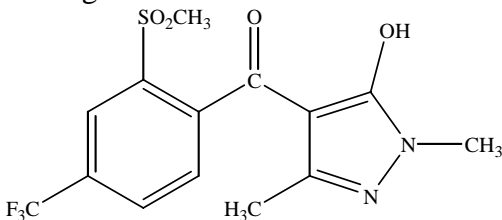
NOTICE

Pyrasulfotole

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of pyrasulfotole, a new active constituent for use in agricultural chemical products. Pyrasulfotole is initially to be used for post-emergent control of various broadleaf weeds in cereals.

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

Particulars of Active Constituent

Common Name:	Pyrasulfotole
IUPAC Name:	(5-Hydroxy-1,3-dimethylpyrazol-4-yl)(α,α,α -trifluoro-2-mesyl- <i>p</i> -tolyl)methanone
CA Name:	(5-Hydroxy-1,3-dimethyl-1 <i>H</i> -pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone
Manufacturer's Code:	AE 0317309
CAS Number:	365400-11-9
Minimum Purity:	960 g/kg
Molecular Formula:	$C_{14}H_{13}F_3N_2O_4S$
Molecular Weight:	362.3 gmol^{-1}
Structure:	

Chemical Family:	Pyrazolone
Mode of Action:	Inhibition of carotenoid biosynthesis at the phytoene desaturase step (Group F herbicide)

Summary of the APVMA's Evaluation of Pyrasulfotole Active Constituent

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

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

Constituent	Specification	Level
Pyrasulfotole	Pyrasulfotole	Not less than 960 g/kg
Cyanide	Cyanide	Not more than 50 mg/kg

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

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

An Acceptable Daily Intake (ADI) of 0.01 mg/kg bw/day has been established based on a no observed effect level (NOEL) of 1 mg/kg bw/day in a chronic toxicity study in rats, and applying a 100-fold safety factor. An Acute Reference Dose (ARfD) of 0.2 mg/kg bw has been established based on a lowest observed effect level (LOEL) of 200 mg/kg bw for systemic effects in an acute neurotoxicity study in rats, and applying a 1000-fold safety factor.

The National Drugs and Poisons Schedule Committee (NDPSC) has considered pyrasulfotole to be appropriate for inclusion in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

The APVMA is satisfied that the proposed importation and use of pyrasulfotole 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 pyrasulfotole 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

AVIAN INFLUENZA VIRUS H7N1

[in the product: : POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Commonwealth Department of Agriculture Fisheries and Forestry, for the approval of new active constituent, *Avian influenza virus H7N1* Strain A/CK/Italy/1067/99. The APVMA also has before it an application from the same applicant, for the registration of a new product, 'POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE' containing the above active constituent. The product is for the immunisation of chickens and turkeys against avian influenza type A, subtype H7 serotype to reduce mortality, clinical signs and/ or lesions due to these diseases.

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 'POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE' 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 Active Constituent

Common name:	<i>Avian influenza virus H7N1</i>
Strain/serotype:	Strain A/CK/Italy/1067/99
Identity and purity:	Carried out by the OIE Reference Laboratory for Newcastle Disease and Avian Influenza,
Sterility:	As per European Pharmacopoeia
Extraneous agents:	As per European Pharmacopoeia
Mycoplasma:	As per European Pharmacopoeia
Mode of action:	Inducing immunological responses
Gene technology:	Not applicable
Applicant Name:	Department of Agriculture Fisheries and Forestry Edmund Barton Building Blackall Street Barton ACT 2601
Summary of Use:	This active is to be incorporated in a vaccine for the immunisation of chickens and turkeys against avian influenza type A, subtype H7 serotype to reduce mortality, clinical signs and/ or lesions due to this disease.

Particulars of the Product

Proposed name

POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE'

Active constituent

Avian influenza virus H7N1 Strain A/CK/Italy/1067/99

Adjuvant

Liquid light paraffin

Pharmaceutical form

Emulsion for injection

Target species

Chickens and turkeys

Indications for use

For the immunisation of chickens and turkeys against avian influenza type A, subtype H7 serotype to reduce mortality, clinical signs and/ or lesions due to these diseases

Directions for use

Chickens: From 14 days old, two injections of 0.5 mL given intramuscularly at least 14 days between vaccinations

Turkeys: From 8 days old, two injections of 0.5 mL given subcutaneously at approximately 21 days interval

Contraindications

Do not administer intramuscularly in chickens less than 2 weeks old.

Do not administer to birds in lay or less than 4 weeks before the birds come into lay

Caution

This vaccine has not been tested in other species. The level of efficacy for other species may differ from that observed in chickens and turkey

User safety information

This product contains mineral oil. Extreme caution should be used when administering oil emulsion vaccine to avoid injecting yourself. Accidental-self injection may cause inflammatory reaction, severe pain and swelling that requires correct medical management. Seek medical attention as soon as possible in the event of accidental-self injection.

Incompatibilities

Do not mix with any other medicinal product.

Withholding period

Nil

Applicant name

Department of Agriculture Fisheries and Forestry
Edmund Barton Building
Blackall Street Barton ACT 2601

Conditions of supply and use

POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE can only be released on the authority of the Chief Veterinary Officer (CVO) in the relevant State or Territory. The product can only be used under the control of the CVO of the jurisdiction in accordance with a decision of the Consultative Committee on Exotic Animal Diseases (CCEAD).

POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE can only be used by authorised personnel or persons otherwise authorised under State/Territory legislation. The product must be used in accordance with the approved label directions/instructions or as specified by the CCEAD, or the CVO of the relevant jurisdiction.

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

The chemistry and manufacturing aspects of *Avian influenza virus H7N1* Strain A/CK/Italy/1067/99 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 *Avian influenza virus H7N1* Strain A/CK/Italy/1067/99 in POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE for active immunisation of chickens and turkeys against avian influenza type A, subtype H7 serotype to reduce mortality, clinical signs and/ or lesions due to this disease 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 of POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE 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 *Avian influenza virus H7N1* Strain A/CK/Italy/1067/99, and the registration of the product POULVAC FLUFEND i AI H7N1 (INACTIVATED) VACCINE 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

AVIAN INFLUENZA VIRUS H5N9

[in the product: POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Commonwealth Department of Agriculture Fisheries and Forestry, for the approval of a new active constituent, *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998. The APVMA also has before it an application from the same applicant, for the registration of a new product, 'POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE' containing the above active constituent. The product is for the immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to these diseases.

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 'POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE' 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 Active Constituent

Common name:	<i>Avian influenza virus H5N9</i>
Strain/serotype:	Strain A/CK/Italy/22A/H5N9/1998
Identity and purity:	Carried out by the OIE Reference Laboratory for Newcastle
Disease and	Avian Influenza,
Sterility:	As per European Pharmacopoeia
Extraneous agents:	As per European Pharmacopoeia
Mycoplasma:	As per European Pharmacopoeia
Mode of action:	Inducing immunological responses
Site of manufacture:	Recognised by the APVMA
Gene technology:	Not applicable
Applicant Name:	Department of Agriculture Fisheries and Forestry Edmund Barton Building Blackall Street Barton ACT 2601
Summary of Use:	This active is to be incorporated in a vaccine for the immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to this disease.

Particulars of the Product

Proposed product name

POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE

Active Constituent

Avian influenza virus H5N9 Strain A/CK/Italy/22A/H5N9/1998

Adjuvant

Liquid light paraffin

Pharmaceutical form

Emulsion for injection

Target species

Chickens and turkeys

Indications for use

For the immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to these diseases.

Directions for use

Chickens: From 14 days old, two injections of 0.5 mL given intramuscularly at least 14 days between vaccinations. Turkeys: From 8 days old, two injections of 0.5 mL given subcutaneously at approximately 21 days interval.

Contraindications

Do not administer intramuscularly in chickens less than 2 weeks old.

Do not administer to birds in lay or less than 4 weeks before the birds come into lay

Caution

This vaccine has not been tested in other species. The level of efficacy for other species may differ from that observed in chickens and turkey

User safety information

This product contains mineral oil. Extreme caution should be used when administering oil emulsion vaccine to avoid injecting yourself. Accidental-self injection may cause inflammatory reaction, severe pain and swelling that requires correct medical management. Seek medical attention as soon as possible in the event of accidental-self injection.

Incompatibilities

Do not mix with any other medicinal product.

Withholding eriod

Nil

Applicant name

Department of Agriculture Fisheries and Forestry
Edmund Barton Building

Blackall Street Barton ACT 2601

Conditions of supply and use

POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE' can only be released on the authority of the Chief Veterinary Officer (CVO) in the relevant State or Territory. The product can only be used under the control of the CVO of the jurisdiction in accordance with a decision of the Consultative Committee on Exotic Animal Diseases (CCEAD).

POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE can only be used by authorised personnel or persons otherwise authorised under State/Territory legislation. The product must be used in accordance with the approved label directions/instructions or as specified by the CCEAD, or the CVO of the relevant jurisdiction.

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

The chemistry and manufacturing aspects of *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998 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 *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998 in POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE for active immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to this disease 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 of POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE 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 *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998, and the registration of the product POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE 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

AVIAN INFLUENZA VIRUS H5N2

[in the product: NOBILIS (R) INFLUENZA H5N2 (INACTIVATED) VACCINE]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Commonwealth Department of Agriculture Fisheries and Forestry, for the approval of new active constituent, *Avian influenza virus H5N2* Strain A/duck/Potsdam/1402/86. The APVMA also has before it an application from the same applicant, for the registration of a new product, 'NOBILIS (R) INFLUENZA H5N2 (INACTIVATED) VACCINE' containing the above active constituent. The product is for the immunisation of chickens against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to these diseases.

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 'NOBILIS (R) INFLUENZA H5N2 (INACTIVATED) VACCINE' 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:	<i>Avian influenza virus H5N2</i>
Strain/serotype:	Strain Strain A/duck/Potsdam/1402/86
Identity and purity:	Carried out by the OIE Reference Laboratory for Newcastle
Disease and	Avian Influenza,
Sterility:	As per European Pharmacopoeia
Extraneous agents:	As per European Pharmacopoeia
Mycoplasma:	As per European Pharmacopoeia
Mode of action:	Inducing immunological responses
Gene technology:	Not applicable
Applicant Name:	Department of Agriculture Fisheries and Forestry Edmund Barton Building Blackall Street Barton ACT 2601
Summary of Use:	This active is to be incorporated in a vaccine for the immunisation of chickens against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to this disease.

Particulars of the Product

Proposed name

NOBILIS (R) INFLUENZA H5N2 (INACTIVATED) VACCINE

Active constituent

Avian influenza virus H5N2 Strain Strain A/duck/Potsdam/1402/86

Adjuvant

Liquid light paraffin

Pharmaceutical form

Emulsion for injection

Target species

Poultry

Indications for use

For the immunisation of healthy poultry as an aid in the control of Avian Influenza type A, subtype H5.

Directions for use

From 8-10 days of age. Laying hens and breeders should get a second vaccination 6-10 weeks after first vaccination. Subcutaneous or intramuscular injection of 0.5ml is advised. For poultry up to the age of 6 weeks a dose of 0.25 is recommended.

Caution

This vaccine has not been tested in other species. The level of efficacy for other species may differ from that observed in chickens

User safety information

This product contains mineral oil. Extreme caution should be used when administering oil emulsion vaccine to avoid injecting yourself. Accidental-self injection may cause inflammatory reaction, severe pain and swelling that requires correct medical management. Seek medical attention as soon as possible in the event of accidental-self injection.

Incompatibilities

Do not mix with any other medicinal product.

Withholding period

Nil

Applicant name

Department of Agriculture Fisheries and Forestry
Edmund Barton Building
Blackall Street Barton ACT 2601

Conditions of supply and use

NOBILIS (R) INFLUENZA H5N2 (INACTIVATED) VACCINE can only be released on the authority of the Chief Veterinary Officer (CVO) in the relevant State or Territory. The product can only be used under the control of the CVO of the jurisdiction in accordance with a decision of the Consultative Committee on Exotic Animal Diseases (CCEAD).

NOBILIS (R) INFLUENZA H5N2 (INACTIVATED) VACCINE can only be used by authorised personnel or persons otherwise authorised under State/Territory legislation. The product must be used in accordance with the approved label directions/instructions or as specified by the CCEAD, or the CVO of the relevant jurisdiction.

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

The chemistry and manufacturing aspects of *Avian influenza virus H5N2* Strain A/duck/Potsdam/1402/86 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 *Avian influenza virus H5N2* Strain A/duck/Potsdam/1402/86 in NOBILIS (R) INFLUENZA H5N2 VACCINE H5N2 (Inactivated) Vaccine for active immunisation of chickens against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to this disease 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 of NOBILIS (R) INFLUENZA H5N2 VACCINE H5N2 (Inactivated) Vaccine 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 *Avian influenza virus H5N2* Strain A/duck/Potsdam/1402/86, and the registration of the product NOBILIS (R) INFLUENZA H5N2 VACCINE H5N2 (Inactivated) Vaccine of 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

profoxydim

[in the product: *AURA HERBICIDE*]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from BASF Australia Limited for registration of a new product containing the active constituent profoxydim. The product, *AURA HERBICIDE*, is for the post-emergence control of barnyard grass and silvertop grass in rice.

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:	AURA HERBICIDE
Applicant Company:	BASF Australia Ltd.
Active Constituents:	Profoxydim
Poisons Sheduling:	Schedule 5
Statement of Claims:	For the control of barnyard & silvertop grass in rice Pack sizes: 5L, 20L
Withholding Period:	Rice: Harvest: Not required when used as directed. Grazing: Do not graze or cut for stock food for 28 days after application.

Summary of the APVMA's evaluation of *AURA HERBICIDE* in accordance with Section 14(3)(e) and (f) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of *AURA HERBICIDE* 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, Office of Chemical Safety (Occupational Health and Safety) [OCS (OHS)] section has conducted a risk assessment on *AURA HERBICIDE* and concluded that it can be used safely.

Profoxydim has displayed low acute oral, dermal and inhalational toxicity in mice, rats and rabbits and is a slight skin and eye irritant in rabbits, but not a skin sensitiser in guinea pigs.

The product, *AURA HERBICIDE*, was considered likely to exhibit low acute oral, dermal and inhalational toxicity but likely to be a moderate skin and eye irritant; it is not likely to cause skin-sensitisation.

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

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

- (ii) The APVMA is satisfied that the proposed use of *AURA HERBICIDE* 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 associated Withholding Periods (WHPs) are recommended for *AURA HERBICIDE* when used on rice.

Based on the data provided, the following residue definition is considered appropriate: “Sum of profoxydim and all metabolites converted to dimethyl-3-(3-thianyl) glutarate-S-dioxide after oxidation and treatment with acidic methanol, expressed as profoxydim.”

The recommended WHPs for *AURA HERBICIDE* are stated on the draft label. Profoxydim MRLs are recommended for rice (0.05mg/kg), edible offal (mammalian) (0.5mg/kg), eggs (*0.05mg/kg), meat (mammalian) (*0.05mg/kg), milks (*0.01mg/kg), poultry meat (*0.05mg/kg), poultry, edible offal of (*0.05mg/kg).

- (iii) The APVMA is satisfied that the proposed use of the active constituent profoxydim in *AURA HERBICIDE* 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, profoxydim, and finds that the chemistry and manufacturing details of the product are acceptable. The proposed product has been assessed by the National Drugs and Poisons Scheduling Committee and has been included in Schedule 5 of the SUSDP. The appropriate Signal Heading appears on the label. First Aid and Safety Directions (hazard statements) for profoxydim and *AURA HERBICIDE* have been recommended by the Commonwealth Department of Health and Ageing, OCS (toxicology) section, and have been included on the label.

The product will be formulated overseas and imported ready to use in HDPE containers. *AURA HERBICIDE* is determined to be a hazardous substance, based on NOHSC hazard classification of active and non-active constituents and product toxicology information provided.

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 the new active constituent profoxydim in the product *AURA HERBICIDE* on rice 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 assessed the data submitted in support of the registration of *AURA HERBICIDE*, together with other relevant information. A full environmental fate and ecotoxicity data set was submitted. Laboratory studies indicate that profoxydim will degrade in the environment through aqueous oxidation, aqueous and soil photolysis and microbial processes. Field dissipation studies confirm that profoxydim and its initial oxidation metabolite dissipate rapidly in soil and water in rice crop application scenarios and do not move down the soil profile. Profoxydim is practically non-toxic to birds. As the active constituent or as a formulation, it varies in toxicity to terrestrial invertebrates and aquatic organisms, and the metabolites tested also range in toxicity.

The concentrations predicted in bird diet, in soils in sprayed crops, in water as a consequence of direct overspray, spray drift or from residues in newly sprayed soil, and on insects directly exposed, have been compared with the ecotoxicity test results. Based on these comparisons, which show an acceptable risk in all cases, DEW recommended that the APVMA be satisfied that use of *AURA HERBICIDE* as proposed and in accordance with good agricultural practice would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

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

- (v) The APVMA is satisfied that the proposed use of profoxydim in *AURA HERBICIDE* would not adversely affect trade between Australia and places outside Australia.

No detectable residues of profoxydim are expected to occur in harvested rice grain or in poultry fed on grain grown from treated rice crops. Residues in meat and milk from livestock fed on treated forage are expected to be below the limits of quantification (LOQ).

The overall risk to export trade in rice and animal commodities from the registration of *AURA HERBICIDE* is considered to be negligible.

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

- (vi) The APVMA is satisfied the data from trials supporting the efficacy of *AURA HERBICIDE* adequately demonstrates that under local conditions this product will be effective for the proposed uses.

Public Release Summary

A Public Release Summary of the evaluation is available by contacting Verity Scarlett on telephone (02) 62104748. Written submissions on the APVMA's proposal to grant the application for registration should be addressed in writing to:

Ranjit Gajanayake
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4760
Fax: (02) 6210 4776

NOTICE

DIMETHENAMID – P

[in the product: Frontier–P Herbicide]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from BASF Australia Ltd. for registration of a new product containing the active constituent Dimethenamid–P. The product, Frontier-P Herbicide, is for the control of certain broadleaf and grass weeds in green beans, navy beans, sweet corn, corn, poppies, green peas, pumpkins and kabocha.

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

Product Name:	Frontier-P Herbicide
Applicant Company:	BASF Australia Ltd
Active Constituent:	Dimethenamid–P
Poisons Scheduling:	Schedule 6
Statement of claims:	For the control of certain broadleaf and grass weeds in green beans, navy beans, sweet corn, corn, poppies, green peas, pumpkins and kabocha.
Pack sizes:	5L & 10L
Withholding Period:	Green beans, Maize, Kabocha, Navy beans, Peas, Pumpkin, Sweet corn, Oilseed poppies Harvest: Not required when used as directed Grazing: Do not graze or cut for stockfeed for 4 weeks after application

Summary of the APVMA's evaluation of Frontier-P Herbicide in accordance with Section 14(3)(e) and (f) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of Frontier-P Herbicide 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, Office of Chemical Safety (Occupational Health and Safety) [OCS (OHS)] has conducted a risk assessment on Frontier-P Herbicide and concluded that it can be used safely.

Based on the findings of the toxicological studies evaluated, Frontier-P Herbicide was considered to have low acute oral, dermal and inhalational toxicity. It is likely to be a moderate skin irritant, a severe eye irritant but not a skin sensitizer. The appropriate safety directions including personal protective equipment (PPE) requirements have been set and included on the proposed product label.

Frontier-P Herbicide is determined to be a hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances.

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

- (ii) The APVMA is satisfied that the proposed use of Frontier-P Herbicide 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 associated Withholding Periods are recommended for Dimethenamid-P in Frontier-P Herbicide when used according to the proposed label.

Based on the data provided, the following residue definition is considered appropriate:
“Sum of dimethenamid-P and its (R)-isomer.”

The recommended WHPs for Frontier-P herbicide are stated on the proposed draft label. Dimethenamid-P MRLs are recommended for Common bean (*0.02mg/kg); Maize (*0.02mg/kg); Peas (*0.02 mg/kg); Poppy seed (*0.01mg/kg); Pulses (*0.02 mg/kg); Pumpkins(*0.02mg/kg); Sweet corn (on the cob) (*0.02 mg/kg); Edible offal (Mammalian) (*0.01mg/kg); Eggs (*0.01 mg/kg); Meat (mammalian) (*0.01mg/kg); Milks (*0.01mg/kg); Poultry, Edible offal of (*0.01mg/kg) Poultry meat (*0.01mg/kg). Dimethenamid-P MRLs have also been set at *0.02 mg/kg, for the following animal feed commodities: Bean fodder, Bean forage (green), Forage and fodder of maize and Sweet corn, Forage and fodder of pulses, Pea hay or Pea fodder (dry); Pea vines (green). [Note: * denotes that the MRL has been set at the limit of quantitation.]

The use of Frontier-P Herbicide would not be an undue hazard to people exposed to its residues in food.

Detectable residues of dimethenamid are not expected to occur in any agricultural commodities. The use of Frontier-P Herbicide is unlikely to unduly prejudice export trade.

- (iii) The APVMA is satisfied that the proposed use of the active constituent Dimethenamid-P in Frontier-P Herbicide is not likely to be harmful to human beings if used according to the product label directions.

The active constituent in the proposed product has been assessed by the National Drugs and Poisons Scheduling Committee and has been placed in Schedule 6 of the SUSDP. The appropriate Signal Heading is on the label. First Aid and Safety Directions (hazard statements and PPE requirements) for Frontier-P Herbicide have been recommended by the Commonwealth Department of Health and Ageing, OCS, and have been included on the draft label.

The product will be formulated overseas and imported to Australia in ready to sell packages. Frontier-P Herbicide is determined to be a hazardous substance, based on NOHSC hazard classification of active and non-active constituents and product toxicology information provided.

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 new product Frontier-P Herbicide, containing the new active constituent dimethenamid-P, would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The Department of the Environment and Heritage has assessed data in support of the proposed use and has concluded that the risks to the environment from the proposed use are acceptable.

The main breakdown pathways for dimethenamid-P are photolysis, which is relatively fast, and microbial degradation rated as being moderate under aerobic conditions (soil and water) and slightly longer under anaerobic conditions. Dimethenamid-P is very mobile in soils but field studies showed it to be much less mobile, although the metabolites were more mobile.

Dimethenamid-P is practically non-toxic to birds, soil microbes, honeybees and most beneficial insects except for predatory mites and parasitic wasps. It is moderately toxic to fish and aquatic invertebrates and very highly toxic to algae and aquatic plants with the most sensitive being duckweed. Earthworms were shown to be slightly sensitive. It is herbicidal to non-target plants, with ryegrass the most sensitive.

No acute or chronic hazard is expected for birds, earthworms, honeybees, soil microbes and arthropods. Spraydrift is not expected to pose an unacceptable hazard to fish, aquatic invertebrates, aquatic plants, algae or other aquatic organisms when used according to the recommended label directions, including a downwind buffer zone. Risks to algae and terrestrial and aquatic plants have also been identified from run-off events and recommendations have been made to manage these risks.

The APVMA has considered the findings of the Department of the Environment and Water Resources and accepts its recommendations on this criterion.

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

- (v) The APVMA is satisfied that the data from trials supporting the efficacy of the proposed use of Frontier-P Herbicide, adequately demonstrates that under local conditions this product will be effective for the stated uses.

Public Release Summary

A Public Release Summary (PRS) of the evaluation is available on the APVMA website, www.apvma.gov.au or by contacting Verity Scarlett on telephone (02) 6210 4748. Submissions on the APVMA's proposal to grant the application for registration should be in writing and addressed to:

Jay Kottege
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4759
Fax: (02) 6210 4776
email: jay.kottege@apvma.gov.au

NOTICE

DICHLORPROP - P

[in the product: Nufarm Corasil Plant Growth Regulator]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Nufarm Australia Ltd. for registration of a new product containing the active constituent Dichlorprop – P – 2 – ethylhexyl (Dichlorprop-P). The product, Nufarm Corasil Plant Growth Regulator, is for use as a growth regulator in oranges and mandarins.

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

Product Name:	Nufarm Corasil Plant Growth Regulator
Applicant Company:	Nufarm Australia Ltd
Active Constituent:	Dichlorprop – P – 2 – ethylhexyl
Poisons Scheduling:	Schedule 6
Statement of claims:	For use as a plant growth regulator in oranges and mandarins.
Pack sizes:	5L, 10L, & 20L
Withholding Period:	Harvest: Not required when used as directed

Summary of the APVMA's evaluation of Nufarm Corasil Plant Growth Regulator 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 Nufarm Corasil Plant Growth Regulator 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, Office of Chemical Safety (Occupational Health and Safety) [OCS (OHS)] has conducted a risk assessment on Nufarm Corasil Plant Growth Regulator and concluded that it can be used safely.

Dichlorprop - P displayed low acute oral, dermal and inhalational toxicity. It was a severe eye irritant, a moderate skin irritant and not a skin sensitizer.

Based on the findings of the toxicological studies evaluated, Nufarm Corasil Plant Growth Regulator was considered to have low acute oral, dermal and inhalational toxicity. It is likely to be a moderate skin irritant, a severe eye irritant but not a skin sensitizer. The appropriate safety directions including personal protective equipment (PPE) requirements have been set and included on the proposed product label.

Nufarm Corasil Plant Growth Regulator is determined to be a hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances.

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

- (ii) The APVMA is satisfied that the proposed use of Nufarm Corasil Plant Growth Regulator 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 associated Withholding Periods are recommended for Dichlorprop-P in Nufarm Corasil Plant Growth Regulator when used in oranges and mandarins.

The following residue definition is supported: 'sum of dichlorprop acid, its esters and conjugates, hydrolysed to dichlorprop acid, and expressed as dichlorprop acid.'

The available data supported an MRL of 0.2 mg/kg for Citrus Fruits, with no withholding period required based on the application timings as indicated on the proposed draft label.

Using publicly available information and data supplied with the application, MRLs were recommended for milk, mammalian meat and offal, poultry meat and offal, and eggs. These MRLs have been established at the applicable limit of quantitation.

The estimated long term and acute dietary intakes of dichlorprop are acceptable, and do not exceed the proposed health standards.

The APVMA proposes that use of the product in accordance with the required instructions could potentially unduly prejudice trade and commerce between Australia and places outside Australia as per section 14(3)(e)(iv) of the Agvet Codes. The relevant commodities in the current application are exported and detectable residues are expected to occur above the standards of key export markets. Accordingly, a determination of undue prejudice to trade or commerce will be made following the completion of the trade consultation process. Any areas of concern and possible management strategies have been outlined in the draft Public Release Summary.

- (iii) The APVMA is satisfied that the proposed use of the active constituent Dichlorprop - P in Nufarm Corasil Plant Growth Regulator is not likely to be harmful to human beings if used according to the product label directions.

The active constituent in the proposed product has been assessed by the National Drugs and Poisons Scheduling Committee and has been placed in Schedule 6 of the SUSDP. The appropriate Signal Heading is on the label. First Aid and Safety Directions (hazard statements and PPE requirements) for Nufarm Corasil Plant Growth Regulator have been

recommended by the Commonwealth Department of Health and Ageing, OCS, 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 new product Nufarm Corasil Plant Growth Regulator, containing the new active constituent Dichlorprop-P, would not be 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 assessed the data submitted in support of the registration of Nufarm Corasil Plant Growth Regulator, together with other relevant information.

Corasil will be applied to citrus foliage at a low rate for fruit sizing. Most of the applied active is expected to be intercepted by the plant. Any residues that enter soil or water will be at very low levels, and unlikely to persist.

Dichlorprop-P 2-ethylhexyl ester has low toxicity to non-target terrestrial animals and is non-toxic to aquatic organisms at concentrations below its solubility limit, but is toxic to plants because it is a herbicide. Corasil will be applied at low rates for fruit sizing rather than vegetation control, and is not expected to harm non-target plants when used as proposed.

The Department of the Environment and Water Resources recommends that the APVMA be satisfied that use of Corasil Plant Growth Regulator as proposed and according to good agricultural practice would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

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

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

- (v) The APVMA is satisfied that the data from trials supporting the efficacy of proposed use of new product Nufarm Corasil Plant Growth Regulator, adequately demonstrates that under local conditions this product will be effective for the proposed uses.

Public Release Summary

A Public Release Summary (PRS) of the evaluation is available on the APVMA website, www.apvma.gov.au or by contacting Verity Scralett on telephone (02) 6210 4748. Submissions on the APVMA's proposal to grant the application for registration should be in writing and addressed to:

Jay Kottege
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4759
Fax: (02) 6210 4776
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NOTICE

Application Summaries

The APVMA publishes complete application summaries on the APVMA website (http://www.apvma.gov.au/data_protection/appl_summaries.shtml). They are published in weekly instalments using the date the application was accepted for assessment. If an application summary has been amended, the APVMA will publish the amended version on the website and list it separately in the APVMA Gazette Notice for Application Summaries. As a requirement of Regulations 8C and E, some product names will appear as 'NOT AVAILABLE'. A summary will be removed from the website 28 days after the application has been finalised. Therefore, some summaries published in this notice may have already been removed prior to the Gazette being published.

Application summaries published since APVMA Gazette No. 7, 3 July 2007.

Application No	Product/Active Constituent Name
41641	RICHGRO LIME SULFUR FUNGICIDE AND INSECTICIDE
42224	FOCUS ULTRACHLOR
38180	NOT AVAILABLE
39575	NOT AVAILABLE
40099	ATRAZINE
41011	NOT AVAILABLE
41118	NOT AVAILABLE
41120	NOT AVAILABLE
41122	NOT AVAILABLE
41186	NOT AVAILABLE
41190	NOT AVAILABLE
41191	NOT AVAILABLE
41457	MAC PRE FLIGHT SPRAY LONG LIFE AIRCRAFT INSECTICIDE
41458	MAC CABIN SPRAY TOP OF DESCENT AIRCRAFT INSECTICIDE
41459	MAC HOLD SPRAY AIRCRAFT INSECTICIDE
41501	SPLASH STEP 3 ALGAECIDE
41542	NOT AVAILABLE
41592	NOT AVAILABLE
41804	POULVAC FLUFEND I AI H5N9 INACTIVATED AVIAN INFLUENZA VIRUS H5N9 (STRAIN
41807	A/CK/ITALY/22A/H5N9/1998)
41821	GLUFOSINATE-AMMONIUM
41854	NOT AVAILABLE
41860	MACSPRED HEXMAC 750WG HERBICIDE SUNSENSE NATURAL REPELLENT SUNSCREEN CREAM, 3 HOURS: INSECT
41986	REPELLENT, WATER RESISTANT, SPF 30+, UV-A AND UV-B PROTECTION
42066	NOT AVAILABLE
42099	FLUTRIAFOL
42100	PROCHLORAZ
42129	NOT AVAILABLE
42218	DAVID GRAYS RTU ANTEX OUTDOOR PEST CONTROL
42221	SUREGUARD MOTH BALLS LAVENDER
42222	SUREGUARD MOTH BALLS NATURAL
42287	NOT AVAILABLE
42288	NOT AVAILABLE
42289	NOT AVAILABLE
42299	AQUAPRO BROM TABS
42292	NOT AVAILABLE
42300	NOT AVAILABLE

42301 NOT AVAILABLE
42342 AGROCELHONE LIQUID INJECTABLE FUMIGANT
42354 SPACARE BROMINATING TABLETS SPA AND HOT TUB SANITISER
42371 1,3-DICHLOROPROPENE
42379 IMAZAPIC
42383 NOT AVAILABLE
42386 NOT AVAILABLE
42387 NOT AVAILABLE
42449 TEAT CARE-MASTER IODINE READY TO USE
42466 CHEMFORCE TRALKOXYDIM WG HERBICIDE
42485 NOT AVAILABLE
42565 CLOQUINTOCET-MEXYL
41366 NOT AVAILABLE
38321 NOT AVAILABLE
38779 KENSO AGCARE SAVAGE 200 INSECTICIDE
41561 MAXCEL PLANT GROWTH REGULATOR
41583 MULTICROP KEEP OFF DOG & CAT REPELLENT SPRAY
41609 CHEMAG REGAL 800 WG INSECTICIDE
41612 QM CYPERMETHRIN 200 INSECTICIDE
41736 MOVENTO 240 SC INSECTICIDE
41766 SPIROTETRAMAT
41771 NOT AVAILABLE
41840 NOT AVAILABLE
41973 NOT AVAILABLE
41981 LIBERTY 200 HERBICIDE
42026 BRODIFACOUM
42049 PARACOX 8 ANTICOCCIDIAL VACCINE FOR CHICKENS
42079 AFFINITY FORCE HERBICIDE
42105 BIOPREN 4GR MOSQUITO LARVICIDE
42283 GRINGO INSECTICIDE/MITICIDE
42290 NOT AVAILABLE
42291 NOT AVAILABLE
42297 NOT AVAILABLE
42338 HEALTHGUARD EC MITICIDE
42358 NOT AVAILABLE
42393 AXE INSECTICIDE
42414 SHARP SHOOTER ENVIRO PEST OIL INSECT SPRAY
42470 ATLAS FLY & INSECT KILLER FAST KNOCKDOWN FOR HOME USE
42486 AQUA MASTER AQUARIUM ALGAE CONTROL BLOCK
42487 AQUA MASTER POND ALGAE BLOCKS
42526 ATLAS FLY & INSECT KILLER FAST KNOCKDOWN FOR HOME USE
40134 YODIMASPEN
41359 NOT AVAILABLE
41360 NOT AVAILABLE
41361 JUROCLAV 500 BROAD SPECTRUM ANTIBIOTIC TABLETS
41534 ELANCO AF1304 ELANCOBAN G MONENSIN SODIUM PREMIX
41972 NUFARM BROMICIDE 200 SELECTIVE HERBICIDE
42029 FACTOR WG HERBICIDE
42130 NOT AVAILABLE
42223 PARACOX-5 ANTICOCCIDIAL VACCINE FOR CHICKENS
42442 TRANSIT HERBICIDE
42444 NUFARM REGENT 200SC INSECTICIDE
42469 TITAN METRIBUZIN 750 WG HERBICIDE
42525 NUFARM THROTTLE 500 FUNGICIDE
42572 TITAN DIURON 900 WG HERBICIDE
42583 ALLFIRE ATRAZINE 900WG HERBICIDE
42603 MODDUS YIELD & QUALITY ENHANCER FOR SUGARCANE
37822 GENFARM GUARDIAN AQUAFLOW 500 SC FUNGICIDE
37923 ALLFIRE GLYPHOSATE 510 HERBICIDE
40682 GENERATION PELLET SINGLE-FEED RODENTICIDE

41448	QUICKBAYT SPRAYABLE FLY BAIT
41559	TITAN ATLAS 500 WG APHICIDE
41563	NOT AVAILABLE
41923	DUPONT SAVANNAH HERBICIDE
42067	NOT AVAILABLE
42069	NOT AVAILABLE
42082	LOW IRRITANT FLY AND INSECT SPRAY
42127	NOT AVAILABLE
42128	VIRUKILL DISINFECTANT
42261	NOT AVAILABLE
42264	2,4-D-2-ETHYLHEXYL ESTER
42296	AQUAPRO PURE-CHLOR FOR SPAS
42479	INNOVA TEBUCONAZOLE 25C FLOWABLE SEED DRESSING
42548	PREMIUM QUALITY EZY SANITISER PLUS
42551	OSPRAY THIRAM / THIABENDAZOLE LIQUID SEED DRESSING FUNGICIDE
42560	INNOVA OXYFLUORFEN 240 EC HERBICIDE
42574	TITAN ATRAZINE 900 WG HERBICIDE
42576	TITAN SIMAZINE 900 WG HERBICIDE
42584	ALLFIRE SIMAZINE 900WG HERBICIDE
42597	NOT AVAILABLE
42598	GENFARM BROMOXYNIL 200 SELECTIVE HERBICIDE
42617	INNOVA BIFENTHRIN 100 MITICIDE / INSECTICIDE
42673	TRIPICRIN SOIL FUMIGANT

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

Application No	Product/Active Constituent Name
40385	METSUN 600 HERBICIDE
37408	COSMIC FUMIGANT
37445	CARBONYL SULFIDE
37231	NUFARM CORASIL PLANT GROWTH REGULATOR
41081	CONQUEST ALPHA DUO 100 INSECTICIDE
39947	RODILON PASTE PROFESSIONAL RODENTICIDE
41820	TREFLAN 480 HERBICIDE
41519	NBL STATUS 240 EC HERBICIDE
41139	4FARMERS HALOXYFOP 520 HERBICIDE
40067	STARANE 333 HERBICIDE
39969	RENTOKIL MOUSE KILLER BOX
38169	CAPRIMEC BROAD SPECTRUM ORAL ANTHELMINTIC SOLUTION FOR GOATS
39773	CAPRIMEC BROAD SPECTRUM ORAL ANTHELMINTIC SOLUTION FOR GOATS
39188	CIDR PIG INSERT

Contact:

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Australian Pesticides and Veterinary Medicines Authority
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KINGSTON ACT 2604

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NOTICE

Reconsideration of Registrations Related to Methyl Bromide

The APVMA, in accordance with Part 2, Division 4, of the Agvet Codes, has reconsidered the registrations of all products containing methyl bromide, and the approvals of all associated product labels listed in Table 1.

Methyl bromide, a colourless gas at room temperature, is a potent biocide with insecticidal, fungicidal and herbicidal properties. Products containing methyl bromide have been registered in Australia since 1945. There are currently 14 registered products¹ containing methyl bromide in Australia (as listed in Table 1 below).

In Australia, the primary uses of methyl bromide are for soil fumigation, post harvest protection (e.g. stored grain or dried fruit) and quarantine and pre-shipment (QPS) treatments. It is also used as an industrial pre-cursor in the production of other chemicals.

The APVMA decided to review methyl bromide as it is the most potent ozone-depleting substance still in widespread use in Australia today. Methyl bromide product labels in their current form contain uses that are not consistent with *The Montreal Protocol on Substances that Deplete the Ozone Layer* (the “Montreal Protocol”), an international treaty to control ozone-depleting substances to which Australia is a signatory.

Therefore the APVMA review focussed on the warnings and uses/instructions on product labels, particularly in respect of known environmental concerns with methyl bromide, and Australia’s obligations under the Montreal Protocol. This was to ensure that uses of methyl bromide on product labels are consistent with the approved uses under the Montreal Protocol. The review has involved consultation with the Department of the Environment and Water Resources [DEW²], the Department of Agriculture, Fisheries and Forestry [DAFF] and the Australian Quarantine and Inspection Service [AQIS].

Variation of Current Labels

Following the finalisation of its reconsideration of methyl bromide, the APVMA was satisfied that the current conditions of the 14 label approvals could be varied in a way to ensure compliance with the requirements for continued label approval. Therefore the APVMA has varied the conditions of label approval for the labels listed in Table 1.

Consequently the APVMA is now satisfied that labels carrying approval numbers listed in the right hand side column of Table 1 below:

- comply with the prescribed requirements under paragraph 14(3)(d) of the Agvet Code; and
- contain adequate instructions relating to the matters referred to in paragraph 14(3)(g) of the Agvet Code.

¹ There were 16 registered products during the review, but two were voluntarily cancelled in May 2007.

² This organisation was previously known as the Department of the Environment and Heritage [DEH].

Affirmation of Product Registrations

The APVMA is satisfied that, as the labels for products listed in Table 1 have been varied, these products now meet the prescribed requirements for continued registration.

On this basis, the APVMA is satisfied that continued registration of the products in accordance with their instructions for use:

- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment;

and therefore the product registrations listed in Table 1 below are affirmed.

Table 1: Products registrations that have been affirmed and label approvals varied as an outcome of the review

Product number	Product name	Registrant	Label approval number to be varied	Approval number of varied-labels
32106	Agrigas M Methyl Bromide Fumigant	BOC Ltd	32106/01	32106/12-100Kg/0607
34060	Agrigas MC Methyl Bromide Fumigant	BOC Ltd	Ψ	34060/12-100Kg/0607
34066	Nufarm Methyl Bromide 980 Fumigant	Nufarm Australia Limited	34066/0604	34066/35-100kg/0607
34067	Nufarm Methyl Bromide 1000 Fumigant	Nufarm Australia Limited	34067/0604	34067/35-100kg/0607
41303	SA Rural Methyl Bromide 980 Fumigant	S.A. Rural Agencies Pty Ltd	41303/0802	41303/100kg/0607
41390	Dibbs Brom-O-Gas 1000 Fumigant	RA Dibbs & Sons Pty Ltd	41390/0303	41390/50-100kg/0607
41394	Dibbs Brom-O-Gas 980 Fumigant	RA Dibbs & Sons Pty Ltd	41394/0203	41394/50-100kg/0607
51126	Nufarm Vertafume Soil Fumigant	Nufarm Australia Limited	51126/0204	51126/100kg/0607
51208	Rural Soil Fumigant 500-500	S.A. Rural Agencies Pty Ltd	51208/1202	51208/100kg/0607
52781	Southern Cross Methyl Bromide 1000 Fumigant	Commercial Fumigation Services Pty Ltd	52781/0503	52781/100kg/0607
53267	Rural Methyl Bromide 1000 Fumigant	S.A. Rural Agencies Pty Ltd	53267/1202	53267/100kg/0607
58001	Southern Cross Methyl Bromide 980 Fumigant	Commercial Fumigation Services Pty Ltd	58001/1103	58001/100kg/0607
59240	Southern Cross Soil Fumigant 500-500	Commercial Fumigation Services Pty Ltd	59240/1104	59240/100kg/0607
59241	Southern Cross Soil Fumigant 700-300	Commercial Fumigation Services Pty Ltd	59241/1104	59241/100kg/0607

Ψ : Label approved prior to the commencement of the Agvet Codes

Cancellation of Prior Labels

Following the finalisation of its reconsideration, the APVMA is not satisfied that methyl bromide products with previously-approved labels, when used in accordance with the former (“old”) instructions for use:

- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

As an outcome of the review, prior label approvals of methyl bromide products, as listed in Table 2 below, have been cancelled.

Table 2: Cancelled methyl bromide label approvals.

Product number	Product name	Registrant	Non-current label approval numbers to be cancelled
32106	Agrigas M Methyl Bromide Fumigant	BOC Ltd	Ψ
34060	Agrigas MC Methyl Bromide Fumigant	BOC Ltd	N/A
34066	Nufarm Methyl Bromide 980 Fumigant	Nufarm Australia Limited	34066/0204 34066/0298 Ψ
34067	Nufarm Methyl Bromide 1000 Fumigant	Nufarm Australia Limited	34067/0204 34067/0298 Ψ
41303	SA Rural Methyl Bromide 980 Fumigant	S.A. Rural Agencies Pty Ltd	Ψ
41390	Dibbs Brom-O-Gas 1000 Fumigant	RA Dibbs & Sons Pty Ltd	41390/1002 Ψ
41394	Dibbs Brom-O-Gas 980 Fumigant	RA Dibbs & Sons Pty Ltd	41394/1002 Ψ
51126	Nufarm Vertafume Soil Fumigant	Nufarm Australia Limited	51126/0998
51208	Rural Soil Fumigant 500-500	S.A. Rural Agencies Pty Ltd	51208/1198
52781	Southern Cross Methyl Bromide 1000 Fumigant	Commercial Fumigation Services Pty Ltd	52781/1200 52781/0400
53267	Rural Methyl Bromide 1000 Fumigant	S.A. Rural Agencies Pty Ltd	53267/1000
58001	Southern Cross Methyl Bromide 980 Fumigant	Commercial Fumigation Services Pty Ltd	N/A
59240	Southern Cross Soil Fumigant 500-500	Commercial Fumigation Services Pty Ltd	N/A
59241	Southern Cross Soil Fumigant 700-300	Commercial Fumigation Services Pty Ltd	N/A

Ψ : Label transitioned from the states and not having an approval number

N/A : Not Applicable

Consequently the only approved label for each product is the one bearing the approval number in the right hand side column of Table 1 (above).

Note also that the APVMA has decided on a 2-year phase out for existing stocks of methyl bromide products which bear cancelled labels or labels that were the basis for the varied labels above (e.g. 32106/01).

The detailed reasons for these reconsiderations can be found in the APVMA Final Review Report and Regulatory Decision. Copies of the report or further information can be obtained from the APVMA website: www.apvma.gov.au or by request to the Chemical Review Contact Officer on (02) 6210 4700 or chemrev@apvma.gov.au.

NOTICE

Licensing of Veterinary Chemical Manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemical Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has issued, amended or cancelled the manufacturing licences in respect of the following veterinary chemical manufacturers, with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the APVMA's web site: <http://www.apvma.gov.au>.

1. NEW LICENCES:

NIL

2. CHANGES TO EXISTING LICENCES:

APEX LABORATORIES PTY LTD
ACN: 000 397 240
61 Chivers Road
SOMERSBY NSW 2250

Product Types:*

Category 2: Tablets, capsules, creams/lotions, ointments, pastes, powders, sprays, aerosols, liquids, hormone-impregnated foam sponges

Step(s) of Manufacture:

Formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, dry milling, wet milling, granulation, tableting, tablet coating, capsule filling from bulk, storage and release for supply

Licence No: 2119

Amended licence issued 06/06/07, extension of licence scope, change of key personnel.

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

BAYER CROPSCIENCE PTY LTD

ACN: 000 226 022

261 Tingira Street
PINKENBA QLD 4008

Product Types:*

Category 3: 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: 3025

Amended licence issued 20/06/2007, change of key personnel.

DELVET PTY LTD

ACN: 072 484 167

B4, 26 Powers Road
SEVEN HILLS NSW 2147

Product Types:*

Category 2: Tablets, pastes and powders

Category 4: Supplements

Step(s) of Manufacture:

Quality assurance (QA) of raw materials, formulation including blending, filling, granulation, tableting, tablet coating, packaging, labelling, analysis and testing (physical), storage, and release for supply.

Licence No: 2126

Amended licence issued 13/06/07, extension of licence scope.

DERMCARE-VET PTY LTD

ACN: 010 280 010

22 Aranda Street
SPRINGWOOD QLD 4127

Product Types:*

Category 1: Sterile and immunobiological products

Step(s) of Manufacture:

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

Licence No: 1052

Amended licence issued 20/06/07, extension of licence scope, change of key personnel.

3. LICENCE CANCELLATIONS:

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

HI FORM AUSTRALIA PTY LTD
Trading as: Hi Form Equine

ACN: 078 443 446

Pakenham Industrial Estate
Factory 15/18 Racecourse Road
PAKENHAM VIC 3810

Licence No: 4069

Cancelled: 6/06/07

Reason for cancellation: s127(1)(d) and (e)

* *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

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

APVMA Contact:

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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

* *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

AMENDMENT No.2K

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)
ADD:		
Abamectin		
MF 0814	Goat fat	0.1
	Goat kidney	0.01
	Goat liver	0.05
	Goat muscle	0.01
ML 0814	Goat milk	0.005
Acibenzolar-S-methyl		
DELETE:		
SO 0691	Cotton seed	T*0.02
ADD:		
SO 0691	Cotton seed	*0.02
MO 0105	Edible offal (mammalian)	*0.02
PE 0112	Eggs	*0.02
MM 0095	Meat (mammalian)	*0.02
ML 0106	Milks	*0.005
PO 0111	Poultry, edible offal of	*0.02
PM 0110	Poultry meat	*0.02
ADD:		
Cloquintocet-mexyl		
GC 0650	Rye	*0.1
GC 0653	Triticale	*0.1
Dimethomorph		
DELETE:		
VA 0388	Shallot	T0.5
VA 0389	Spring Onions	T0.5
ADD:		
VA 0388	Shallot	0.5
VA 0389	Spring Onions	2
Dimetridazole		
DELETE:		

Dimetridazole
DELETE:

	MO	0818	Pig, Edible offal of	*0.005
	MM	0818	Pig meat	*0.005
	PO	0111	Poultry, Edible offal of	*0.005
	PM	0110	Poultry meat	*0.005
ADD:				
	PE	0112	Eggs	T*0.0001
	MO	0818	Pig, Edible offal of	T*0.0001
	MM	0818	Pig meat	T*0.0001
	PO	0111	Poultry, Edible offal of	T*0.0001
	PM	0110	Poultry meat	T*0.0001
ADD:				
Imidacloprid				
	VR	0575	Burdock, greater	T0.05
			Ginger, Japanese	T5
	HS	0784	Ginger, root	T0.05
	VR	0591	Radish, Japanese	T0.05
	VR	0505	Taro	T0.05
	VR	0600	Yams	T0.05
	VR	0601	Yam bean	T0.05
ADD:				
Iprodione				
	VL	0054	Brassica leafy vegetables	15
Methabenzthiazuron				
DELETE:				
	VA	0384	Leeks	T0.2
ADD:				
	VA	0384	Leeks	T*0.05
	VA	0388	Shallot	T0.2
	VA	0389	Spring Onion	T0.2
Prothioconazole				
DELETE:				
	PO	0111	Poultry, Edible offal of [in the fat]	T*0.05
	PM	0110	Poultry meat	T*0.05
ADD:				
	PO	0111	Poultry, Edible offal of	T*0.05
	PM	0110	Poultry meat [in the fat]	T*0.05
ADD:				
Pyraflufen-ethyl				
	GC	0080	Cereal grains	*0.02

SO	0691	Cotton seed	*0.02
MO	0105	Edible offal (mammalian)	*0.02
PE	0112	Eggs	*0.02
MM	0095	Meat (mammalian)	*0.02
ML	0812	Milks	*0.02
PO	0111	Poultry, edible offal of	*0.02
PM	0110	Poultry meat	*0.02

TABLE 3: RESIDUE DEFINITION

Where MRL(s) are recommended, the following residue definitions are applicable.

COMPOUND	RESIDUE
ADD:	
Acibenzolar-S-methyl	Acibenzolar-S-methyl and all metabolites containing the benzo[1,2,3]thiadiazole-7-carboxyl moiety hydrolysed to benzo[1,2,3]thiadiazole-7-carboxylic acid, expressed as acibenzolar-S-methyl.
DELETE:	
Dimetridazole	Dimetridazole
ADD:	
Dimetridazole	Sum of dimetridazole and its hydroxy metabolite (2-hydroxymethyl-1-methyl-5-nitromidazole), expressed as dimetridazole.
ADD:	
Pyraflufen-ethyl	Sum of pyraflufen-ethyl and its acid metabolite (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid).

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)
Cloquintocet-mexyl		
DELETE		
AS	0640 Barley straw and fodder, dry	*0.1
AS	0654 Wheat straw and fodder, dry	*0.1
ADD:		
AS	0081 Straw and fodder (dry) of cereal	

		grains except rice	*0.1
ADD:			
Fenoxaprop-ethyl		Cereal forage (fresh weight)	*0.01
ADD:			
Pyraflufen-ethyl			
AS	0081	Straw and fodder (dry) of cereal grains	1.0
Trinexapac-ethyl			
DELETE			
AS	0650	Rye straw and fodder, dry	3
ADD			
AS	0162	Hay or fodder (dry) of grasses	3

TABLE 5: USES OF SUBSTANCES WHERE MAXIMUM RESIDUE LIMITS ARE NOT NECESSARY

SUBSTANCE	USE
ADD: Pine Oil	When used as a herbicide in carrots, corn, orchards, potatoes, vineyards and bare earth / fallow / non-crop situations.

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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. 7, 3 July 2007

For Use in Agricultural Chemical Products:

Brodifacoum	GARRARDS PTY LTD	TAEGEUK CORPORATION #189-2 NAEUEA-RI, GOA-MYEN KUMI CITY KYUNGBUK KOREA	56139
Florasulam manufacturing concentrate	DOW AGROSCIENCES AUSTRALIA LIMITED	DOW AGROSCIENCES LLC F. JOH. KWIZDA GMBH WERK LEOBENDORF B6 LAAER STRABE / KWIZDA-ALLEE 2100 LEOBENDORF AUSTRIA	61236
Fluazuron	TIGER INVESTMENTS PTY LTD T/A TIGER CHEMICAL COMPANY	CHANGSHA AMPHENOM FINE CHEMICAL R&D LTD FURONG ROAD (2ND SECTION) 251 CHANGSHA HUNAN PROV PR CHINA	60754
Tebuconazole	GULMOHAR PTY LTD	SUPER SPRING AGROCHEMICAL LTD NO 233 YAOXIN RD ECONOMY AND TECHNOLOGY DEVELOPMENT ZONE NANJING 210046 PR CHINA	61240

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