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AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, www.apvma.gov.au/publications/gazette/.

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APVMA CONTACTS

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Agricultural Chemical Products and Approved Labels

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 relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

1. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	57827
Product name:	GF-2685 Herbicide
Active constituent/s:	100 g/kg halauxifen as the methyl ester, 100 g/kg cloquintocet-mexyl
Applicant name:	Dow AgroSciences Australia Limited
Applicant ACN:	003 771 659
Summary of use	For post-emergent control of broadleaf weeds in wheat and barley
Date of registration/approval:	26 March 2015
Product registration no.:	65055
Label approval no.:	65055/57827

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	100063
Product name:	Surefire Buffalo Pro, Bindi & Broadleaf Weedkiller
Active constituent/s:	200 g/L bromoxynil present as the n-octanoyl ester, 200 g/L MCPA present as the ethyl hexyl ester
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use	For the control of certain broadleaf weeds in wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf
Date of registration/approval:	23 February 2015
Product registration no.:	80024
Label approval no.:	80024/100063

Application no.:	100317
Product name:	Surefire Cultar Plant Growth Regulator
Active constituent/s:	250 g/L paclobutrazol
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use	For use in mango, stone fruit and apple trees
Date of registration/approval:	5 March 2015
Product registration no.:	80149
Label approval no.:	80149/100317

Application no.:	100314
Product name:	Surefire Maxigibb Plant Growth Regulator
Active constituent/s:	200 g/kg gibberellic acid
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use	For the foliar spray application to certain varieties of grapes, citrus and prunes to promote desirable harvest effects
Date of registration/approval:	5 March 2015
Product registration no.:	80147
Label approval no.:	80147/100314

Application no.:	101016
Product name:	Maracana 100 EC Insect Growth Regulator
Active constituent/s:	100 g/L pyriproxyfen
Applicant name:	Proplan Plant Protection Company S.L
Applicant ACN:	N/A
Summary of use	For the control of silverleaf whitefly (bemisia tabaci biotype B) in cotton
Date of registration/approval:	6 March 2015
Product registration no.:	80513
Label approval no.:	80513/101016

Application no.:	100955
Product name:	Apparent Wetter 600 Surfactant
Active constituent/s:	600 g/L nonyl phenol ethylene oxide condensate
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of use	For use with insecticides, fungicides and herbicides
Date of registration/approval:	10 March 2015
Product registration no.:	80492
Label approval no.:	80492/100955

Application no.:	100954
Product name:	Apparent GlyAssist 1040 Surfactant
Active constituent/s:	1040g/L octyl phenol ethoxylate
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of use	Non-ionic surfactant for use with Roundup Power Max herbicide, Roundup CT Broadacre herbicide, Roundup Dry herbicide, Roundup herbicide, Nufarm Glyphosate CT herbicide and Weedmaster Duo herbicide, when treating annual ryegrass, silvergrass and perennial grasses
Date of registration/approval:	11 March 2015
Product registration no.:	80491
Label approval no.:	80491/100954

Application no.:	100767
Product name:	Apparent Knock-Out 540 K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of use	For the control of many annual and perennial weeds
Date of registration/approval:	13 March 2015
Product registration no.:	80392
Label approval no.:	80392/100767

Application no.:	100471
Product name:	Smart Penetrator Spray Adjuvant
Active constituent/s:	700 g/L vegetable oil ester
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use	A methylated vegetable oil product to assist in the effectiveness of agricultural chemicals
Date of registration/approval:	13 March 2015
Product registration no.:	80248
Label approval no.:	80248/100471

Application no.:	62856
Product name:	Wellfarm Chlorpyrifos 500 EC Insecticide
Active constituent/s:	500 g/L chlorpyrifos (an anti-cholinesterase compound)
Applicant name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of use	For use in fruit, vegetables, oilseeds, cotton, cereals, pasture, turf and other situations for the control of insect pests
Date of registration/approval:	19 March 2015
Product registration no.:	70266
Label approval no.:	70266/62856

Application no.:	101025
Product name:	Mission Snail-Dead Bait
Active constituent/s:	50 g/kg metaldehyde
Applicant name:	Mission Bell Holdings Pty Ltd
Applicant ACN:	149 573 651
Summary of use	For the control of snails and slugs
Date of registration/approval:	19 March 2015
Product registration no.:	80516
Label approval no.:	80516/101025

Application no.:	62944
Product name:	Wellfarm Imidacloprid 600 SC Seed Dressing Insecticide
Active constituent/s:	600 g/L imidacloprid
Applicant name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of use	For the control of various insect pests in a range of crops and the protection of spread of barley yellow dwarf virus in cereal crops
Date of registration/approval:	19 March 2015
Product registration no.:	70293
Label approval no.:	70293/62944

Application no.:	63129
Product name:	Wellfarm MCPA 750 SL Herbicide
Active constituent/s:	750 g/L MCPA present as the dimethylamine salt
Applicant name:	Wellfarm Pty Ltd
Applicant ACN:	158 518 551
Summary of use	For the selective control of broadleaf weeds in cereals, linseed, oilseed poppies, pastures, rice, sugar cane and turf
Date of registration/approval:	19 March 2015
Product registration no.:	70320
Label approval no.:	70320/63129

Application no.:	61442
Product name:	Vertimec Pro Insecticide / Miticide
Active constituent/s:	18 g/L abamectin
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	For the control of certain mites and insect pests on apples, capsicums, citrus, hops, pears, tomatoes, strawberries and ornamentals
Date of registration/approval:	19 March 2015
Product registration no.:	69685
Label approval no.:	69685/61442

Application no.:	60959
Product name:	Nufarm Eliminar C Herbicide
Active constituent/s:	250 g/L bromoxynil present as the octanoate, 25 g/L picolinafen
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use	For the control of a range of broadleaf weeds in winter cereals
Date of registration/approval:	23 March 2015
Product registration no.:	69510
Label approval no.:	69510/60959

Application no.:	100003
Product name:	Proclex 500 Fungicide
Active constituent/s:	500 g/L procymidone
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain fungal diseases on various crops
Date of registration/approval:	23 March 2015
Product registration no.:	80001
Label approval no.:	80001/100003

Application no.:	63112
Product name:	Solo 800WG Fungicide and Miticide
Active constituent/s:	80 0 g/kg sulphur (S)
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of use	For the control of certain fungal diseases and mites in grapevines and other crops
Date of registration/approval:	23 March 2015
Product registration no.:	70314
Label approval no.:	70314/63112

Application no.:	62393
Product name:	Alkaforce Soluble Concentrated C.I.P. Alkaline Detergent
Active constituent/s:	375 g/L sodium hydroxide, 125 g/L potassium hydroxide
Applicant name:	Dasco Proprietary Limited
Applicant ACN:	004 581 113
Summary of use	For cleaning milking machines and bulk tanks
Date of registration/approval:	24 March 2015
Product registration no.:	70056
Label approval no.:	70056/62393

Application no.:	63116
Product name:	MacPhersons TOJO 700 WG Herbicide
Active constituent/s:	700 g/kg imazamox
Applicant name:	TGAC Australia Pty. Ltd
Applicant ACN:	134 570 700
Summary of use	For the post-emergent control of certain annual grass and broadleaf weeds in field peas, legume-based pastures, lucerne, peanuts, and soybeans
Date of registration/approval:	24 March 2015
Product registration no.:	70316
Label approval no.:	70316/63116

Application no.:	62975
Product name:	Combat Roach Killing Bait Strips
Active constituent/s:	0.1 g/kg fipronil
Applicant name:	Henkel Australia Pty Ltd
Applicant ACN:	001 302 996
Summary of use	For control of cockroaches in household situations
Date of registration/approval:	24 March 2015
Product registration no.:	70308
Label approval no.:	70308/62975

Application no.:	100030
Product name:	Sabakem Synergist 700 Surfactant
Active constituent/s:	350 g/L soyal phospholipids, 350 g/L propionic acid
Applicant name:	Sabakem Pty Ltd
Applicant ACN:	151 682 138
Summary of use	For use as an acidifying and penetrating surfactant which can also reduce chemical hydrolysis
Date of registration/approval:	25 March 2015
Product registration no.:	80011
Label approval no.:	80011/100030

Application no.:	100112
Product name:	Ultraforce Cockroach Powder
Active constituent/s:	5 g/kg fipronil
Applicant name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of use	For the control of cockroaches in food preparation and storage areas of domestic, industrial and institutional premises
Date of registration/approval:	25 March 2015
Product registration no.:	80043
Label approval no.:	80043/100112

Application no.:	63272
Product name:	Trailblaster Herbicide
Active constituent/s:	224 g/L acifluorfen (present as the sodium salt)
Applicant name:	Grow Choice Pty Limited
Applicant ACN:	069 839 961
Summary of use	For the selective control of certain broadleaf weeds and grasses in mung beans, peanuts, soybeans, green beans and seed crops of Siratro and Stylo
Date of registration/approval:	26 March 2015
Product registration no.:	70359
Label approval no.:	70359/63272

Application no.:	63322
Product name:	Expedient Spray Adjuvant
Active constituent/s:	704 g/L ethyl and methyl esters of fatty acids derived from refined canola oil
Applicant name:	Tollman Pty Ltd
Applicant ACN:	100 545 962
Summary of use	For use to enhance the penetrating properties of certain herbicides and pyrethroid insecticides
Date of registration/approval:	27 March 2015
Product registration no.:	70378
Label approval no.:	70378/63322

Application no.:	63383
Product name:	Farmalinx Dimop 375 EC Herbicide
Active constituent/s:	375 g/L diclofop-methyl
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For the post-emergent herbicide control of annual ryegrass, common barbgrass and wild oats in wheat, linseed, peas and other crops and for the control of crowsfoot grass in turf
Date of registration/approval:	27 March 2015
Product registration no.:	70403
Label approval no.:	70403/63383

Application no:	63460
Product name:	Goodthings Mosquito Band
Active constituent/s:	0.75 g per band citronella oil
Applicant name:	3P Pty Ltd
Applicant ACN:	000 572 207
Summary of use	For repelling mosquitoes and other insects
Date of registration/approval:	27 March 2015
Product registration no.:	70439
Label approval no.:	70439/63460

Application no.:	63279
Product name:	Raid Automatic Advanced Multi-Insect System
Active constituent/s:	5.6 g/kg transfluthrin, 1.5 g/kg d-phenothrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of use	For the control of insect pests in household situations
Date of registration/approval:	27 March 2015
Product registration no.:	70363
Label approval no.:	70363/63279

Application no.:	62421
Product name:	Lawn Solutions Australia Professional Pre-Emergent Herbicide and Fertiliser 22-0-5
Active constituent/s:	7.5 g/kg pendimethalin
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use	For the pre-emergence control of wintergrass, summergrass, crab grass and crowsfoot in turf
Date of registration/approval:	27 March 2015
Product registration no.:	70067
Label approval no.:	70067/62421

3. VARIATIONS OF REGISTRATION

Application no:	101904
Product name:	Brunnings Triple Action Rose Pro Insect, Mite And Disease Control
Active constituent/s:	0.167 g/L difenoconazole, 0.1 g/L thiamethoxam, 0.015 g/L abamectin
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To change the product name from 'BRUNNINGS TRIPLE ACTION ROSE SPRAY INSECT, MITE AND DISEASE CONTROL' to 'BRUNNINGS TRIPLE ACTION ROSE PRO INSECT, MITE AND DISEASE CONTROL'
Date of variation:	10 March 2015
Product registration no.:	80400
Label approval no.:	80400/101904

Application no:	101937
Product name:	Yates Zero Weedkiller Ready to use Spray Twice as Fast as Regular Zero
Active constituent/s:	7.2 g/L glyphosate as ammonium salt
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the product name from 'YATES ZERO WEEDKILLER RAPID WORKS TWICE AS FAST' to 'YATES ZERO WEEDKILLER READY TO USE SPRAY TWICE AS FAST AS REGULAR ZERO'
Date of variation:	10 March 2015
Product registration no.:	62561
Label approval no.:	62561/101937

Application no:	101903
Product name:	Yates Weed n' Feed Granular
Active constituent/s:	50 g/kg iron as ferrous sulfate
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the product name from 'YATES DOUBLE ACTION WEED'N'FEED' to 'YATES WEED N' FEED GRANULAR'
Date of variation:	10 March 2015
Product registration no.:	39868
Label approval no.:	39868/101903

Application no:	62619
Product name:	Attrathor Targeted Insecticide
Active constituent/s:	26 g/L fipronil
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of variation:	To extend use to include control of ants in and around commercial, industrial and residential premises
Date of variation:	19 March 2015
Product registration no.:	68053
Label approval no.:	68053/62619

Application no:	100316
Product name:	Farmalinx Soldier Herbicide
Active constituent/s:	480 g/L clomazone
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of variation:	To include additional uses in rice to control barnyard grass and silver top grass
Date of variation:	20 March 2015
Product registration no.:	68843
Label approval no.:	68843/100316

Application no:	58532
Product name:	Off! Clip-On Mosquito Repellent
Active constituent/s:	312 g/kg metofluthrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of variation:	To amend the scheduling from S6 to S5 and update the product label
Date of variation:	24 March 2015
Product registration no.:	64830
Label approval no.:	64830/58532

Application no:	100733
Product name:	Trespass 350 Insecticide
Active constituent/s:	350 g/L imidacloprid
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To add additional uses; bananas, sugar cane (plant cane) and potatoes and also to update storage and disposal and safety directions
Date of variation:	25 March 2015
Product registration no.:	68705
Label approval no.:	68705/100733

Application no:	62269
Product name:	Rabbit Haemorrhagic Disease Virus (Lyophilised)
Active constituent/s:	3000 ID_{50} units rabbit haemorrhagic disease virus (CAPM V-351)
Applicant name:	NSW Department of Primary Industries
Applicant ACN:	N/A
Summary of variation:	To change the product name from 'from RABBIT HAEMORRHAGIC DISEASE VIRUS SUSPENSION' to 'RABBIT HAEMORRHAGIC DISEASE VIRUS (LYOPHILISED)' and change the pack size.
Date of variation:	26 March 2015
Product registration no.:	50675
Label approval no.:	50675/62269

Application no:	63271
Product name:	Crop Care Dragon 700 WG Fungicide
Active constituent/s:	700 g/kg dithianon
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To reduce application rate for control of downy mildew in grapevines from 50 g/100L to 25 g/100L and to reduce associated spray interval from 10 days to 7–10 days
Date of variation:	27 March 2015
Product registration no.:	68856
Label approval no.:	68856/63271

Application no:	101554
Product name:	Perigen Defence Residual Insecticide
Active constituent/s:	500 g/L permethrin (25:75 CIS:TRANS)
Applicant name:	Bayer CropScience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To add a new/alternative label name for the product, 'Masterline Permethrin 500 Timber and Residual Insecticide'
Date of variation:	27 March 2015
Product registration no.:	57184
Label approval no.:	57184/101554

Veterinary Chemical Products and Approved Labels

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 relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

1. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	58064
Product name:	Apoquel 16 mg Tablets for Dogs
Active constituent/s:	Each tablet contains 16 mg oclacitinib maleate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use	For the treatment of pruritus associated with allergic dermatitis and treatment of the clinical manifestations of atopic dermatitis in dogs
Date of Registration/approval:	20 March 2015
Product registration no.:	68310
Label approval no.:	68310/58064

Application no.:	58065
Product name:	Apoquel 3.6 mg Tablets for Dogs
Active constituent/s:	Each tablet contains 3.6mg oclacitinib maleate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use	For the treatment of pruritus associated with allergic dermatitis and treatment of the clinical manifestations of atopic dermatitis in dogs
Date of Registration/approval:	20 March 2015
Product registration no.:	68311
Label approval no.:	68311/58065

Application no.:	58066
Product name:	Apoquel 5.4 mg Tablets for Dogs
Active constituent/s:	Each tablet contains 5.4 mg oclacitinib maleate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use	For the treatment of pruritus associated with allergic dermatitis and treatment of the clinical manifestations of atopic dermatitis in dogs
Date of Registration/approval:	20 March 2015
Product registration no.:	68312
Label approval no.:	68312/58066

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	100590
Product name:	Topdec Pour-On For Cattle And Red Deer
Active constituent/s:	5 g/L moxidectin
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For use in the treatment and control of moxidectin—sensitive internal and external parasites of cattle, and for the treatment and control of lungworm and gastrointestinal roundworms of red deer
Date of registration/approval:	4 March 2015
Product registration no.:	80308
Label approval no.:	80308/100590

Application no.:	100570
Product name:	Moximax Pour-On For Cattle And Red Deer
Active constituent/s:	5 g/L moxidectin
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For use in the treatment and control of moxidectin—sensitive internal and external parasites of cattle, and for the treatment and control of lungworm and gastrointestinal roundworms of red deer
Date of registration/approval:	4 March 2015
Product registration no.:	80298
Label approval no.:	80298/100570

Application no.:	100809
Product name:	Vets Choice For Puppies And Small Dogs Up To 4 kg Fleas And Ticks
Active constituent/s:	100 g/L imidacloprid, 500 g/L permethrin (40:60)
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the control of fleas, ticks and lice on dogs; the reduction of the incidence of flea allergy dermatitis on dogs; the repelling and killing of ticks, mosquitoes and sandflies on dogs; and the repelling of stable flies on dogs
Date of registration/approval:	4 March 2015
Product registration no.:	80405
Label approval no.:	80405/100809

Application no.:	100779
Product name:	Vets Choice For Kittens And Small Cats Up To 4 kg Fleas
Active constituent/s:	100 g/L imidacloprid
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the control of fleas in kittens and small cats up to 4 kg
Date of registration/approval:	5 March 2015
Product registration no.:	80401
Label approval no.:	80401/100779

Application no.:	100818
Product name:	Vets Choice For Cats Over 4 kg Fleas
Active constituent/s:	100 g/L imidacloprid
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the control of fleas in cats over 4 kg
Date of registration/approval:	5 March 2015
Product registration no.:	80406
Label approval no.:	80406/100818

Application no.:	100858
Product name:	Vets Choice for Dogs 10–25 kg Fleas, Heartworm And Worms
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the treatment and prevention of fleas on dogs; the reduction of the incidence of flea allergy dermatitis on dogs; the prevention of heartworm infection in dogs; for the treatment and control of roundworms, hookworms, whipworm, generalised demodicosis, sarcoptic manage and lice on dogs
Date of registration/approval:	6 March 2015
Product registration no.:	80436
Label approval no.:	80436/100858

Application no.:	100857
Product name:	Vets Choice For Dogs Over 25 kg Fleas, Heartworm And Worms
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the treatment and prevention of fleas on dogs; the reduction of the incidence of flea allergy dermatitis on dogs; the prevention of heartworm infection in dogs; for the treatment and control of roundworms, hookworms, whipworm, generalised demodicosis, sarcoptic mange and lice on dogs
Date of registration/approval:	6 March 2015
Product registration no.:	80435
Label approval no.:	80435/100857

Application no.:	100862
Product name:	Vets Choice For Cats Over 4 kg Fleas, Heartworm And Worms
Active constituent/s:	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the prevention of heartworm and the control of intestinal worms and larvae and for the treatment and prevention of fleas (*ctenocephalides spp.)* and reduction in the incidence of flea allergy dermatitis
Date of registration/approval:	11 March 2015
Product registration no.:	80439
Label approval no.:	80439/100862

Application no.:	100828
Product name:	Vets Choice For Dogs 10-25 Kg Fleas And Ticks
Active constituent/s:	100 g/L imidacloprid, 500 g/L permethrin (40:60)
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the control of fleas, ticks and lice on dogs; the reduction of the incidence of flea allergy dermatitis on dogs; the repelling and killing of ticks, mosquitoes and sandflies on dogs; and the repelling of stable flies on dogs
Date of registration/approval:	13 March 2015
Product registration no.:	80407
Label approval no.:	80407/100819

Application no.:	100829
Product name:	Vets Choice For Dogs 4–10 Kg Fleas And Ticks
Active constituent/s:	100 g/L imidacloprid, 500 g/L permethrin (40:60)
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the control of fleas, ticks and lice on dogs; the reduction of the incidence of flea allergy dermatitis on dogs; the repelling and killing of ticks, mosquitoes and sandflies on dogs; and the repelling of stable flies on dogs
Date of registration/approval:	13 March 2015
Product registration no.:	80417
Label approval no.:	80417/100829

Application no.:	100819
Product name:	Vets Choice For Dogs Over 25 Kg Fleas And Ticks
Active constituent/s:	100 g/L imidacloprid, 500 g/L permethrin (40:60)
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the control of fleas, ticks and lice on dogs; the reduction of the incidence of flea allergy dermatitis on dogs; the repelling and killing of ticks, mosquitoes and sandflies on dogs; and the repelling of stable flies on dogs
Date of registration/approval:	13 March 2015
Product registration no.:	80407
Label approval no.:	80407/100819

Application no.:	62665
Product name:	Metaject CBG Calcium Borogluconate Injection
Active constituent/s:	29.7 g/L calcium (as calcium borogluconate)
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use	For use in the treatment of milk fever in cattle and sheep
Date of registration/approval:	18 March 2015
Product registration no.:	70167
Label approval no.:	70167/62665

Application no.:	100863
Product name:	Vets Choice for Kittens and Small Cats up to 4 kg Fleas, Heartworm And Worms
Active constituent/s:	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the prevention of heartworm and the control of intestinal worms and larvae and for the treatment and prevention of fleas (*Ctenocephalides spp.*) and reduction in the incidence of flea allergy dermatitis in kittens, small cats and ferrets
Date of registration/approval:	23 March 2014
Product registration no.:	80440
Label approval no.:	80440/100863

Application no.:	59667
Product name:	Orbenin L.A. Lactating Cow Intramammary Antibiotic Infusion with prolonged action
Active constituent/s:	Each 3 g syringe contains 200 mg cloxacillin as sodium cloxacillin
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use	For the treatment of mastitis caused by bacteria susceptible to cloxacillin in dairy cows
Date of registration/approval:	24 March 2015
Product registration no.:	69024
Label approval no.:	69024/59667

Application no.:	100859
Product name:	Vets Choice for Dogs 4-10 Kg Fleas, Heartworm And Worms
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the prevention of heartworm and the control of intestinal worms and larvae and for the treatment and prevention of fleas (*Ctenocephalides spp.*) and reduction in the incidence of flea allergy dermatitis
Date of registration/approval:	24 March 2015
Product registration no.:	80437
Label approval no.:	80437/100859

Application no.:	100860
Product name:	Vets Choice for Puppies and Small Dogs up to 4 kg Fleas, Heartworm and Worms
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	For the prevention of heartworm and the control of intestinal worms and larvae and for the treatment and prevention of fleas (*Ctenocephalides spp.*) and reduction in the incidence of flea allergy dermatitis
Date of registration/approval:	24 March 2015
Product registration no.:	80438
Label approval no.:	80438/100860

3. VARIATIONS OF REGISTRATION

Application no.:	101753
Product name:	Aristopet Animal Health Flea & Tick Shampoo For Dogs And Puppies
Active constituent/s:	10 g/L piperonyl butoxide, 1 g/L pyrethrins
Applicant name:	Aristopet Pty Ltd
Applicant ACN:	145 418 882
Summary of variation:	To change the product name from 'ARISTOPET ANIMAL HEALTH FLEA & TICK SHAMPOO FOR DOGS, CATS, PUPPIES AND KITTENS' to 'ARISTOPET ANIMAL HEALTH FLEA AND TICK SHAMPOO FOR DOGS AND PUPPIES' and to remove use on cats
Date of variation:	24 February 2015
Product registration no.:	46728
Label approval no.:	46728/101753

Approved Active Constituents

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 approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

1. ACTIVE CONSITUTENT

Application no.:	101580
Active constituent/s:	Oclacitinib maleate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	20 March 2015
Approval no.:	80767/101580

Application no.:	63372
Active constituent/s:	Fluroxypyr-meptyl
Applicant name:	Zhejiang Yingxin Chemical Co. Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	25 March 2015
Approval no.:	70398/63372

Application no.:	59626
Active constituent/s:	Acetamiprid
Applicant name:	Nippon Soda Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	26 March 2015
Approval no.:	69006/59626

Application no.:	57828
Active constituent/s:	Halauxifen-methyl
Applicant name:	Dow AgroSciences Australia Limited
Applicant ACN:	003 771 659
Summary of use:	For use in agricultural chemical products
Date of approval:	26 March 2015
Approval no.:	68243/57828

Application no.:	63476
Active constituent/s:	Ametryn
Applicant name:	Sixon AgroSciences Australia Pty Ltd
Applicant ACN:	169 409 134
Summary of use:	For use in agricultural and veterinary chemical products
Date of approval:	27 March 2015
Approval no.:	70452/63476

Application no.:	63270
Active constituent/s:	Atrazine
Applicant name:	Sixon AgroSciences Australia Pty Ltd
Applicant ACN:	169 409 134
Summary of use:	For use in agricultural and veterinary chemical products
Date of approval:	27 March 2015
Approval no.:	70358/63270

Application no.:	63377
Active constituent/s:	Metribuzin
Applicant name:	Zhejiang Yingxin Chemical Co. Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	27 March 2015
Approval no.:	70402/63377

New Agricultural Active Constituent approved under Section 14a EUBACTERIUM SP. STRAIN BBSH 797

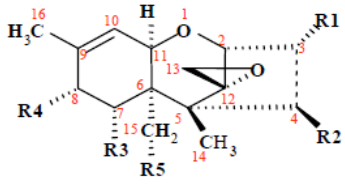
The Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing to add EUBACTERIUM SP. STRAIN BBSH 797 to the list of Active Constituents Not Requiring Evaluation. EUBACTERIUM SP. STRAIN BBSH 797 has been evaluated and has met the criteria under Section 14A of the Agvet Code.

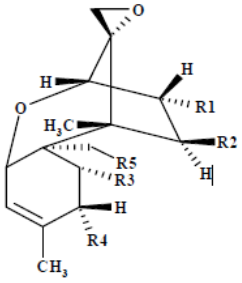
The APVMA is satisfied under Section 14A(1)(b) of the Agvet Code, 'having regard to information that is readily available, that the constituent would meet the safety criteria.'

Common Name: EUBACTERIUM SP. STRAIN BBSH 797

Scientific Information: Trichothecenes are a large family of structurally-related mycotoxins (~150 recognised members). They are characterised by the presence of a tetracyclic sesquiterpene skeleton containing a six-membered oxane ring, a stable epoxide group in positions 12 and 13 and a 9,10 olefinic bond (Figure 1). They have been classified into four groups on the basis of the pattern of substitution at position 8 (groups A and B), the presence of a second epoxy function at 7, 8 or 9, 10 (group C) or a macrocyclic ring between positions 4 and 5 (group D) (Ueno 1985). Further information can be gained from an EFSA JOUNAL (2005) http://www.efsa.europa.eu/en/efsajournal/doc/169.pdf

General structure of trichothecenes:





MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission to the proposal to include EUBACTERIUM SP. STRAIN BBSH 797 on the list of Active Constituents Not Requiring Evaluation. . Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval via the section 14A route. These grounds include chemistry and manufacture, and toxicity. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact below. All submissions to the APVMA will be acknowledged in writing via email or by post. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

- contact name
- company or Group name (if relevant)
- postal Address
- email Address (if available)
- the date you made the submission.

All personal and *confidential commercial information (CCI)*[1] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant approval for EUBACTERIUM SP. STRAIN BBSH 797 that relate to the grounds for approval should be marked attention to the Director, Chemistry and Manufacture Section, Scientific Assessment and Chemical Review Program in writing to:

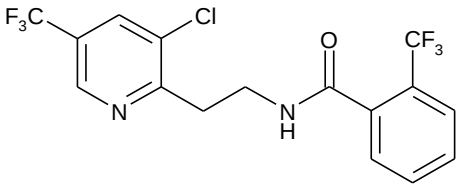
The Director
Chemistry and Manufacture Section
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4936
Fax: +61 2 6210 4840
Email: chemistry@apvma.gov.au

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

New Agricultural Active Constituent Fluopyram

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, fluopyram for use as a fungicide.

Common Name:	fluopyram
IUPAC Name:	*N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-o-toluamide
CAS Name:	*N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide
CAS Registry Number:	658066-35-4
Manufacturer's Code:	AE C656948
Minimum Purity:	960 g/kg
Molecular Formula:	$C_{16}H_{11}ClF_6N_2O$
Molecular Weight:	396.72
Structure:	
Chemical Family:	pyridinyl ethylbenzamides
Mode of Action:	fungicide

SUMMARY OF THE APVMA'S EVALUATION OF FLUOPYRAM ACTIVE CONSTITUENT

The Pesticides Program of the APVMA has evaluated the chemistry aspects of fluopyram 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 fluopyram active constituent:

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

Compounds of toxicological significance are not expected to occur in fluopyram TGAC as a result of the raw materials and the synthetic route used.

The Office of Chemical Safety (OCS) has considered the toxicological aspects of fluopyram TGAC, 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/d has been set, based on a No-Observed Adverse Effect Level (NOAEL) of 1.2 mg/kg bw/d in a 2–year study, after applying a safety factor of 100. An Acute Reference Dose (ARfD) of 0.5 mg/kg bw has been set based on a NOAEL of 50 mg/kg bw in a single dose acute neurotoxicity study in rats.

Based on the toxicity profile, on 5 February 2015 the delegate to the Secretary of the Department of Health published an interim scheduling decision to create a new Schedule 5 listing of fluopyram in the Standard for the Uniform Scheduling of Medicines and Poisons, except in products containing 500 g/L or less which are exempt from scheduling.

The OCS has not specified toxicologically significant impurities in technical fluopyram.

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

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

MAKING A SUBMISSION

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 fluopyram should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. These grounds include chemistry and manufacture, and toxicity. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

- contact name
- company or Group name (if relevant)
- postal Address
- email Address (if available)
- the date you made the submission.

All personal and *confidential commercial information (CCI)*[2] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant approval for fluopyram that relate to the grounds for approval should be addressed in writing to:

Director, Chemistry and Manufacture Section
Scientific Assessment and Review Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4936
Fax: +61 2 6210 4840
Email: chemistry@apvma.gov.au

[2] A full definition of 'confidential commercial information' is contained in the Agvet Code.

Fluopyram in the product Luna Privilege Fungicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd, for registration of a new product containing the active constituent fluopyram. The product luna privilege fungicide is for use on grapes for dried fruit production and table grapes.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Luna Privilege Fungicide
Applicant company:	Bayer CropScience Pty Ltd
Name of active constituent:	Fluopyram
Signal heading:	Exempt
Summary of proposed use:	For the control of botrytis bunch rot and powdery mildew in grapes for dried fruit production and table grapes.
Pack sizes:	1–100 L
Withholding period:	Grapes: DO NOT harvest for 7 days after application. DO NOT graze livestock in treated vineyards.

SUMMARY OF THE APVMA'S EVALUATION OF LUNA PRIVILEGE FUNGICIDE IN ACCORDANCE WITH SECTIONS 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 luna privilege fungicide containing the active constituent fluopyram would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the product and concluded that it can be used safely.

The main occupational use of the product will be by farmers and their workers. Workers will be exposed to the product when opening containers, mixing/loading, during application, and cleaning up spills and equipment. The main route of exposure to the product/spray will be dermal and inhalation, although ocular exposure is also possible.

In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide was used to estimate exposure. Exposure to the product when preparing and using the spray for airblast and low and high pressure handwand application was at an acceptable level without the need for any specific personal protective equipment (PPE). Exposure to the product during backpack application was at an acceptable level when a single layer of clothing (cotton overalls or equivalent clothing) was worn during application. However for backpack/knapsack application exposure was at an acceptable level when cotton overalls buttoned to the neck and wrist (or equivalent clothing) are worn.

Based on the risk assessment, First Aid Instructions, Safety Directions and Re-entry statements have been recommended for the product label.

(ii) The APVMA is satisfied that the proposed use of Luna Privilege Fungicide containing the active constituent fluopyram will not be an undue hazard to the safety of people using anything containing its residues.

The APVMA is satisfied that the proposed use of luna privilege fungicide will not be an undue hazard to the safety of people using anything containing its residues provided the product is used in accordance with the proposed label directions.

Long term (chronic) dietary exposure as estimated by the national estimated dietary intake calculation is acceptable. The short term (acute) dietary exposure as estimated by the national estimated sort term intake calculation is also acceptable.

Maximum Residue Limits (MRLs) for dried gapes and table grapes have been recommended.

(iii) The APVMA is satisfied that the proposed use of luna privilege fungicide containing the active constituent fluopyram is not likely to be harmful to human beings if used according to the product label directions.

Fluopyram was quickly adsorbed and 90% of the administered dose was excreted within 168 hours. There was evidence of significant enterohepatic circulation. Only minor sex specific effects in toxicokinetics have been observed although systemic exposure was higher and enterohepatic circulation more pronounced in females. An analysis of metabolism revealed a number of metabolites. There were no significant gender differences in metabolic profiles.

Based on the findings of the acute toxicological studies evaluated, fluopyram is of low acute oral, dermal, and inhalation toxicity in rats, is not a skin or eye irritant in rabbits, and is not a skin sensitiser in mice (LLNA).

In short term and subchronic oral studies the liver proved to be the main target organ in rats, mice and dogs. Hepatotoxicity became apparent by a dose-related increase in organ weight, alterations of clinical chemical parameters and histopathological findings such as centrilobular hypertrophy or periportal or midzonal vacuolation or macrovacuolation.

The long-term toxicity and the oncogenic potential of fluopyram were assessed in both the mouse and rat. In both species, the liver, the thyroid and the kidney were the main target organs of chronic toxicity. Carcinogenic effects comprised of liver tumours in female rats and thyroid tumours in male mice but were confined to the highest dose levels in the respective studies. Overall it was considered that mechanistic studies only indicated a likely mode of action (MOA) for fluopyram induced liver tumours in female rats similar to that developed for phenobarbital, and further information is required on the association of fluopyram exposure and aryl hydrocarbon receptor activation and its possible influence on liver tumourigenicity. Consequently, in the absence of such data the relevance of these tumours to humans cannot be entirely dismissed. However, the weight of evidence supports a conclusion that these tumours occurred by a non-genotoxic mechanism in female rats at high doses (89 mg/kg bw/d), and a threshold for the induction of such tumours was identified (i.e. no treatment-related induction of liver tumours occurred in female rats at 8.6 mg/kg bw/d). In contrast, it was considered that the MOA deduced for fluopyram rodent thyroid tumours was not relevant to humans.

An impairment of motor and locomotor activity was seen in an acute neurotoxicity study in rats when fluopyram was administered by oral gavage, while no such findings were observed in a 90-day neurotoxicity study in rats when fluopyram was administered in the diet.

Fluopyram was not an in vivo genotoxicant, a reproductive or teratogenic toxicant, and studies on plant metabolites provided no data that indicates that the observed level of these metabolites and their limited toxicity profile presents a toxicological concern.

Based on the findings of the acute toxicological studies evaluated, the product luna privilege fungicide has low acute oral, dermal and inhalational toxicity in rats, is not a skin or eye irritant in rabbits, and is not a skin sensitiser in mice (LLNA).

The APVMA has considered the findings of the Department of Health and accepts these conclusions. Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of luna privilege fungicide when used in accordance with the label directions.

(iv) The APVMA is satisfied that the proposed use of luna privilege fungicide containing the active constituent fluopyram, would not be likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

Data on the environmental fate and ecotoxicity of fluopyram were assessed in support of the proposed use. It was concluded that the risks to the environment from this use are acceptable.

Fluopyram is stable with minimal degradation by abiotic processes and undergoes slow degradation by biotic processes in both soil and water under laboratory conditions and also in soil in field dissipation studies. There is potential for significant residue carryover to following cropping seasons if application is performed annually. Fluopyram is moderately mobile in soil. In most studies, metabolites of fluopyram were only present at minor levels. A fish bioconcentration study indicated low bioconcentration/bioaccumulation potential.

Fluopyram is practically nontoxic to birds with acute exposure, but some effects on reproduction were shown. It is slightly to very slightly toxic to fish and aquatic and benthic invertebrates with chronic exposure, but with acute exposure is not toxic up to the solubility limit. It is moderately toxic to green and blue-green algae, diatoms and aquatic plants. It is very slightly toxic to bees and earthworms with acute exposure, and not harmful to earthworm reproduction, terrestrial and ground-dwelling arthropod species or soil microbial processes at the rates tested. No phytotoxic effects were evident in most plant species tested at rates up to the maximum rate tested.

In the risk assessment, particular attention was given to the potential risk to organisms in the environment arising from persistence of fluopyram in soil and sediment. The risk to birds, mammals, plants, bees, earthworms and other non-target terrestrial invertebrates was found acceptable, and no harmful impact on soil nitrogen and carbon metabolism is expected from the proposed uses. Based on the acute and chronic aquatic toxicity studies provided, with the proposed uses the risk to aquatic and sediment-dwelling organisms from spray drift, run-off or if groundwater were returned to the surface were found acceptable, with no Downwind No-Spray Zone being required.

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

(v) The APVMA is considering whether the proposed use of luna privilege fungicide containing the active constituent fluopyram would not adversely affect trade between Australia and places outside Australia.

Comment is sought on the ability of industry to manage the risks associated with the proposed use of luna privilege fungicide and the potential for the proposed uses to unduly prejudice Australian trade.

(vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, www.apvma.gov.au/news-and-publications/public-consultations or by contacting the evaluator listed below.

MAKING A SUBMISSION

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 of luna privilege fungicide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds include occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address
- the date you made the submission.

All personal and *confidential commercial information (CCI)*[3] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

[3] A full definition of 'confidential commercial information' is contained in the Agvet Code.

Cancellation of Label Approval at the Request of the Holder

At the request of the holder, following the recent approval of a new label for this product, the APVMA has cancelled the following label approval that had been previously suspended:

Product no.	Product name	Approval holder	Cancelled label approval	Date of effect
58374	CROPRO STALK INSECTICIDE	PCT HOLDINGS PTY LTD	58374/0504	30 March 2015

The following instructions set out how a person can deal with the product bearing the cancelled label. Please note that the recent label approval for this product 58374/100973 has not been cancelled and the directions on that label must be followed.

SUPPLY

A person may supply or cause to be supplied product bearing the cancelled label only in accordance with the instructions at the end of this notice, at wholesale and retail level, until 30 March 2016.

After 30 March 2016 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product bearing the cancelled label.

USE

A person may continue to use the product bearing the cancelled label only in accordance with the instructions at the end of this notice, until 30. March 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product bearing the cancelled label after the approval has been cancelled until 30 March 2016.

Permits, with modified instructions for use of dimethoate products, have been issued under section 114 of the Agvet Code (PER 13155 for agricultural products). The instructions for use have been reproduced at the end of this Notice. This permit still applies to product bearing this cancelled label.

WARNING

The cancelled label approval, (58374/0504) listed in Table 1 above has been cancelled. Prior to the cancellation of this label it was suspended with new instructions for use during the period of suspension. These instructions also apply during this period of phase out. Since 6 October 2011, when these product labels were first suspended and new instructions issued, a person can only possess, have custody of, use or otherwise deal with products bearing the label approvals identified above in accordance with permit PER13155 issued by the APVMA and the instructions set out at the end of this Notice.

The APVMA may cancel this permit and issue replacement permits at any time during the phase out period. Before using, supplying or otherwise dealing with products containing dimethoate, suppliers and users need to be satisfied that the instructions set out at the end of this Notice continue to apply, and that their activities are authorised by a permit. Current permits are available at https://portal.apvma.gov.au/permits

Failure to comply with the instructions in this Notice attracts a penalty under section 45C(5) of the Agvet Code. The penalty is 300 penalty units (equivalent to $51,000 for individuals and $255,000 for corporations).

APVMA CONTACT

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
SYMONSTON ACT 2609

Phone: +61 2 6210 4749
Fax: +61 2 6210 4776
Email: chemicalreview@apvma.gov.au

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH REGISTERED PRODUCTS CONTAINING DIMETHOATE BEARING CANCELLED LABELS

Possession and custody

A person may possess, have custody of, use or otherwise deal with the registered dimethoate products, bearing a cancelled label only in accordance with these instructions or permits PER 13155 for agricultural products issued by the APVMA.

Supply

A person may supply or cause to be supplied product bearing the cancelled label approval 58374/0504 at wholesale and retail level only in accordance with the instructions in this notice, until 30 March 2016.

After 30 March 2016 it will be an offence against the Agvet Codes to have possession or custody of a product bearing a cancelled label with the intention to supply.

All suppliers must at the time of the supply of a product covered by these instructions provide to the person taking responsibility for the supplied product:

- a copy of the relevant permit (PER 13155 for agricultural products) in full setting out the conditions and instructions for use, and
- supply product with a copy of the instructions contained in that permit securely affixed to each container of product.

Use

PERSONS who wish to use registered products containing dimethoate, bearing cancelled labels (as listed above) must read, or have read to them, the instructions included in the relevant APVMA permit. Users who have had the instructions read to them must confirm to the reader that they understand the instructions.

READ THESE INSTRUCTIONS before using or otherwise handling the product.

When using or otherwise handling the product, follow the instructions of the current label except as follows:

PROHIBITED CROP USES: AGRICULTURAL PRODUCTS
The existing (cancelled) label may include instructions for use on the crops listed below. The use of dimethoate on these crops is no longer approved and the following restraints apply.

DO NOT USE as a post-harvest treatment for capsicums or tomatoes**.**

DO NOT USE as a post-harvest quarantine treatment for capsicums or tomatoes**.**

DO NOT USE on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels.

DO NOT USE on cherry, grape or mini tomatoes

DO NOT USE as a foliar, post-harvest or quarantine treatment on:
- Tropical or subtropical edible peel fruit [babacos, carambolas (Five Corner), figs and edible peel varieties of guavas, kiwifruit and persimmons].
- Pome fruit [apples, loquats, pears, quinces],
- Stone fruit after petal fall [apricots, cherries, nectarines, peaches, plums, apricot],
- Grapes after commencement of flowering,
- Berry fruit, (other than blackberries, raspberries, bilberries, blueberries and other vaccinium berries)
- Strawberries (except strawberry runners – vegetative planting material only)
- Cucurbits (other than melons, watermelons and zucchini)
- Vegetables, other than those listed below
    - Dimethoate may be used on artichoke (globe), asparagus, beans, beetroot, broccoli, cabbage (drumhead varieties only),capsicums, carrot, cauliflower, celery, chilli peppers, peas, potatoes and sweet potatoes, onion, parsnips, radish, rhubarb, sweetcorn, tomatoes for processing, tomatoes (large field grown for fresh consumption, prior to commencement of flowering), turnip and zucchini,

Directions for Use:

These directions for use must be used in conjunction with existing label directions and the restraint statements. Where the instructions in this notice are inconsistent with the label instructions, the instructions in this notice must be followed.

Table 1 Crops where existing label directions may continue to be followed.

Fruit crops	Vegetable crops	Non-food crops
Abius Avocado Banana Blackberries Cactus Fruit Casimiroas (White Sapote) Chinese Gooseberries (Kiwifruit) (inedible peel varieties ONLY) Citrus Fruit Custard Apple and cherimoya Feijoa Granadillas Guavas (inedible peel varieties only) Litchis (Lychee) Mangoes Passionfruit and Banana passionfruit Pawpaw (papaya) Persimmons (American -inedible peel varieties ONLY) Pomegranates Raspberries Santols Sapodillas (Chikus) Tamarillos Wax Jambus	*Existing labels include preharvest uses only* Asparagus Melons and watermelons Onions Rhubarb Watermelons Zucchini Seed dressings (vetches, lupins, peas, lucerne, clover, linseed, canola)	Duboisia, Farm and forest trees Eucalyptus Kurrajongs Oil tea-tree Ornamentals, Protea Shrubs Umbrella trees Wildflowers

Table 2: Crops that are subject to additional restrictions/variations to their existing approved use patterns.

Crop	Additional use restrictions
Blueberries, bilberries and other vaccinium berries	**DO NOT** exceed a maximum number of 7 applications per crop per season with a minimum retreatment interval of 21 days between consecutive applications. **DO NOT** harvest for 1 day after final application.
Grapes	**DO NOT** use after flowering commences
Stone fruit	**DO NOT** use after petal fall
Artichoke, Globe	**DO NOT** harvest for 14 days after final application
Beetroot	
Beans	**DO NOT** harvest for 7 days after application **DO NOT** graze or cut for stockfood for 7 days after application
Broccoli	**DO NOT** harvest for 21 days after final application
Cabbage specified drumhead varieties only when grown to maturity to be harvested as head cabbages (see Attachment 3)	**DO NOT** harvest for 21 days after final application
Capsicum	**DO NOT USE** as a post-harvest treatment for capsicums. **DO NOT USE** as a post-harvest quarantine treatment for capsicums**.**.
Chilli	**Preharvest uses** **DO NOT** harvest for 3 days after application
Carrots	**DO NOT** harvest for 14 days after final application
Cauliflower	**DO NOT** harvest for 21 days after final application
Celery	
Peas	**DO NOT** harvest for 7 days after application **DO NOT** graze or cut for stockfood for 7 days after application
Parsnips	**DO NOT** harvest for 14 days after final application
Potatoes	**DO NOT** harvest for 14 days after final application
Sweet potatoes	
Radishes	**DO NOT** harvest for 14 days after application
Strawberry (runner production – vegetative planting material only)	**DO NOT use on fruiting strawberries**
Sweet corn	**DO NOT** harvest for 7 days after application **DO NOT** graze or cut for stockfood for 7 days after application
Tomatoes for processing only	**DO NOT** harvest for 21 days after final application **DO NOT USE** as a post-harvest treatment for tomatoes. **DO NOT USE** as a post-harvest quarantine treatment for tomatoes. **DO NOT USE** on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels **DO NOT USE** on cherry, grape or mini tomatoes
Tomatoes, large, field grown for fresh consumption	**DO NOT** apply after commencement of flowering **DO NOT USE** on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels. **DO NOT USE** as a post-harvest treatment for tomatoes. **DO NOT USE** as a post-harvest quarantine treatment for tomatoes. **DO NOT USE** on cherry, grape or mini tomatoes
Turnips	**DO NOT** harvest for 14 days after final application
Cereals, (including maize, sorghum)	**DO NOT** harvest for 4 weeks after application **DO NOT** graze or cut for stockfood for 14 days after application
Cotton	**DO NOT** harvest for 14 days after application **DO NOT** Feed Cotton Fodder, Stubble or Trash To Livestock
Oilseeds, Pulses (grain legumes)	**DO NOT** harvest for 14 days after application **DO NOT** graze or cut for stockfood for 14 days after application
Pastures, forage crops and leucaena	**DO NOT** graze or cut for stockfood for 14 days after application

WITHHOLDING PERIODS (see Additional Use Restrictions above)

Citrus
DO NOT harvest for 7 days after application

Blueberries (and other vaccinium berries including bilberries)
DO NOT harvest for 1 day after application

Blackberries, Raspberries
DO NOT harvest for 7 days after application

Grapes, Stone fruit
Harvest withholding period: Not required when used as directed

Assorted Sub-Tropical and Tropical Fruit – Inedible Peel (other than Mango and Pineapple), including Abui, Avocado, Banana, Banana Passionfruit, Casimiroas (White Sapote), Cherimoya, Custard Apple, Granadillas, Litchi/Lychee, Passionfruit, Paw Paw, Santols, Sapodillas (Chikus), Wax Jambus
DO NOT harvest for 7 days after application

Mango
DO NOT harvest for 3 days after application

Post Harvest Dipping (Avocados, Bananas, Cactus Fruit, Chilli, Custard Apples, Feijoas, Guavas, Kiwifruit (Chinese Gooseberries inedible peel varieties), Litchis (Lychees), Mangoes, Melons, Passionfruit, Banana Passionfruit, Pawpaws, Persimmons (inedible peel varieties), Pomegranates, Tamarillos, Watermelons)
NOT REQUIRED WHEN USED AS DIRECTED (dip uses only)

Litchis (Lychees) (pre-planting dip)
Harvest withholding period: Not required when used as directed

Asparagus, Onions, Rhubarb, Sweet Corn
DO NOT harvest for 7 days after application

Beans, Peas (green vegetables), Sweetcorn
DO NOT harvest for 7 days after application
DO NOT graze or cut for stockfood for 7 days after application

Beetroot, Carrot, Globe artichoke, Parsnips Potatoes, Radish, Sweet Potatoes, Turnip
DO NOT harvest for 14 days after application.

Broccoli, Cauliflower, Celery
DO NOT harvest for 21 days after application

Strawberry plants (runner production – vegetative planting material only)
NOT REQUIRED WHEN USED AS DIRECTED

Tomatoes (for processing)
DO NOT harvest for 21 days after application

Tomatoes, large, field grown for fresh consumption
Harvest withholding period: **NOT REQUIRED WHEN USED AS DIRECTED**
(ie. **DO NOT** apply after commencement of flowering)

Drumhead cabbage (specified varieties only)
DO NOT harvest for 21 days after application

Capsicums, Chilli peppers
DO NOT harvest for 3 days after application

Melons (including watermelons), Zucchini
DO NOT harvest for 1 day after application

Cereals, (including maize, sorghum)
DO NOT harvest for 4 weeks after application
DO NOT graze or cut for stockfood for 14 days after application

Cotton
DO NOT harvest for 14 days after application
DO NOT Feed Cotton Fodder, Stubble or Trash To Livestock

Oilseeds, Pulses (grain legumes)
DO NOT harvest for 14 days after application
DO NOT graze or cut for stockfood for 14 days after application

Pastures, forage crops and leucaena
DO NOT graze or cut for stockfood for 14 days after application

Seed dressings (Vetches, Lupins, Peas, Lucerne, Clover, Linseed Canola),
NOT REQUIRED WHEN USED AS DIRECTED

Table 3: Specified varieties of drumhead cabbage. Dimethoate may be used on these varieties to be grown to maturity to be harvested as head cabbages

Seed company	Drumhead Cabbage varieties
Fairbanks Seed	Avachat F_1, Grandslam F_1, Superba
Terranova	Neptune, Winterhead, Red Queen, Green coronet, Eureka
Lefroy Valley seeds	Conquistador, Burton, Landini
Rijk Zwaan	Racoma RZ F_1
Ace	Major F_1, Red Gem
S&G Seeds	Maxfield
SPS	Arixos, Asia, Kameron, Red jewel
Bejo Seeds	Ducat F_1, Gazelle F_1, Megaton F_1, Benelli F_1, Gonzales F_1, Mandy F_1, Field Glory F_1, Score F_1
Eden seeds	Golden acre, Mammoth red rock
King seeds	Campra F1, Sunta
Yates	Racer Drumhead, Red Dutch
Australian Seed	Mammoth Red Rock, All seasons

Cancellation of Registration at the Request of the Holder

At the request of the holder, the APVMA has cancelled the registration and the associated label approval of the following product:

Product no.	Product name	Approval holder	Date of effect
58953	SPECTRUS CT1300 BIOCIDE	GE BETZ PTY LIMITED TRADING AS GE WATER & PROCESS TECH	30 March 2015

The following instructions set out how a person can deal with the cancelled product.

SUPPLY

A person may supply or cause to be supplied product manufactured prior to 30 March 2015 at wholesale and retail level, until the 30 March 2016.

After 30 March 2016 it will be an offence against the Agvet Codes to have possession or custody of the product with the intention to supply, or to supply the product.

USE

A person may continue to use the product according to its label instructions until 30 March 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product after the registration has been cancelled until 30 March 2016.

The supply and use of the product must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product listed in the table in a manner that contravenes the above instructions.

APVMA CONTACT

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
SYMONSTON ACT 2609

Phone: +61 2 6210 4749
Fax: +61 2 6210 4776
Email: chemicalreview@apvma.gov.au

Megasphaera elsdenii strain 41125 (active) in the Product Lacticon

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from BEC Feed Solutions Pty Ltd for the approval of a new active constituent *Megasphaera elsdenii* strain 41125. The APVMA also has before it an application from the same applicant for the registration of a new product LACTICON containing the new active constituent. The product is for use as an aid in the transition from roughage to grain rations by metabolising lactic acid produced in the gastrointestinal tract where management practices could be expected to result in rumen lactic acidosis in cattle and sheep.

PARTICULARS OF THE ACTIVE CONSTITUENT

Applicant company:	BEC Feed Solutions Pty Ltd
Name of active constituent:	*Megasphaera elsdenii strain 41125*
Common name:	*M. elsdenii strain 41125*
Appearance and Identity:	A mixed culture of anaerobic *Megasphaera elsdenii* bacterium originally isolated from a South African Cattle.
Poisons Schedule:	Appendix B—Substance considered not to require control by scheduling
Gene technology:	Not applicable
Mode of action:	*M. elsdenii* strain 41125 metabolises lactic acid in the gastrointestinal tract.

SUMMARY OF THE APVMA'S EVALUATION OF M. ELSDENII STRAIN 41125 ACTIVE CONSTITUENT

M. elsdenii strain 41125 is a new active constituent and there is no compendial specification available. *M. elsdenii strain 41125* active specifications and quality controls are compliant with international standards.

The APVMA has evaluated the chemistry and manufacturing aspects of *M. elsdenii strain 41125* and is satisfied that the method by which the constituent is to be manufactured would not yield impurities of human or environmental concern and that the active is being produced to GMP standards.

The Department of Sustainability, Environment, Water, Population and Communities has assessed data in support of the proposed use of *M. elsdenii* strain 41125 in the product Lacticon and has concluded that the risks to the environment from this use are acceptable. *M. elsdenii* NCIMB 41125 is a mutualistic microorganism which is highly adapted to the gastrointestinal tract of ruminants. This strain prefers a low pH and requires an anaerobic environment and the presence of certain essential nutrients. Due to these factors, it is unlikely that *M. elsdenii* NCIMB 41125 will be competitive with other anaerobic bacteria outside the rumen, and populations in the wider environment are likely to be limited. As there are no native ruminants in Australia, there are unlikely to be significant effects on Australian native species or ecosystems following the limited use of the product as an oral drench in cattle and sheep. Beneficial effects on feral ruminants are unlikely given the limited use and individual dose application.

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the new active constituent and found that the submitted data supports the safety of the constituent from a toxicological perspective.

This bacterial active is naturally found in the rumen of cattle and sheep and in the gastrointestinal tract of non-ruminant mammals, including humans. No members of the taxonomic group containing *M. eldenii* are known to be pathogenic or

The data submission comprised of skin and eye irritation studies in rabbits, and a GPMT skin sensitisation study, all with the product Lacticon, and prevalence studies of the bacterium in human faeces, colon, and conjunctivae, as well as similar studies in mice, chimpanzees and dogs. The applicant also provided scientific argument and information from the public domain.

The information provided by the applicant were considered by OCS to be justified, and the data package was considered to be sufficient to enable hazard characterisation. Based on the findings of toxicological studies evaluated, the product was not an eye or skin irritant in rabbits, nor a skin sensitiser in guinea pigs (GPMT method). Based on its natural occurrence in humans and the absence of pathogenicity factors, no ADI or ARfD are considered necessary for *M. eldenii* Strain 41125.

The Secretary of the Department of Health and Aging has considered the new active constituent *M. eldenii* Strain 41125 and has included it in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons—a substance not requiring control by scheduling.

The APVMA has considered and accepted these findings and recommendations. The APVMA is satisfied that the proposed use of *M. eldenii* Strain 41125 in the product would not be an undue hazard to the safety of people exposed to it during its handling or use.

Since *M. eldenii* Strain 41125 is a direct fed microbial used at low dosage levels in animal feeds and will be eventually digested in the animals gut or excreted in faeces, no tissue residues is likely to result. Therefore a WHP/ESI of Zero (0) Days has been applied.

The APVMA has evaluated the application in relation to human and environmental safety and trade under section 14(3)(e) of the Agvet Code in combination with the end use product and its proposed label. The APVMA is satisfied that the new active constituent *M. elsdenii strain 41125* when formulated into the proposed end use product would not be an undue hazard to the safety of people exposed to it during its handling or a prejudice to trade. For a full summary see sections (i) and (v) in the 'Summary of the product evaluation' section below.

PARTICULARS OF THE PRODUCT APPLICATION

Proposed Product Name(s):	LACTICON
Applicant Company:	BEC Feed Solutions Pty Ltd
Name of Active Constituents:	*Megasphaera elsdenii strain 41125*
Signal Heading:	None
Summary of Proposed Use:	To aid in the transition from roughage to grain rations by metabolising lactic acid produced in the gastrointestinal tract where management practices could be expected to result in rumen lactic acidosis
Pack Sizes:	1 L, 5 L, 20 L, 50 L

Withholding Period:	**Withholding Periods:**
	MEAT: Zero (0) days
	EGGS: Zero (0) days

SUMMARY OF THE APVMA'S EVALUATION OF THE PRODUCT, LACTICON

The APVMA has evaluated the application in relation to human and environmental safety and trade under section 14(3)(e) and efficacy under section 14(3)(f) of the Agvet Code. It proposes to determine that:

(i) The APVMA is satisfied that the proposed use of LACTICON containing the new active constituent *Megasphaera elsdenii strain 41125*, would not be an undue hazard to the safety of people exposed to it during its handling (section 14(3)(e)(i)).

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the new product, Lacticon and found that the submitted data supports the safety of the constituent from a toxicological perspective.

The data submission comprised of skin and eye irritation studies in rabbits, and a GPMT skin sensitisation study, all with the product Lacticon, and prevalence studies of the bacterium in human faeces, colon, and conjunctivae, as well as similar studies in mice, chimpanzees and dogs. Based on the findings of toxicological studies evaluated, Lacticon was not an eye or skin irritant in rabbits, nor a skin sensitiser in guinea pigs (GPMT method) and the active constituent in Lacticon was deemed not to require control by scheduling.

The APVMA has considered and accepted the findings and recommendations of the OCS.

(ii) The APVMA is satisfied that the proposed use of LACTICON containing the new active constituent *Megasphaera elsdenii strain 41125*, will not be an undue hazard to the safety of people using anything containing its residues (section 14(3)(e)(i)).

Lacticon contains Megasphaera eldenii strain 41125 as the only active constituent. This bacteria is naturally found in the rumen of cattle and sheep and in the gastrointestinal tract of non-ruminant mammals, including humans. This direct-fed microbial product is used at low dosage levels in the form of a drench to influence gut microflora populations. Since the active is a microbe, it is used at low dosage levels and will be eventually digested in the animals gut or excreted in faeces, no tissue residues is likely to result.

The product has been assigned a zero (0) day withholding period.

(iii) The APVMA is satisfied that the proposed use of LACTICON containing the new active constituent *Megasphaera elsdenii strain 41125*, is not likely to be harmful to human beings (section 14(3)(e)(ii).

The delegate to the Secretary of the Department of Health and Aging has included the active in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons—a substance not requiring control by scheduling. Consequently, the product Lacticon requires no signal headings on label.

The following statements were applied to the product:
First aid: a - If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
Safety Directions: Nil

(iv) The APVMA is satisfied that the proposed use of LACTICON containing the new active constituent *Megasphaera elsdenii strain 41125*, would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 14(3)(e)(iii)) if used according to the product label instructions.

The Department of Sustainability, Environment, Water, Population and Communities has assessed data in support of the proposed use and has concluded that the risks to the environment from this use are acceptable.

M. elsdenii NCIMB 41125 is a mutualistic microorganism which is highly adapted to the gastrointestinal tract of ruminants. This strain prefers a low pH (maximum growth at pH 5.5), and requires an anaerobic environment and the presence of certain essential nutrients. Due to these factors, it is unlikely that *M. elsdenii* NCIMB 41125 will be competitive with other anaerobic bacteria outside the rumen, and populations in the wider environment are likely to be limited.

The primary action of the product is to increase the proportion of lactic acid metabolising bacteria in the rumen of cattle and sheep to prevent ruminal acidosis. As there are no native ruminants in Australia, there are unlikely to be significant effects on Australian native species or ecosystems following the limited use of the product as an oral drench in cattle and sheep. Beneficial effects on feral ruminants (e.g. goat and camel) are unlikely given the limited use and individual dose application.

The risk assessment has determined that the biological product is unlikely to pose an environmental risk to either Australian native species or ecosystems due to the characteristics of the anaerobic bacterium and the limited use of the product as an oral drench.

The efficacy and safety aspects of Lacticon were assessed by an external reviewer who found the use of Lacticon to be efficacious and safe for use in the adaptation of beef cattle, dairy cattle and sheep to the transition from roughage to grain concentrate rations. Efficacy and safety have been demonstrated for a series of 14 trials in beef cattle, dairy cattle and in lambs and weaners. No adverse events were seen in any of these trials and an overall reduction in morbidity, reduction in rumen pathology and improvement of production parameters was observed. Therefore Lacticon is safe for use in cattle and sheep when used as per label directions.

(v) The APVMA is satisfied that the proposed use of LACTICON containing the new active constituent *Megasphaera elsdenii strain 41125*, would not adversely affect trade between Australia and places outside Australia. (section 14(3)(e)(iv)).

The use of Lacticon is not expected to result in detectable residues above normal background levels in sheep and cattle. There is no potential for prejudice to trade from use of the product in accordance with the label directions.

(vi) The APVMA is satisfied that the proposed use of LACTICON containing the new active constituent *Megasphaera elsdenii strain 41125*, in accordance with its proposed label instructions would be effective according to criteria determined by the APVMA for the product (section 14(3)(f)).

The applicant provided 14 *in vivo* clinical/field studies pertaining to the use of the product Lacticon in beef/dairy cattle and sheep using the final formulation. These studies were carried out in the USA and Canada. From these studies, it is concluded that the use of Lacticon, containing a minimum of 1×10^8 cfu/ml *Megasphaera elsdenii* as the only active constituent, has been demonstrated to be efficacious and safe for use in the adaptation of beef cattle, dairy cattle and sheep to the transition from roughage to grain concentrate rations where management practices could be expected to result in rumen lactic acidosis. The applicant also provided an extensive literature review that includes publication of research data from Australia and provides the ability to link the international clinical/field trial data with Australian management practices.

MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of LACTICON should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the application. These grounds include occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

- contact name
- company or group name (if relevant)
- postal address
- email address (if available).

The date you made the submission.

All personal and confidential commercial information (CCI)[4] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant registration that relate to the grounds for registration should be addressed in writing to:

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

Phone: +61 2 6210 4700
Fax: +61 2 6210 4741
Email: enquiries@apvma.gov.au

[4] A full definition of 'confidential commercial information' is contained in the Agvet Code.