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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 53(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

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

If you would like to receive email notification when a new edition is published, please subscribe on the APVMA website.

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NOTICE OF REGISTRATIONS

Agricultural 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.

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name:	MacPhersons Tribenuron-Methyl 750 WG Herbicide
Active Constituent/s:	750 g/kg tribenuron-methyl
Applicant Name:	Ronic International Pty Limited
Applicant ACN:	101 193 131
Summary of Use:	For the control of certain broadleaf weeds in fallow and pre-crop situations
Date of Registration:	13 May 2014
Label Approval No:	67722/56727

Product Name:	Yates Buffalopro Weed'n'feed
Active Constituent/s:	6 g/L bromoxynil (present as potassium salt), 6 g/L MCPA (present as potassium salt)
Applicant Name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of Use:	For selective control of broadleaf weeds in home garden lawns
Date of Registration:	15 May 2014
Label Approval No:	68746/59002

Product Name:	Macro Protect Metribuzin 750 WG Herbicide
Active Constituent/s:	750 g/kg metribuzin
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For selective weed control in cereals, pastures and various crops
Date of Registration:	16 May 2014
Label Approval No:	69832/61856

Product Name:	Macro Protect Tralkoxydim 400 WG Herbicide
Active Constituent/s:	400 g/kg tralkoxydim
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	To control wild oats, annual ryegrass and suppression of annual phalaris in wheat, barley, rye and triticale
Date of Registration:	16 May 2014
Label Approval No:	69840/61864

Product Name:	Macro Protect Triasulfuron 750 WG Herbicide
Active Constituent/s:	750 g/kg triasulfuron
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For pre-plant control of annual ryegrass, paradoxa grass and certain broadleaf weeds in wheat and for post-emergent control of wild radish in wheat, oats and barley
Date of Registration:	16 May 2014
Label Approval No:	69836/61860

Product Name:	Macro Protect Trifluralin 480 EC Selective Herbicide
Active Constituent/s:	480 g/L trifluralin
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For the control of annual grasses and broadleaf weeds in horticultural and agricultural crops
Date of Registration:	16 May 2014
Label Approval No:	69837/61861
Product Name:	Fluxia 750 Herbicide
Active Constituent/s:	750 g/kg isoxaflutole
Applicant Name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of Use:	For use in sugarcane and chickpeas for the control and suppression of various broadleaf weeds and grasses
Date of Registration:	16 May 2014
Label Approval No:	68581/58637
Product Name:	Macro Protect Paraquat 250 SL Herbicide
Active Constituent/s:	250 g/L paraquat present as paraquat dichloride
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For the control of a wide range of grasses and broadleaf weeds
Date of Registration:	19 May 2014
Label Approval No:	69833/61857
Product Name:	Unity 240 EW Herbicide
Active Constituent/s:	240 g/L carfentrazone-ethyl
Applicant Name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of Use:	For control of broadleaf weeds in winter cereals and pyrethrum
Date of Registration:	19 May 2014
Label Approval No:	69527/61026
Product Name:	Macro Protect Imidacloprid 600 SC Insecticide
Active Constituent/s:	600 g/L imidacloprid
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
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:	19 May 2014
Label Approval No:	69838/61862
Product Name:	Macro Protect Clethodim 240 EC Herbicide
Active Constituent/s:	240 g/L clethodim
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans
Date of Registration:	19 May 2014
Label Approval No:	69793/61745

Product Name:	Maxforce Fusion Cockroach Gel
Active Constituent/s:	21.5 g/kg imidacloprid
Applicant Name:	Bayer CropScience Pty Ltd
Applicant ACN:	000 226 022
Summary of Use:	For control of cockroaches in a range of urban situations
Date of Registration:	19 May 2014
Label Approval No:	69488/60922
Product Name:	Macro Protect MCPA 500 Selective Herbicide
Active Constituent/s:	500 g/L MCPA present as the dimethylamine salt
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For the selective control of broad leaf weeds in cereals, linseed, pastures, sugar cane and turf
Date of Registration:	19 May 2014
Label Approval No:	69841/61865
Product Name:	Macro Protect Propiconazole 250 EC Fungicide
Active Constituent/s:	250 g/L propiconazole
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For the control of certain fungal diseases of bananas, oats, peanuts, perennial ryegrass, pineapples, stone fruit, sugar cane, wheat and other crops
Date of Registration:	20 May 2014
Label Approval No:	69842/61866
Product Name:	Sanonda Herbicide Glyphosate 700SG
Active Constituent/s:	700 g/kg glyphosate present as the mono-ammonium salt
Applicant Name:	Sanonda (Australia) Pty Ltd
Applicant ACN:	059 813 973
Summary of Use:	For the non-selective control of many annual and perennial weeds in certain situations
Date of Registration:	20 May 2014
Label Approval No:	69769/61688
Product Name:	Rainbow Chlorothalonil 720 SC Fungicide
Active Constituent/s:	720 g/L chlorothalonil
Applicant Name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of Use:	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes, turf and vegetables
Date of Registration:	20 May 2014
Label Approval No:	69652/61325
Product Name:	Cee-Bee Aircraft Disinfectant
Active Constituent/s:	2% w/w d-phenothrin
Applicant Name:	Mcgean-Rohco, Inc
Applicant ACN:	N/A
Summary of Use:	For use as a Top-Of-Descent aircraft disinfectant
Date of Registration:	20 May 2014
Label Approval No:	69762/61681

Product Name:	Conquest Knockout Dry 700 SG Herbicide
Active Constituent/s:	700 g/kg glyphosate present as the mono-ammonium salt
Applicant Name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of Use:	For the control of annual and perennial weeds
Date of Registration:	20 May 2014
Label Approval No:	69727/61508
Product Name:	Macro Protect Clodinafop 240 EC Selective Herbicide
Active Constituent/s:	60 g/L cloquintocet-mexyl, 240 g/L clodinafop-propargyl
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For the control of wild oats, paradoxa grass (annual phalaris), canary grass and annual rye in wheat
Date of Registration:	21 May 2014
Label Approval No:	69794/61748
Product Name:	Macro Protect Tebuconazole 430 SC Fungicide
Active Constituent/s:	430 g/L tebuconazole
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
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:	21 May 2014
Label Approval No:	69834/61858
Product Name:	Macro Protect Abamectin 18 EC Insecticide/Miticide
Active Constituent/s:	18 g/L abamectin
Applicant Name:	Louis Dreyfus Commodities Australia Pty. Ltd
Applicant ACN:	004 088 000
Summary of Use:	For the control of pest mites on pears, apples, tomatoes, citrus, hops, strawberries and ornamentals and for the control of pest mites in native budworm on cotton
Date of Registration:	21 May 2014
Label Approval No:	69791/61743
Product Name:	Bushman Plus Personal Insect Repellent Pump Spray
Active Constituent/s:	11 g/L n-octyl bicycloheptene dicarboximide, 11 g/L di-n-propyl isocinchomeronate, 200 g/L diethyltoluamide
Applicant Name:	Juno Limited
Applicant ACN:	N/A
Summary of Use:	For use as a personal insect repellent against mosquitoes, sandflies, flies, ticks and leeches
Date of Registration:	22 May 2014
Label Approval No:	69463/60859
Product Name:	AC Discord 750 WG Herbicide
Active Constituent/s:	750 g/kg chlorthal dimethyl
Applicant Name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of Use:	For pre-emergent weed control in certain vegetable crops including: onions, beans, cabbages, cauliflowers, potatoes, carrots and for weed control in strawberries, cotton, lucerne, perennial grass crops, lawns and ornamentals as specified in the directions for use table
Date of Registration:	23 May 2014
Label Approval No:	69680/61434

Product Name:	Amgrow Eraze Rapid Weedkiller Ready To Use
Active Constituent/s:	136 g/L pine oil
Applicant Name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For the control of weeds and grasses around the home and garden
Date of Registration:	23 May 2014
Label Approval No:	69597/61196
Product Name:	Pinnacle- Peracetic Acid Biocide
Active Constituent/s:	110 g/L hydrogen peroxide, 160 g/L peracetic acid
Applicant Name:	Sopura Australia Pty Ltd
Applicant ACN:	080 038 062
Summary of Use:	For use in post-harvest fruit and vegetable processing for the control of bacteria
Date of Registration:	23 May 2014
Label Approval No:	67028/54987
Product Name:	Permethor Magnetic Insecticidal Dust With Magthanite
Active Constituent/s:	10 g/kg permethrin
Applicant Name:	Ensystem Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of Use:	For the control of various insect pests in indoor and outdoor situations
Date of Registration:	26 May 2014
Label Approval No:	68833/59182
Product Name:	Kenso Agcare Gundy 700 WG Herbicide
Active Constituent/s:	700 g/kg imazapic
Applicant Name:	Kenso Corporation (M) Sdn. Bhd
Applicant ACN:	N/A
Summary of Use:	For the control of certain annual grasses and broadleaf weeds in fallow situations and sugarcane
Date of Registration:	26 May 2014
Label Approval No:	69339/60532
Product Name:	Chrome 480 Herbicide
Active Constituent/s:	480 g/L clomazone
Applicant Name:	Sinon Australia Pty Limited
Applicant ACN:	102 741 024
Summary of Use:	For the control of certain annual grasses in rice and certain annual broadleaf weeds in cucurbits, green beans, navy beans, poppies, potatoes, and tobacco
Date of Registration:	26 May 2014
Label Approval No:	69054/59726

2. VARIATIONS

Product Name:	Terbyne Xtreme 875 WG Herbicide
Applicant Name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of Variation:	To extend the use to include the control and suppression of various weeds in wheat, barley and oats
Date of Variation:	13 May 2014
Label Approval No:	68613/60476

Product Name:	Cheminova Thidiazuron 500 Flowable Cotton Defoliant
Applicant Name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of Variation:	To change the product name from 'OSPRAY THIDIAZURON 500 FLOWABLE COTTON DEFOLIANT' to 'CHEMINOVA THIDIAZURON 500 FLOWABLE COTTON DEFOLIANT' and to add a pack size range
Date of Variation:	19 May 2014
Label Approval No:	58421/62112
Product Name:	Cheminova Olympus Fungicide
Applicant Name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of Variation:	To change the product name from 'CHEMINOVA EPOXICONAZOLE 125 SC FUNGICIDE' to 'CHEMINOVA OLYMPUS FUNGICIDE'
Date of Variation:	19 May 2014
Label Approval No:	69613/61867
Product Name:	Interface Stressgard Turf Fungicide
Applicant Name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of Variation:	To change the product name from 'INTERFACE TURF FUNGICIDE' to 'INTERFACE STRESSGARD TURF FUNGICIDE'
Date of Variation:	19 May 2014
Label Approval No:	68029/62128
Product Name:	Cheminova Diquat 200 Herbicide
Applicant Name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of Variation:	To change the product name from 'OSPRAY DIQUAT 200 HERBICIDE' to 'CHEMINOVA DIQUAT 200 HERBICIDE'
Date of Variation:	19 May 2014
Label Approval No:	66120/61956
Product Name:	Cheminova Diclofop Methyl Herbicide
Applicant Name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of Variation:	To change the product name from 'OSPRAY DICLOFOP METHYL HERBICIDE' to 'CHEMINOVA DICLOFOP METHYL HERBICIDE' and other label changes
Date of Variation:	21 May 2014
Label Approval No:	59554/61692
Product Name:	Melpat Hydrocop WG Fungicide/Bactericide
Applicant Name:	Melpat International Pty Ltd
Applicant ACN:	066 067 507
Summary of Variation:	To change the product name from 'MELPAT HYDROCOP FUNGICIDE' to 'MELPAT HYDROCOP WG FUNGICIDE/BACTERICIDE' and amend the label claims to include post-flowering application in almonds
Date of Variation:	21 May 2014
Label Approval No:	62910/53040
Product Name:	Accensi Ant Killer Granular Insecticide
Applicant Name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of Variation:	To change the product name from 'COUNTRY ANT KILLER GRANULAR INSECTICIDE' to 'ACCENSI ANT KILLER GRANULAR INSECTICIDE' and add a different container type and specification for 500 g and 1 kg pack sizes within the currently approved pack size range
Date of Variation:	21 May 2014
Label Approval No:	63572/61712

Product Name:	Accensi Bifenthrin 100 Low Odour Termiticide & Insecticide
Applicant Name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of Variation:	To extend the claims against spiders and various insects to include internal areas of domestic, commercial, public and industrial buildings and structures, and to update the relevant label particulars
Date of Variation:	21 May 2014
Label Approval No:	68548/61022
Product Name:	Senator 700WG Insecticide
Applicant Name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of Variation:	To approve additional uses for foliar application, stem injection and soil application for various crops
Date of Variation:	22 May 2014
Label Approval No:	68192/62041
Product Name:	Cheminova 2,4-D Amine 625 Selective Herbicide
Applicant Name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of Variation:	To change the product name from 'OSPRAY 2,4-D AMINE 625 SELECTIVE HERBICIDE' to 'CHEMINOVA 2,4-D AMINE 625 SELECTIVE HERBICIDE', to instigate a pack size range of 5 L – 1000 L and to update the relevant label particulars
Date of Variation:	22 May 2014
Label Approval No:	60545/61386
Product Name:	Rancona Dimension Seed Treatment
Applicant Name:	Chemtura Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of Variation:	To add suppression of crown rot in wheat and barley
Date of Variation:	22 May 2014
Label Approval No:	67985/61035
Product Name:	Bithor Dual Action Insecticide
Applicant Name:	Ensystem Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of Variation:	To change the product name from 'BITHOR WATER-BASED INSECTICIDE' to 'BITHOR DUAL ACTION INSECTICIDE', to include uses for control of additional urban pests and to add a pack size range
Date of Variation:	26 May 2014
Label Approval No:	66870/60284

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.

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name:	Quantum Blue 5 G
Active Constituent/s:	5000 FT U/g 6-phytase (EC 3.1.3.26).
Applicant Name:	Roal Oy
Applicant ACN:	N/A
Summary of Use:	For use as an enzyme feed supplement in poultry and pigs to improve phosphorus digestibility
Date of Registration:	13 May 2014
Label Approval No:	68771/59049

Product Name:	RWR Mor-N-Mectin Oral Horse Worming Paste
Active Constituent/s:	Each gram of paste contains 4 mg abamectin, 167 mg morantel tartrate
Applicant Name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of Use:	For use in the treatment and control of tapeworms, roundworms, bots and parasitic skin lesions in horses
Date of Registration:	21 May 2014
Label Approval No:	69678/61422

Product Name:	Silirum Vaccine
Active Constituent/s:	2.5 mg/mL <i>Mycobacterium avium</i> subsp. <i>paratuberculosis</i>
Applicant Name:	Zoetis Australia Pty Ltd
Applicant ACN:	158 433 053
Summary of Use:	For the active immunisation of cattle against <i>Mycobacterium avium</i> subsp. <i>paratuberculosis</i> , as an aid in the control of Bovine Johne's Disease (BJD) or paratuberculosis
Date of Registration:	22 May 2014
Label Approval No:	59642/54408

2. VARIATIONS

Product Name:	Vetafarm Avian Insect Liquidator Ready To Use
Applicant Name:	Vetafarm Pty.Ltd.
Applicant ACN:	059 895 153
Summary of Variation:	To change the product name from 'ETAFARM AVIAN INSECT LIQUIDATOR RESIDUAL INSECTICIDE AND INSECT GROWTH REGULATOR READY TO USE' to 'VETAFARM AVIAN INSECT LIQUIDATOR READY TO USE'
Date of Variation:	20 May 2014
Label Approval No:	53451/62120

OTHER NOTICES

Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012*. The *MRL Standard* lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

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. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* with effect from 31 May 2014.

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2014 (No. 6)*.

The amendments will be incorporated into the compilation of the [Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#).

The *MRL Standard* is accessible via the ComLaw website www.comlaw.gov.au or the links above.

For further information please contact:

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Proposal to Amend Standard 1.4.2 of the Australia New Zealand Food Standards Code

In the previous notice, the APVMA gazetted particular amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*.

Under Section 82 of the *Food Standards Australia New Zealand Act 1991* the APVMA is proposing to incorporate these variations (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2014 (No. 6)*) to MRLs into Standard 1.4.2 – Maximum Residue Limits of the Australia New Zealand Food Standards Code.

MRLs contained in Standard 1.4.2 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Standard 1.4.2 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and FSANZ are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Standard 1.4.2 in the APVMA *Gazette*. The variations will take effect as from the date of that subsequent notice.

DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

Note: The following amendments are in a format that accords with the proposed amending Legislative Instrument which, in turn, has to be consistent with the existing format of Standard 1.4.2 (Maximum Residue Limits) of the *Australia New Zealand Food Standards Code*.

PROPOSED AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2014 (NO. 6))

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunseting.

To commence: on gazettal of variation

Standard 1.4.2 of the *Australia New Zealand Food Standards Code* is varied by –

1. inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals –

Abamectin	
Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Blueberries	T*0.02
Emamectin	
Sum of emamectin B1a and emamectin B1b	
Pulses	*0.01
Penflufen	
Penflufen	
Potato	T*0.01
Propyzamide	
Propyzamide	
Edible offal (mammalian)	*0.2
Meat (mammalian)	*0.05
Rape seed (canola)	0.02
Quinoxifen	
Quinoxifen	
Strawberry	T*0.01

2. omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals –

Propyzamide	
Propyzamide	
Cattle, edible offal of	*0.2
Cattle meat	*0.05

3. omitting from Schedule 1, under the entries for the following chemicals, the maximum residue limit for the food, substituting –

Buprofezin Buprofezin	
Celery	T5
Propyzamide Propyzamide	
Poppy seed	0.02

INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Standard 1.4.2–Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

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

Submissions must be made in writing and should be clearly marked as a ‘submission on the proposed amendment to Standard 1.4.2’ and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: 6 pm (AEST) 1 July 2014

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Phone: +61 2 6210 4897
Fax: +61 2 6210 4840
Email: residues@apvma.gov.au

¹ A full definition of ‘confidential commercial information’ is contained in the Agricultural and Veterinary Chemicals Code (Agvet Code), which is scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Variations to Standard 1.4.2 of the Australia New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA *MRL Standard* and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Standard 1.4.2—Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. This notice pertains to proposals (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2014 (No. 3)*) gazetted on 11 March 2014 (No. APVMA 5).

Submissions have been sought on these proposals and the APVMA has written separately to each person or organisation that made a submission. All matters raised in the submissions have been resolved.

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Standard 1.4.2. A copy of the Amendment Instrument (No. APVMA 5, 2014) accompanies this notice. For a complete and up-to-date version of Standard 1.4.2, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislative Instrument available on the Comlaw website at www.comlaw.gov.au.

Based on dietary exposure assessments and current health standards, the APVMA and FSANZ are satisfied that these MRLs are not harmful to public health. MRLs contained in Standard 1.4.2 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Standard 1.4.2 permits the sale of treated foods and protects public health by minimising residues in foods consistent with the effective control of pests and diseases.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Food Standards Australia New Zealand (FSANZ) made Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) in relation to these variations and no comment was received in response to that notice.

A copy of these variations have been given to FSANZ.

The variations take effect as from the date of this notice.

This notice is published in accordance with subsection 82(7) of the *Food Standards Australia New Zealand Act 1991*.

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: residues@apvma.gov.au

Australia New Zealand
Food Standards Code —
Standard 1.4.2—Maximum Residue Limits
Amendment Instrument No. APVMA 5, 2014

I, Rajumati Bhula, Executive Director, Pesticides Program and delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Rajumati Bhula
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this twenty-eighth day of May 2014

Part 1 Preliminary

1 Name of Instrument

This Instrument is the *Australia New Zealand Food Standards Code—Standard 1.4.2—Maximum Residue Limits Amendment Instrument No. APVMA 5, 2014*.

2 Commencement

Pursuant to subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this Amendment Instrument commences on the day a copy of it is published in the *Gazette*.

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia *Agricultural and Veterinary Chemicals Gazette* No. APVMA 11 of 3 June 2014.

3 Object

The object of this Instrument is for the APVMA to make variations to Standard 1.4.2—Maximum Residue Limits of the *Australia New Zealand Food Standards Code* to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

4 Interpretation

In this Instrument: —

APVMA means the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and

Principal Instrument means Standard 1.4.2—Maximum Residue Limits of the *Australia New Zealand Food Standard Code* as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that code. The whole of the *Australia New Zealand Food Standard Code* (including Standard 1.4.2) was further published in *Gazette* P 30 of 20 December 2000.

Part 2 Variations to Standard 1.4.2—Maximum Residue Limits

5 Variations to Standard 1.4.2

The Schedule to this Instrument sets out the variations made to the Principal Instrument by this Amendment Instrument.

Schedule

Variations to Standard 1.4.2–Maximum Residue Limits

1 Variations

(1) The Principal Instrument is varied by:

(a) *inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals –*

Abamectin	
Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Kaffir lime leaves	T0.5
Lemon grass	T0.5
Watercress	T0.5
Maldison	
Maldison	
Onion, Welsh	T0.1
Vegetables [except beans (dry); cauliflower; chard (Silver beet); egg plant; garden pea; kale; kohlrabi; lentil (dry); onion, welsh; Peppers, Sweet; root and tuber vegetables; shallot; spring onion; tomato; turnip, garden]	2

(b) *omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals –*

Maldison	
Maldison	
Vegetables [except beans (dry); cauliflower; chard (Silver beet); egg plant; garden pea; kale; kohlrabi; lentil (dry); Peppers, Sweet; root and tuber vegetables; shallot; spring onion; tomato; turnip, garden]	2

(c) *omitting from Schedule 1, under the entries for the following chemicals, the maximum residue limit for the food, substituting –*

Maldison	
Maldison	
Shallot	T0.1
Spring onion	T0.1

Cancellation of Label Approval at the Request of the Registrant

In accordance with Section 42 of the Agvet Code, if an interested or approved person in relation to an approval or registration has given to the APVMA a written notice requesting the APVMA to cancel that approval or registration, then the APVMA must give written notice of its decision on the request to the person(s) who made the request.

This Gazette notice satisfies the requirement in section 45A (1) of the Agvet Code, that the APVMA must also give notice to any other person to whom, in its opinion such a notice should be given.

At the request of the registrant, following the recent approval of a new label for this product, the APVMA has cancelled the previous label approvals of the following product:

Product No.	Product Name	Registrant	Cancelled Label Approval Number	Date of Effect
36791	ELANCO AF0050 TYLAN 50 TYLOSIN PHOSPHATE PREMIX	ELANCO ANIMAL HEALTH A DIV OF ELI LILLY AUST PTY LTD	36791/01 36791/0301 36791/0402 36791/0702 36791/1106	20 May 2014

The following instructions set out how a person can deal with any product bearing a cancelled label approval.

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 20 May 2014 at wholesale and retail level, until 20 May 2016.

After 20 May 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.

USE

A person may continue to use the product according to its cancelled label instructions until 20 May 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the product bearing a cancelled label 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 labels have been cancelled until 20 May 2016.

The supply and use of the product bearing a cancelled label must be in accordance with the label instructions, 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/AERP Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4749

Fax: +61 2 6210 4776

Email: chemicalreview@apvma.gov.au

Cancellation of Label Approval at the Request of the Registrant

In accordance with Section 42 of the Agvet Code, if an interested or approved person in relation to an approval or registration has given to the APVMA a written notice requesting the APVMA to cancel that approval or registration, then the APVMA must give written notice of its decision on the request to the person(s) who made the request.

This Gazette notice satisfies the requirement in section 45A (1) of the Agvet Code, that the APVMA must also give notice to any other person to whom, in its opinion such a notice should be given.

At the request of the registrant, following the recent approval of a new label for this product, the APVMA has cancelled the previous label approvals of the following product:

Product No.	Product Name	Registrant	Cancelled Label Approval Number	Date of Effect
45175	LIENERT TYLAN 50 PREMIX	LIENERT AUSTRALIA PTY. LTD.	45175/01 45175/0406 45175/0708 45175/54992	21 May 2014

The following instructions set out how a person can deal with any product bearing a cancelled label approval.

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 21 May 2014 at wholesale and retail level, until 21 May 2016.

After 21 May 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.

USE

A person may continue to use the product according to its cancelled label instructions until 21 May 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the product bearing a cancelled label 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 labels have been cancelled until 21 May 2016.

The supply and use of the product bearing a cancelled label must be in accordance with the label instructions, 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.

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This Gazette notice satisfies the requirement in section 45A (1) of the Agvet Code, that the APVMA must also give notice to any other person to whom, in its opinion such a notice should be given.

At the request of the registrant, following the recent approval of a new label for this product, the APVMA has cancelled the previous label approvals of the following product:

Product No.	Product Name	Registrant	Cancelled Label Approval Number	Date of Effect
59735	INTERVIX HERBICIDE FOR CLEARFIELD CROPS	BASF AUSTRALIA LTD.	59735/0206 59735/57994	7 May 2014

The following instructions set out how a person can deal with any product bearing a cancelled label approval.

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 7 May 2014 at wholesale and retail level, until 7 May 2016.

After 7 May 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.

USE

A person may continue to use the product according to its cancelled label instructions until 7 May 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the product bearing a cancelled label 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 labels have been cancelled until 7 May 2016.

The supply and use of the product bearing a cancelled label must be in accordance with the label instructions, 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/AERP Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
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KINGSTON ACT 2604

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Cancellation of Label Approval at the Request of the Registrant

In accordance with Section 42 of the Agvet Code, if an interested or approved person in relation to an approval or registration has given to the APVMA a written notice requesting the APVMA to cancel that approval or registration, then the APVMA must give written notice of its decision on the request to the person(s) who made the request.

This Gazette notice satisfies the requirement in section 45A (1) of the Agvet Code, that the APVMA must also give notice to any other person to whom, in its opinion such a notice should be given.

At the request of the registrant, following the recent approval of a new label for this product, the APVMA has cancelled the previous label approvals of the following product:

Product No.	Product Name	Registrant	Cancelled Label Approval Number	Date of Effect
63747	SAS MOTHBALLS	PJ SAS TRADING PTY LIMITED	63747/50721 63747/0409	22 May 2014

The following instructions set out how a person can deal with any product bearing a cancelled label approval.

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 22 May 2014 at wholesale and retail level, until 22 November 2014.

After 22 November 2014 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.

USE

A person may continue to use the product according to its cancelled label instructions until 22 November 2014.

Any person who possesses, has custody of, uses, or otherwise deals with the product bearing a cancelled label 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 labels have been cancelled until 22 November 2014.

The supply and use of the product bearing a cancelled label must be in accordance with the label instructions, 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/AERP Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4749

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Email: chemicalreview@apvma.gov.au

Preliminary Review Findings Related to Approvals and Registrations of Fenthion and Notice of inclusion of all products in the review

Fenthion is a broad spectrum organophosphorus (OP) insecticide that has been registered in Australia for over 50 years. Fenthion is used to control insect pests in agricultural, commercial and domestic situations and external parasites on cattle. Fenthion is also used to control pest birds in and around buildings.

The APVMA, in accordance with Part 2, Division 4, of the Agvet Codes, has reviewed whether the ongoing use of the active constituent fenthion and registered products containing fenthion:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, and
- would not be likely to have an effect that is harmful to human beings, and
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment, and
- would not unduly prejudice trade or commerce between Australia and places outside Australia, and
- would be effective when used in accordance with the recommendations for its use.

The review scope included the toxicology, occupational health and safety (OHS), residues (including dietary exposure) environmental and trade aspects of the active constituent approvals, product registrations and label approvals for fenthion. The APVMA has also considered whether product labels carry adequate instructions and warning statements.

Following the completion of the assessment of data for the review of fenthion, the APVMA has determined that there are unacceptable occupational exposure risks, re-entry risks, dietary exposure risks and environmental risks.

Additionally, three products containing fenthion that were registered since the commencement of the review have now been formally included in the review in accordance with section 32 of Schedule 2 Agricultural and Veterinary Chemical Code Act 1994 (Agvet Code). These are marked (A) in Table 3 below.

The active constituent approval and all product registrations and label approvals listed in Tables 1, 2 and 3 below are now all included in the review of fenthion.

Preliminary Review Findings

The key findings of the review are that use of products containing fenthion may, in some situations, pose unacceptable risks to the environment and to human health (via dietary and occupational exposure). However, these risks can be managed by:

- cancellation of the cattle lice control product
- cancellation of all pest control and home garden products, except the fenthion 1% dust product
- variation of the label of the fenthion 1% dust product to delete use in ceilings, wall spaces and crawl spaces and to update the safety directions, and
- variation of the label of the horticultural product to delete all horticultural uses except post-harvest dipping of tropical and subtropical inedible peel fruits and to update the safety directions and warnings.

These are proposed regulatory actions and will not be implemented until after the assessment of submissions received during the three month public comment period (ending 22 August 2014).

The APVMA's detailed findings can be found in the APVMA's Preliminary Review Findings for Part 2 of the review of Fenthion, available on the APVMA website, www.apvma.gov.au.

MAKING A SUBMISSION

The APVMA invites persons and organisations to submit their comments and suggestions on this Preliminary Review Findings document directly to the APVMA. These comments will assist the APVMA in preparing the Final Review Report and Regulatory Decision. Submissions specifically addressing the areas of concern noted in the Preliminary Review Findings report must be in writing and reach the APVMA by 22 August 2014.

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent unless a request for anonymity accompanies the submission. If no request for anonymity is made, the respondent will be taken to have consented to the disclosure of their identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988*.

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and the respondent has provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

When making a submission please include:

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

Written submissions specifically addressing the areas of concern noted in the Preliminary Review Findings report should be addressed in writing to:

Manager Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4700

Fax: +61 2 6210 4776

Email: chemicalreview@apvma.gov.au

Table 1: Active constituent approval for fenthion to be affirmed

(i) Approval No.	(ii) Approval Holder
44383	Bayer CropScience Pty Ltd

Table 2: Registered or suspended products containing fenthion that are to be affirmed following variation of labels and cancellation of previous labels

(iii) Product No.	(iv) Product Name	(v) Registrant	(vi) Label Approval No. to be cancelled or varied
32996	Lebaycid Insecticide Spray	Bayer CropScience Pty Ltd	32996/0110 vary
Proposed label variations. Update first aid and safety directions. Delete all use patterns except:			
<ul style="list-style-type: none"> postharvest treatment (dipping or flood spray) of tropical and sub-tropical fruits (inedible peel varieties only) 			
41138	Amalgamated Pest Control Fenthion 1% Dust Insecticide	Amalgamated Pest Control Pty Ltd	41138/0900 cancel 41138/1208 vary
Proposed label variations. Update first aid and safety directions. Delete use instructions for wall voids, crawl spaces and ceiling voids due to OHS risks on re-entry of treated areas.			

Table 3: Registered or suspended products containing fenthion that are proposed for cancellation

(vii) Product No.	(viii) Product Name	(ix) Registrant	(x) Label Approval No.
33520	Tiguvon Spot-on Cattle Lice Insecticide	Bayer Australia Ltd (Animal Health)	33520/51509 33520/0598 33520/02 33520/01
42202	Control-A-Bird Agent	Control-A-Bird Pty Ltd	42202/1208
50244	Avigrease Pest Bird Eradication Compound	Australian Pest Bird Management Pty Ltd	50244/1208
51627 (A)	David Gray's Mosquito and Spider Spray Insecticide	David Gray & Co Pty Limited	51627/0899 51627/0704
52075 (A)	Avigel Pest Bird Control Agent	ANC Bird Control	52075/1208
61308 (A)	Lebaycid Fruit Fly & Insect Killer	Bayer CropScience Pty Ltd	61308/0907

(A) Products added to the review of fenthion

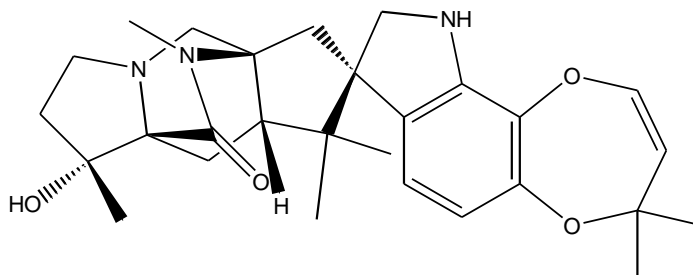
Notice—New Veterinary Active Constituent—Derquantel

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

Derquantel is a semi-synthetic spiroindole anthelmintic with nicotinic cholinergic antagonist action against a broad range of adult and immature gastrointestinal nematodes. It will be used for the treatment of a broad range of adult and immature gastrointestinal nematodes of sheep.

Common Name:	Derquantel
IUPAC Name:	(1' <i>R</i> ,5' <i>aS</i> ,7' <i>R</i> ,8' <i>aS</i> ,9' <i>aR</i>)-2',3',8 <i>a</i> ',9,9',10-hexahydro-1'-hydroxy-1',4,4,8',8',11'-hexamethyl-1',4 <i>H</i> ,5' <i>H</i> ,6' <i>H</i> ,8 <i>H</i> ,8' <i>H</i> -spiro[1,4-dioxepino[2,3- <i>g</i>]indole-8,7'-[5 <i>a</i> ,9 <i>a</i>](iminomethano)cyclopenta[<i>f</i>]indolizin[10']one]
CAS Name:	Spiro[4 <i>H</i> ,8 <i>H</i> -[1,4]dioxepino[2,3- <i>g</i>]indole-8,7'(8' <i>H</i>)-[5 <i>H</i> ,6 <i>H</i> -5 <i>a</i> ,9 <i>a</i>](iminomethano)[1 <i>H</i>]cyclopent[<i>f</i>]indolizin-10'-one, 2'3'8' <i>a</i> ,9,9',10-hexahydro-1'-hydroxy-1',4,4,8',8',11'-hexamethyl-, (1' <i>R</i> ,5' <i>aS</i> ,7' <i>R</i> ,8' <i>aS</i> ,9' <i>aR</i>)-
CAS Registry Number:	187865–22–1
Manufacturer's Codes:	PF-00520904
Minimum Purity:	93.5% on an anhydrous, solvent free basis
Molecular Formula:	C ₂₈ H ₃₇ N ₃ O ₄
Molar Mass:	479.6 g/mol

Structure:



Chemical Family: Spiroindole
Mode of Action: Nicotinic cholinergic antagonist

SUMMARY OF THE APVMA'S EVALUATION OF DERQUANTEL ACTIVE CONSTITUENT

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

Compounds of toxicological significance are not expected to occur in derquantel active constituent.

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of derquantel.

An Acceptable Daily Intake (ADI) of 0.0005 mg/kg bw/d has been set, based on a Low Observed Effect Level (LOEL) of 0.1 mg/kg bw/day in a 90 day dog study and using a 200-fold safety factor.

An acute reference dose (ARfD) of 0.01 mg/kg bodyweight has been established for derquantel, based on a NOEL (No-Observed Effect Level) of 1 mg/kg bodyweight in an acute oral toxicity study in dogs and using a 100-fold safety factor.

On 1 July 2011, the delegate to the Secretary of the Department of Health decided that derquantel be included in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with no cut-offs and an implementation date of 1 January 2012.

The OCS has indicated that there are no objections on toxicological grounds to the approval of the active constituent derquantel.

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

The APVMA is satisfied that the proposed importation and use of derquantel 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 sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of derquantel 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)**¹ material contained in submissions will be treated confidentially.

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

Principal Pharmaceutical Chemist
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4822

Fax: +61 2 6210 4741

Email: vetmedicines@apvma.gov.au

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

Application Summaries

The APVMA publishes complete application summaries on the APVMA website, www.apvma.gov.au. They are published in weekly instalments using the date the application was accepted for assessment. If an application summary has been amended, the APVMA will publish the amended version on the website and list it separately in the APVMA Gazette Notice for Application Summaries.

As a requirement of Regulations 8C and E of the Agvet Code, some product names will appear as 'NOT AVAILABLE'.

A summary will be removed from the website 28 days after the application has been finalised. Therefore, some summaries published in this notice may have already been removed prior to the Gazette being published.

APPLICATION SUMMARIES PUBLISHED SINCE THOSE PUBLISHED IN APVMA GAZETTE NO. 10, 20 MAY 2014.

Application No.	Name
62662	NOT AVAILABLE
62661	APPARENT FLUROXYPYR 200 HERBICIDE
62657	4FARMERS FLUROXYPYR 200 HERBICIDE
62655	WELLFARM HALOXYFOP 520 EC HERBICIDE
62653	SPINOSAD
62651	MEDICATED RID REPELLENT TROPICAL STRENGTH
62649	MEDICATED RID REPELLENT TROPICAL STRENGTH PUMP
62646	GENFARM FLUROXYPYR 200 HERBICIDE
62626	WELLFARM METOLACHLOR 720 EC HERBICIDE
62623	WELLFARM FLUROXYPYR 200 EC HERBICIDE
62589	NOT AVAILABLE
62585	NOT AVAILABLE
62574	IMTRADE WHACK 900 WG FUNGICIDE
62569	NOT AVAILABLE
62525	ECHEM STAROXY 200 HERBICIDE
62515	FUHUA GLYPHOSATE 700 SG HERBICIDE
62488	KERTON MEPIQUAT CHLORIDE 38 AC PLANT GROWTH REGULATOR
62481	ULTRAFORCE COCKROACH BAIT
62466	METACAM 15 MG/ML ORAL SUSPENSION FOR HORSES
62464	BOXER GOLD HERBICIDE
62454	METHOMYL
62449	EPIBROM TABLETS FOR DOGS
62438	ECO - NEEM BOTANICAL INSECTICIDE

Application No.	Name
62435	CEPHAFORTE 600 ANTIBIOTIC TABLETS FOR DOGS
62432	CEPHAFORTE 300 ANTIBIOTIC TABLETS FOR DOGS
62420	IMTRADE SMASH 300 SELECTIVE HERBICIDE
62418	IMTRADE METSULFURON 600 WG HERBICIDE
62417	IMTRADE METAL PLUS 960 EC HERBICIDE
62416	IMTRADE CYCLONE 330 EC HERBICIDE
62415	IMTRADE TRIFLURALIN 480 EC HERBICIDE
62409	NOT AVAILABLE
62406	NOT AVAILABLE
62341	NOT AVAILABLE
62335	DIA-KILL 200 HERBICIDE
62319	PROTECT SKIN TECHNOLOGY DEET FREE INSECT REPELLENT ROLL ON
62309	NOT AVAILABLE
62248	NEOVE APRAMYCIN SOLUBLE POWDER
62222	VALOR 500 WG HERBICIDE
62211	NUFARM WEEDMASTER DST DUAL SALT TECHNOLOGY HERBICIDE
62173	NOT AVAILABLE
62135	PERMATEK IM 30 INSECTICIDE
62083	OSPRAY FIREFIGHTER HERBICIDE
62040	CLIK SPRAY-ON SHEEP BLOWFLY TREATMENT
61998	DORMOSEDAN GEL
61913	WOOLWORTHS SELECT INDOOR AUTOMATIC INSECT CONTROL SYSTEM
61890	PEPTOSYL BISMUTH SALICYLATE ORAL SUSPENSION
61768	YEA-SACC TS
61136	NOT AVAILABLE
61045	SEA HAWK PREMIUM YACHT FINISHES PREMIUM QUALITY AF33 ERODING ANTIFOULING
60902	PEROXPURE 500
60630	NUFARM TALLY 800WG APHCIDE
60431	FAMILY PROTECTION AEROGARD EXTREME PROTECTION 40% DEET 8 HOURS PROTECTION EFFECTIVE IN AREAS OF INTENSE INSECT ACTIVITY INSECT REPELLENT
60387	DANADIM INSECTICIDE
58257	BIOQUELL HPV-AQ
53656	ANTINOL PCSO-524 JOINT SUPPORT FORMULA

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