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**AGRICULTURAL AND  
VETERINARY CHEMICALS**



**Australian Government**

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**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*.

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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

From February 2010, the APVMA will publish the *APVMA Gazette* in electronic format only. The *APVMA Gazette* and information about subscribing to the gazette alert service are available on the APVMA website, [www.apvma.gov.au](http://www.apvma.gov.au).

Copies of the *APVMA Gazette* from November 1999 until July 2009 will remain available from the APVMA website.

## APVMA CONTACTS

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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. RESTRICTED PRODUCT

<b>Product Name:</b>	Mission Bifen NMP 400 EC Termiticide & Insecticide
<b>Active Constituent/s:</b>	400g/L bifenthrin
<b>Applicant Name:</b>	Mission Bell Holdings Pty Ltd
<b>Applicant ACN:</b>	149 573 651
<b>Summary of Use:</b>	For the control of termites and a range of urban pests and the protection of timber and timber based products from damage by borers and termites.
<b>Date of Registration:</b>	18 November 2011
<b>Label Approval No:</b>	66828/54495

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

<b>Product Name:</b>	Smart Accel Spray Adjuvant
<b>Active Constituent/s:</b>	704g/L Methyl & Ethyl Esters of free fatty acids derived from refined canola oil
<b>Applicant Name:</b>	Crop Smart Pty Ltd
<b>Applicant ACN:</b>	093 927 961
<b>Summary of Use:</b>	For use as an adjuvant to enhance the effectiveness of certain herbicides.
<b>Date of Registration:</b>	11 November 2011
<b>Label Approval No:</b>	66971/54842

<b>Product Name:</b>	Pondliners Algae Control
<b>Active Constituent/s:</b>	18.75g/L simazine
<b>Applicant Name:</b>	ML International Pty Ltd
<b>Applicant ACN:</b>	071 659 142
<b>Summary of Use:</b>	For control of algae in freshwater ornamental fish ponds.
<b>Date of Registration:</b>	11 November 2011
<b>Label Approval No:</b>	66586/53943

<b>Product Name:</b>	Apparent Triclopyr 600 EC Herbicide
<b>Active Constituent/s:</b>	600g/L triclopyr present as the butoxyethyl ester
<b>Applicant Name:</b>	Apparent Pty. Ltd.
<b>Applicant ACN:</b>	143 724 136
<b>Summary of Use:</b>	For the control of a range of woody weeds and melons.
<b>Date of Registration:</b>	11 November 2011
<b>Label Approval No:</b>	66997/54893

<b>Product Name:</b>	Genfarm Alpha Cypermethrin 250SC Insecticide
<b>Active Constituent/s:</b>	250g/L alpha-cypermethrin
<b>Applicant Name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of Use:</b>	For the control of certain insect pests, including redlegged earth mite on certain field crops and pastures and certain insect pests on fruit and vegetable crops.
<b>Date of Registration:</b>	14 November 2011
<b>Label Approval No:</b>	66977/54851
<b>Product Name:</b>	Cachet Glyphosate 450 Herbicide
<b>Active Constituent/s:</b>	450g/L glyphosate present as the isopropylamine salt
<b>Applicant Name:</b>	Agrichem Manufacturing Industries Pty. Ltd.
<b>Applicant ACN:</b>	125 437 185
<b>Summary of Use:</b>	A non-selective foliar herbicide that will kill most emerged weeds and plants in situations.
<b>Date of Registration:</b>	14 November 2011
<b>Label Approval No:</b>	67005/54938
<b>Product Name:</b>	Apparent Triclopyr 300 + Picloram 100 Herbicide
<b>Active Constituent/s:</b>	100g/L picloram present as the hexyloxypropylamine salt, 300g/L triclopyr present as the butoxyethyl ester
<b>Applicant Name:</b>	Apparent Pty. Ltd.
<b>Applicant ACN:</b>	143 724 136
<b>Summary of Use:</b>	For control of a range of environmental and noxious woody and herbaceous weeds.
<b>Date of Registration:</b>	14 November, 2011
<b>Label Approval No:</b>	66998/54894
<b>Product Name:</b>	Imtrade Eradicator Ultimate 625 Herbicide
<b>Active Constituent/s:</b>	625g/L glyphosate (present as potassium salt)
<b>Applicant Name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of Use:</b>	For the non-selective control of annual and perennial weeds.
<b>Date of Registration:</b>	15 November 2011
<b>Label Approval No:</b>	65049/49980
<b>Product Name:</b>	Rainbow Glufosinate 200 Herbicide
<b>Active Constituent/s:</b>	200g/L glufosinate-ammonium
<b>Applicant Name:</b>	Shandong Rainbow International Co., Ltd.
<b>Applicant ACN:</b>	N/A
<b>Summary of Use:</b>	For non-residual control of broadleaf and grass weeds in various situations.
<b>Date of Registration:</b>	16 November 2011
<b>Label Approval No:</b>	66593/53957
<b>Product Name:</b>	Titan Imazethapyr 700 WG Herbicide
<b>Active Constituent/s:</b>	700g/kg imazethapyr
<b>Applicant Name:</b>	Titan Ag Pty Ltd
<b>Applicant ACN:</b>	122 081 574
<b>Summary of Use:</b>	For the pre- or post-emergence control of certain weeds in centrosema (cavalcade), chickpeas, faba beans, field peas, lucerne, mung beans, peanuts, serradella, soybeans and subterranean clover.
<b>Date of Registration:</b>	16 November 2011
<b>Label Approval No:</b>	66099/52723

<b>Product Name:</b>	Rainbow Mancozeb 750 WG Fungicide
<b>Active Constituent/s:</b>	750g/kg mancozeb
<b>Applicant Name:</b>	Shandong Rainbow International Co., Ltd.
<b>Applicant ACN:</b>	N/A
<b>Summary of Use:</b>	For control of certain fungus diseases of fruit, field crops, tobacco, turf vegetables and ornamentals.
<b>Date of Registration:</b>	16 November 2011
<b>Label Approval No:</b>	66689/54193

<b>Product Name:</b>	Mission Imidacloprid 350 SC Insecticide
<b>Active Constituent/s:</b>	350g/L imidacloprid
<b>Applicant Name:</b>	Mission Bell Holdings Pty Ltd
<b>Applicant ACN:</b>	149 573 651
<b>Summary of Use:</b>	For the control of greyback and childers canegrub in sugarcane and silverleaf whitefly in various vegetable crops.
<b>Date of Registration:</b>	17 November 2011
<b>Label Approval No:</b>	66856/54541

<b>Product Name:</b>	Agrocelhone NE Soil Fumigant
<b>Active Constituent/s:</b>	333g/kg (439g/L) chloropicrin, 608g/kg (802g/L) 1,3-dichloropropene
<b>Applicant Name:</b>	Agroquimicos De Levante, S.A.
<b>Applicant ACN:</b>	N/A
<b>Summary of Use:</b>	For pre-plant control of plant parasitic nematodes, plant diseases and weed seeds by soil fumigation.
<b>Date of Registration:</b>	17 November 2011
<b>Label Approval No:</b>	65193/50378

<b>Product Name:</b>	Sprayphos 600 Systemic Fungicide
<b>Active Constituent/s:</b>	600g/L phosphorous (phosphonic) acid present as mono and di potassium phosphonate
<b>Applicant Name:</b>	Foliar Fertilizers P/L T/A Spraygro Liquid Fertilizers
<b>Applicant ACN:</b>	007 974 496
<b>Summary of Use:</b>	For the control of phytophthora diseases and downy mildew in various situations.
<b>Date of Registration:</b>	17 November 2011
<b>Label Approval No:</b>	65178/50336

<b>Product Name:</b>	Image 700 WG Herbicide
<b>Active Constituent/s:</b>	700g/kg imazethapyr
<b>Applicant Name:</b>	Grow Choice Pty Limited
<b>Applicant ACN:</b>	069 839 961
<b>Summary of Use:</b>	For the pre or post-emergence control of certain weeds in Centrosema (Cavalcade), faba beans, field peas, lucerne, mung beans, peanuts, serradella, soybeans and subterranean clover.
<b>Date of Registration:</b>	17 November 2011
<b>Label Approval No:</b>	65800/52043

<b>Product Name:</b>	Trio Diflufenican 500 Herbicide
<b>Active Constituent/s:</b>	500g/L diflufenican
<b>Applicant Name:</b>	5 Heads Pty Ltd T/A Perth Progressive Supplies
<b>Applicant ACN:</b>	098 396 546
<b>Summary of Use:</b>	For control of certain weeds in clover-based pasture, field peas, lentils, lupins and oilseed poppies.
<b>Date of Registration:</b>	17 November 2011
<b>Label Approval No:</b>	66627/54052

<b>Product Name:</b>	Pro Ammonium Sulphate Herbicide Adjuvant
<b>Active Constituent/s:</b>	980g/kg ammonium sulphate
<b>Applicant Name:</b>	5 Heads Pty Ltd T/A Perth Progressive Supplies
<b>Applicant ACN:</b>	098 396 546
<b>Summary of Use:</b>	To minimise antagonism when tank mixing glyphosate with flowable herbicides and to improve performance under adverse environmental conditions
<b>Date of Registration:</b>	17 November 2011
<b>Label Approval No:</b>	66966/54836

<b>Product Name:</b>	Mission Fenamiphos 400 Insecticide
<b>Active Constituent/s:</b>	400g/L fenamiphos (an anticholinesterase compound)
<b>Applicant Name:</b>	Mission Bell Holdings Pty Ltd
<b>Applicant ACN:</b>	149 573 651
<b>Summary of Use:</b>	For use in various crops for the control of nematodes and sucking insects
<b>Date of Registration:</b>	17 November 2011
<b>Label Approval No:</b>	66451/53668

<b>Product Name:</b>	Pro Diflufenican 500 Herbicide
<b>Active Constituent/s:</b>	500g/L diflufenican
<b>Applicant Name:</b>	5 Heads Pty Ltd T/A Perth Progressive Supplies
<b>Applicant ACN:</b>	098 396 546
<b>Summary of Use:</b>	For control of certain weeds in clover-based pasture, field peas, lentils, lupins and oilseed poppy.
<b>Date of Registration:</b>	18 November 2011
<b>Label Approval No:</b>	66634/54060

<b>Product Name:</b>	Country MCPA/Picloram 242 Cereal Herbicide
<b>Active Constituent/s:</b>	26g/L picloram present as the potassium salt, 420g/L MCPA present as the potassium salt
<b>Applicant Name:</b>	Accensi Pty Ltd
<b>Applicant ACN:</b>	079 875 184
<b>Summary of Use:</b>	For the control of climbing buckwheat, common sowthistle, skeleton weed, capeweed, doublegee and other broadleaved weeds in winter cereal and linseed crops as per the directions for use table.
<b>Date of Registration:</b>	18 November 2011
<b>Label Approval No:</b>	65827/52121

<b>Product Name:</b>	Checkmate Codling Moth Flo Pheromone Insect Confusing Agent
<b>Active Constituent/s:</b>	140g/L (E,E)-8,10-dodecadien-1-ol
<b>Applicant Name:</b>	Suterra LLC
<b>Applicant ACN:</b>	N/A
<b>Summary of Use:</b>	For the control of codling moth by mating disruption in commercial apple and pear orchards.
<b>Date of Registration:</b>	18 November 2011
<b>Label Approval No:</b>	63892/46841

<b>Product Name:</b>	Mission Diflufenican + MCPA Selective Herbicide
<b>Active Constituent/s:</b>	25g/L diflufenican, 250g/L MCPA present as the ethyl hexyl ester
<b>Applicant Name:</b>	Mission Bell Holdings Pty Ltd
<b>Applicant ACN:</b>	149 573 651
<b>Summary of Use:</b>	For the control of certain broadleaf weeds in winter cereals and clover.
<b>Date of Registration:</b>	21 November 2011
<b>Label Approval No:</b>	66827/54494

<b>Product Name:</b>	The Regulator Part B Bud Fast Plant Growth Regulator
<b>Active Constituent/s:</b>	77g/L chlormequat present as chlormequat chloride
<b>Applicant Name:</b>	Nutrifield Pty Ltd
<b>Applicant ACN:</b>	110 610 145
<b>Summary of Use:</b>	To increase the berry set and yield of wine grapes and increase setting of currants.
<b>Date of Registration:</b>	21 November 2011
<b>Label Approval No:</b>	66121/52768

<b>Product Name:</b>	Mission Triclopyr 600 EC Herbicide
<b>Active Constituent/s:</b>	600g/L triclopyr (present as the butoxyethyl ester).
<b>Applicant Name:</b>	Mission Bell Holdings Pty Ltd
<b>Applicant ACN:</b>	149 573 651
<b>Summary of Use:</b>	For the control of various woody and broadleaf weeds.
<b>Date of Registration:</b>	21 November 2011
<b>Label Approval No:</b>	66850/54536

<b>Product Name:</b>	ACP Silvester 680 Herbicide
<b>Active Constituent/s:</b>	680g/L 2,4-D (present as the 2-ethylhexyl ester).
<b>Applicant Name:</b>	Australis Crop Protection Pty Ltd
<b>Applicant ACN:</b>	150 711 185
<b>Summary of Use:</b>	For the selective control of various weeds in crops, pastures and non-agricultural areas.
<b>Date of Registration:</b>	21 November 2011
<b>Label Approval No:</b>	66567/53902

<b>Product Name:</b>	Mission Flutriafol 250 SC Fungicide
<b>Active Constituent/s:</b>	250g/L flutriafol
<b>Applicant Name:</b>	Mission Bell Holdings Pty Ltd
<b>Applicant ACN:</b>	149 573 651
<b>Summary of Use:</b>	For the control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser or applied as a foliar spray.
<b>Date of Registration:</b>	21 November 2011
<b>Label Approval No:</b>	66826/54493



<b>Product Name:</b>	AC Mut 700 Herbicide
<b>Active Constituent/s:</b>	700g/kg glyphosate (present as the mono-ammonium salt).
<b>Applicant Name:</b>	Axichem Pty Ltd
<b>Applicant ACN:</b>	131 628 594
<b>Summary of Use:</b>	For the control of many annual and perennial weeds in various situations.
<b>Date of Registration:</b>	22 November 2011
<b>Label Approval No:</b>	65463/50985

<b>Product Name:</b>	ACP Trifluralin 480 Selective Herbicide
<b>Active Constituent/s:</b>	480g/L trifluralin
<b>Applicant Name:</b>	Australis Crop Protection Pty Ltd
<b>Applicant ACN:</b>	150 711 185
<b>Summary of Use:</b>	For the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops.
<b>Date of Registration:</b>	22 November 2011
<b>Label Approval No:</b>	66773/54384

<b>Product Name:</b>	Genfarm QPE 200 Herbicide
<b>Active Constituent/s:</b>	200g/L quizalofop-p-ethyl
<b>Applicant Name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of Use:</b>	For the control of certain weeds in broadleaf crops.
<b>Date of Registration:</b>	22 November 2011
<b>Label Approval No:</b>	66956/54811

<b>Product Name:</b>	Cutter Chlorpyrifos 500 EC Insecticide
<b>Active Constituent/s:</b>	500g/L chlorpyrifos (as anticholinesterase compound)
<b>Applicant Name:</b>	Ivorychem Australia Pty Ltd
<b>Applicant ACN:</b>	134 692 318
<b>Summary of Use:</b>	For the control of certain insect pests in fruits, vegetables, field crops, pastures and other situations.
<b>Date of Registration:</b>	28 November 2011
<b>Label Approval No:</b>	66886/54623

### 3. VARIATIONS

<b>Product Name:</b>	Ravensdown Unialphacyper 100 Insecticide
<b>Applicant Name:</b>	Ravensdown Fertiliser Co-Operative Limited
<b>Applicant ACN:</b>	128 889 814
<b>Summary of Variation:</b>	To change product name from "UNITED FARMERS UNIALPHACYPER 100 INSECTICIDE" to "RAVENSDOWN UNIALPHACYPER 100 INSECTICIDE", amend storage and disposal statements, copy uses from a closely similar product and add a 110L pack size.
<b>Date of Variation:</b>	17 November 2011
<b>Label Approval No:</b>	56888/53704

<b>Product Name:</b>	Water Clear Aquatic Weed Control
<b>Applicant Name:</b>	Polo Citrus Australia Pty Limited
<b>Applicant ACN:</b>	064 601 332
<b>Summary of Variation:</b>	To include all states.
<b>Date of Variation:</b>	18 November 2011
<b>Label Approval No:</b>	47864/53051

<b>Product Name:</b>	Pool Sanitiser Swim Tabs
<b>Applicant Name:</b>	Biolab Australia Pty Ltd
<b>Applicant ACN:</b>	005 878 017
<b>Summary of Variation:</b>	To change product name from "BIOGUARD SWIM TABS POOL SANITIZER" to "POOL SANITISER SWIM TABS", update directions for use, safety directions and addition of pack size.
<b>Date of Variation:</b>	21 October 2011
<b>Label Approval No:</b>	30998/54139

<b>Product Name:</b>	Culminate Blossom Thinner
<b>Applicant Name:</b>	SST Australia Pty. Ltd.
<b>Applicant ACN:</b>	052 845 833
<b>Summary of Variation:</b>	To extend the uses to include apples.
<b>Date of Variation:</b>	24 November 2011
<b>Label Approval No:</b>	50112/54099

<b>Product Name:</b>	AC Howl 360 Bio Herbicide
<b>Applicant Name:</b>	Axichem Pty Ltd
<b>Applicant ACN:</b>	131 628 594
<b>Summary of Variation:</b>	To change the product name from "AC HOWL 360 HERBICIDE" to "AC HOWL 360 BIO HERBICIDE" and to update disposal instructions.
<b>Date of Variation:</b>	24 November 2011
<b>Label Approval No:</b>	65117/54577

<b>Product Name:</b>	Belt 240 WG Insecticide
<b>Applicant Name:</b>	Bayer Cropscience Pty Ltd
<b>Applicant ACN:</b>	000 226 022
<b>Summary of Variation:</b>	To extend the use to additional vegetable crops for the control of lepidopteran pests.
<b>Date of Variation:</b>	24 November 2011
<b>Label Approval No:</b>	61224/48220

<b>Product Name:</b>	Farmoz Soprano Fungicide
<b>Applicant Name:</b>	Farmoz Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of Variation:</b>	To add control of Leaf Spot ( <i>Mycosphaerella musicola</i> ) and Leaf Speckle ( <i>M. musae</i> ) in bagged bananas.
<b>Date of Variation:</b>	28 November 2011
<b>Label Approval No:</b>	63293/53009

<b>Product Name:</b>	Sky-7th 200 Herbicide
<b>Applicant Name:</b>	Grow Choice Pty Limited
<b>Applicant ACN:</b>	069 839 961
<b>Summary of Variation:</b>	To change the product name from SCYTHE 200 HERBICIDE to SKY-7TH 200 HERBICIDE.
<b>Date of Variation:</b>	28 November 2011
<b>Label Approval No:</b>	66397/55208

<b>Product Name:</b>	Fungicide/Miticide Wettable Sulphur
<b>Applicant Name:</b>	Manutec Pty. Ltd.
<b>Applicant ACN:</b>	008 030 779
<b>Summary of Variation:</b>	To change the product name from MANUTEC GARDEN CARE PRODUCTS WETTABLE SULPHUR FUNGICIDE/MITICIDE to FUNGICIDE/MITICIDE WETTABLE SULPHUR and add a 500g pack size.
<b>Date of Variation:</b>	29 November 2011
<b>Label Approval No:</b>	49130/54392

<b>Product Name:</b>	Caltex Summer Spray Oil
<b>Applicant Name:</b>	Caltex Australia Petroleum Pty Ltd
<b>Applicant ACN:</b>	000 032 128
<b>Summary of Variation:</b>	To amend label particulars to add cross-reference to tank mix with Green Guard ULV Biological Insecticide for control of nymphs of various locust species.
<b>Date of Variation:</b>	29 November 2011
<b>Label Approval No:</b>	49375/52301

<b>Product Name:</b>	Maxumpro 125 SC Insecticide
<b>Applicant Name:</b>	Sundew Solutions Pty Ltd
<b>Applicant ACN:</b>	135 400 261
<b>Summary of Variation:</b>	To remove the use in poultry sheds.
<b>Date of Variation:</b>	30 November 2011
<b>Label Approval No:</b>	64148/55236

<b>Product Name:</b>	Nufarm Nuprid 350SC Insecticide
<b>Applicant Name:</b>	Nufarm Australia Limited
<b>Applicant ACN:</b>	004 377 780
<b>Summary of Variation:</b>	Extension to use in citrus and non-bearing citrus.
<b>Date of Variation:</b>	30 November 2011
<b>Label Approval No:</b>	60587/54300

<b>Product Name:</b>	Cropro D-Sect EC Insecticide
<b>Applicant Name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of Variation:</b>	To include use around buildings for the control of cockroaches, and to update other label particulars.
<b>Date of Variation:</b>	30 November 2011
<b>Label Approval No:</b>	52005/52706

## 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

<b>Product Name:</b>	Csyro Liquid Sheep Blowfly Treatment
<b>Active Constituent/s:</b>	500g/L cyromazine
<b>Applicant Name:</b>	Australian Animal Health Pty Ltd
<b>Applicant ACN:</b>	142 427 361
<b>Summary of Use:</b>	To protect long wool sheep from blowfly strike ( <i>Lucilia cuprina</i> ) for up to 14 weeks.
<b>Date of Registration:</b>	24 November 2011
<b>Label Approval No:</b>	66589/53946

### 2. VARIATIONS

<b>Product Name:</b>	Humidimix Electrolyte Replacer For Horses
<b>Applicant Name:</b>	Virbac (Australia) Pty Ltd
<b>Applicant ACN:</b>	003 268 871
<b>Summary of Variation:</b>	To change the product name from VETSEARCH HUMIDIMIX ELECTROLYTE REPLACER FOR HORSES to HUMIDIMIX ELECTROLYTE REPLACER FOR HORSES.
<b>Date of Variation:</b>	17 November 2011
<b>Label Approval No:</b>	47673/54420

<b>Product Name:</b>	FBC Bloodfood Blood Building Supplement For Horses
<b>Applicant Name:</b>	Virbac (Australia) Pty Ltd
<b>Applicant ACN:</b>	003 268 871
<b>Summary of Variation:</b>	To change product name from VETSEARCH INTERNATIONAL FBC BLOODFOOD BLOOD BUILDING SUPPLEMENT FOR HORSES to: FBC BLOODFOOD BLOOD BUILDING SUPPLEMENT FOR HORSES
<b>Date of Variation:</b>	21 November 2011
<b>Label Approval No:</b>	51972/54421

<b>Product Name:</b>	Coopers Permatrace 5 Year Selenium Pellets For Sheep
<b>Applicant Name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of Variation:</b>	To change the product name from "RUMETRACE EZYMIN SHEEP SELENIUM PILLS" to "COOPERS PERMATRACE 5 YEAR SELENIUM PELLETS FOR SHEEP".
<b>Date of Variation:</b>	24 November 2011
<b>Label Approval No:</b>	53784/52691

<b>Product Name:</b>	Sea Minerals Dermal Spray
<b>Applicant Name:</b>	Virbac (Australia) Pty Ltd
<b>Applicant ACN:</b>	003 268 871
<b>Summary of Variation:</b>	To change the product name from "SOVEREIGN DOWNS SEA MINERALS DERMAL SPRAY" to "SEA MINERALS DERMAL SPRAY".
<b>Date of Variation:</b>	25 November 2011
<b>Label Approval No:</b>	49019/54379

<b>Product Name:</b>	Young's Dicyclanil 50 Spray-On Sheep Blowfly Treatment
<b>Applicant Name:</b>	Novartis Animal Health Australasia Pty. Limited
<b>Applicant ACN:</b>	076 745 198
<b>Summary of Variation:</b>	Approval of an additional pack size.
<b>Date of Variation:</b>	28 November 2011
<b>Label Approval No:</b>	65668/55298

<b>Product Name:</b>	Elanco AF0342 Rumensin 200 Monensin Sodium
<b>Applicant Name:</b>	Elanco Animal A Div Of Eli Lilly Aust Pty Ltd
<b>Applicant ACN:</b>	000 233 992
<b>Summary of Variation:</b>	To the registered particulars and RLP for extension of use in sheep for the prevention of ovine coccidiosis and for improved weight gain and feed efficiency.
<b>Date of Variation:</b>	29 November 2011
<b>Label Approval No:</b>	46885/54591

<b>Product Name:</b>	Elanco AF0168 Rumensin Granular Monensin Sodium
<b>Applicant Name:</b>	Elanco Animal A Div Of Eli Lilly Aust Pty Ltd
<b>Applicant ACN:</b>	000 233 992
<b>Summary of Variation:</b>	To the registered particulars and RLP for extension of use in sheep for the prevention of ovine coccidiosis and for improved weight gain and feed efficiency.
<b>Date of Variation:</b>	29 November 2011
<b>Label Approval No:</b>	50696/54592

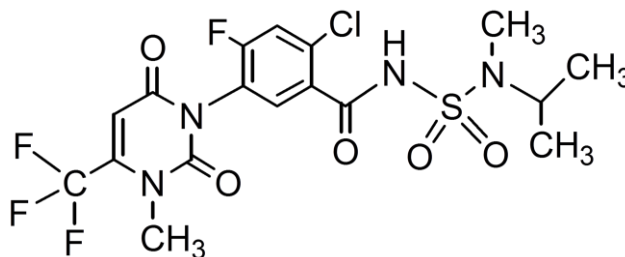
<b>Product Name:</b>	Elanco AF0170 Rumensin Technical Monensin Sodium
<b>Applicant Name:</b>	Elanco Animal A Div Of Eli Lilly Aust Pty Ltd
<b>Applicant ACN:</b>	000 233 992
<b>Summary of Variation:</b>	To the registered particulars and RLP for extension of use in sheep for the prevention of ovine coccidiosis and for improved weight gain and feed efficiency.
<b>Date of Variation:</b>	29 November 2011
<b>Label Approval No:</b>	55725/54594

<b>Product Name:</b>	Bacidox
<b>Applicant Name:</b>	Dox-AI Australia Pty Ltd
<b>Applicant ACN:</b>	079 454 265
<b>Summary of Variation:</b>	To change product name from BACIDOX 150 BMP MICRO GRANULATE FEED ADDITIVE to BACIDOX
<b>Date of Variation:</b>	30 November 2011
<b>Label Approval No:</b>	60252/55184

**NOTICE – NEW AGRICULTURAL ACTIVE CONSTITUENT****Saflufenacil**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, saflufenacil which is a herbicide used for the control of broadleaf weeds prior to establishment of crops, or in commercial or industrial areas. It belongs to the pyrimidindione class of herbicides that acts as a protoporphyrinogen oxidase (PPO) inhibitor and subsequently interferes with the chlorophyll biosynthetic pathway through a process of membrane disruption.

<b>Common Name:</b>	Saflufenacil
<b>IUPAC Name:</b>	<i>N'</i> -(2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl)- <i>N</i> -isopropyl- <i>N</i> -methylsulfamide
<b>CAS Name:</b>	2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2 <i>H</i> )-pyrimidinyl]-4-fluoro- <i>N</i> -[[methyl(1-methylethyl)amino]sulfonyl]benzamide
<b>CAS Registry Number:</b>	372137-35-4
<b>Manufacturer's Code:</b>	BAS 800 H
<b>Minimum Purity:</b>	945 g/kg
<b>Molecular Formula:</b>	C <sub>17</sub> H <sub>17</sub> ClF <sub>4</sub> N <sub>4</sub> O <sub>5</sub> S
<b>Molecular Weight:</b>	500.85
<b>Structure:</b>	



<b>Chemical Family:</b>	Pyrimidindione
<b>Mode of Action:</b>	Group G Herbicide

## SUMMARY OF THE APVMA'S EVALUATION OF SAFLUFENACIL ACTIVE CONSTITUENT

The Pesticides Program of the APVMA has evaluated the chemistry aspects of saflufenacil 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 saflufenacil active constituent and its related impurity dimethyl sulfate:

Constituent	Specification	Level
Saflufenacil	Saflufenacil	Not less than 945 g/kg
Dimethyl sulfate	Dimethyl sulfate	Not more than 1 mg/kg

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

The Office of Chemical Safety has considered the toxicological aspects of saflufenacil TGAC, and advised that there are no toxicological objections to the approval of this chemical.

An Acceptable Daily Intake (ADI) of 0.017 mg/kg bw/d has been recommended, based on a No-Observed Effect Level (NOEL) of 5mg/kg bw/d, after applying a safety factor of 300.

An Acute Reference Dose (ARfD) of 0.017 mg/kg bw has been set based on a developmental rat study, after applying a safety factor of 300.

The National Drugs and Poisons Schedule Committee (NDPSC) has considered saflufenacil active constituent to be appropriate for inclusion in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with an exception noted for water dispersible granule formulations which are recommended for entry in Schedule 5. The APVMA accepts the findings and recommendations of its advisers on these criteria.

The APVMA is satisfied that the proposed importation and use of saflufenacil 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 saflufenacil 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)**<sup>1</sup> material contained in submissions will be treated confidentially.

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

John Hughes  
Chemistry Manager  
Pesticides Program

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

**Phone:** (02) 6210 4936

**Fax:** (02) 6210 4840

**Email:** john.hughes@apvma.gov.au

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



## NOTICE – NEW VETERINARY CHEMICAL PRODUCTS

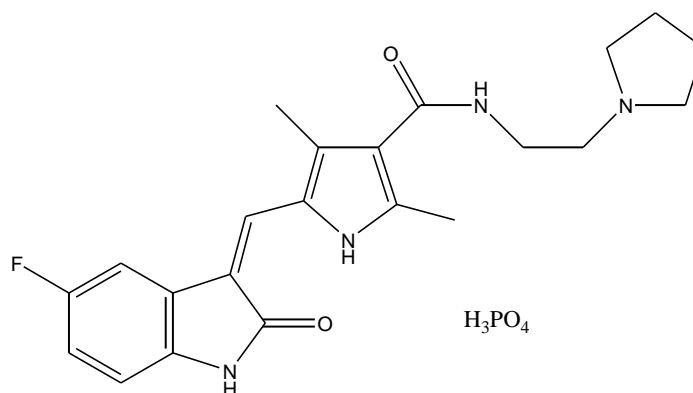
### Toceranib phosphate in the products Palladia 50mg, Palladia 15mg, and Palladia 10mg

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it three applications from Pfizer Animal Health, A division of Pfizer Australia Pty Ltd, for registration of three new products containing toceranib phosphate. The products are **PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG**. The products are to be used for the treatment of Patnaik grade II or III recurrent, cutaneous mast cell tumours in dogs.

#### PARTICULARS OF THE ACTIVE CONSTITUENT

<b>Common Name:</b>	Toceranib phosphate
<b>IUPAC Name:</b>	(Z)-5-[(5-Fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethyl-N-(2-pyrrolidine-1-ylethyl)-1H-pyrrole-3-carboxamide phosphate
<b>CAS Name:</b>	(Z)-5-[(5-Fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethyl-N-(2-pyrrolidin-1-ylethyl)-1H-pyrrole-3-carboxamide phosphate
<b>CAS Registry Number:</b>	874819-74-6
<b>Manufacturer's Codes:</b>	PHA-291639E
<b>Minimum Purity:</b>	970 g/kg
<b>Molecular Formula:</b>	C <sub>22</sub> H <sub>25</sub> FN <sub>4</sub> O <sub>2</sub> .H <sub>3</sub> PO <sub>4</sub>
<b>Molecular Weight:</b>	494.5

**Structure:**



<b>Chemical Family:</b>	Indolinone
<b>Mode of Action:</b>	Receptor tyrosine kinase inhibitor

#### SUMMARY OF THE APVMA'S EVALUATION OF TOCERANIB PHOSPHATE ACTIVE CONSTITUENT

The Pharmaceutical Chemistry Section of the APVMA has evaluated the chemistry and manufacturing aspects of toceranib phosphate and is satisfied that all the data requirements (including the physico-chemical properties, spectral identification,

manufacturing and quality control aspects, impurity formation, active constituent specification, stability, batch analysis data, analytical methods and packaging information) necessary for the approval of this new active constituent have been met.

## PARTICULARS OF THE APPLICATION

<b>Proposed Product Name(s):</b>	<b>PALLADIA 50MG</b> <b>PALLADIA 15MG</b> <b>PALLADIA 10MG</b>
<b>Applicant Company:</b>	Pfizer Animal Health, a Division of Pfizer Australia Pty Ltd
<b>Name of Active Constituent:</b>	Toceranib phosphate
<b>Signal Heading:</b>	Schedule 4
<b>Summary of Proposed Use:</b>	A tyrosine kinase inhibitor for the treatment of Patnaik grade II or III recurrent, cutaneous mast cell tumours in dogs.
<b>Pack Sizes:</b>	20 tablets (blister pack), 30 tablets (bottle)
<b>Withholding Period:</b>	Not Applicable

### **SUMMARY OF THE APVMA'S EVALUATION OF PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994**

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

- (i) The APVMA is satisfied that the proposed use of **PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG** would not be an undue hazard to the safety of people exposed to them during their handling and use.

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

The active constituent, toceranib phosphate, has low acute oral, dermal, and inhalational toxicity. It is not a skin irritant or skin sensitiser, but is a slight eye irritant. However, the presentation of the products as film-coated tablets mitigates the risk of eye irritation, and the likelihood of eye irritation is negligible. Toceranib phosphate is likely to have reproductive toxicity potential, which is addressed by the precautionary statements on the product labelling. First Aid Instructions, Safety Directions, and Safety Precautions are required for these products and are included on the product labels. The APVMA has considered and accepts the findings and recommendations of the OCS evaluation.

- (ii) The APVMA is satisfied that the proposed use of **PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG** will not be an undue hazard to the safety of people using anything containing their residues.

The products are for use in companion animals only. Toceranib phosphate is unlikely to enter the food chain and therefore the determinations of an Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) are not considered necessary.

- (iii) The APVMA is satisfied that the proposed use of **PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG** containing the active constituent toceranib phosphate is not likely to be harmful to human beings if used according to the product label directions.

The APVMA has evaluated and proposes to approve the active constituent toceranib phosphate. The delegate to the Secretary of the Department of Health and Ageing has assessed toceranib phosphate and has included it in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Medicines (SUSMP). The signal heading that corresponds to Schedule 4 and the First Aid instructions and Safety Directions recommended by the OCS appear on the product labels.

- (iv) The APVMA is satisfied that the proposed use of **PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG** is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

Under the proposed use pattern and estimated levels of use, the environmental risk associated with this product is considered to be acceptable. The Department of the Environment, Water, Heritage and the Arts (DEWHA), now known as The Department of Sustainability, Environment, Water, Population and Communities (DSEWPAC), have recommended to the APVMA that the use of the product in the proposed manner is not expected to have an unintended effect that is harmful to animals, plants, things or the environment. The APVMA has considered these findings and accepts the recommendations of DSEWPAC on this criterion.

- (v) The APVMA is satisfied that the proposed use of **PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG** would not adversely affect trade between Australia and places outside Australia as the product is for use in dogs, which are not food-producing animals and do not produce any major Australian export commodities.
- (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.

## 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 **PALLADIA 50MG, PALLADIA 15MG, AND PALLADIA 10MG** 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)**<sup>2</sup> 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:

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

**Phone:** (02) 6210 4701  
**Fax:** (02) 6210 4721  
**Email:** [vetmedicines@apvma.gov.au](mailto:vetmedicines@apvma.gov.au)

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<sup>2</sup> A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

## **BOVINE ROTAVIRUS AND BOVINE CORONAVIRUS in the product Coopers Bovilis Rotavec Corona Calf Scours Vaccine (for Cattle)**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Intervet Australia Pty Ltd (MSD Animal Health) for the approval of two new active constituents, **Bovine rotavirus and Bovine coronavirus**. The APVMA also has before it an application from the same applicant, for the registration of a new product, **COOPERS BOVILIS ROTAVEC CORONA CALF SCOURS VACCINE** ('the product') containing the above active constituents. The product also contains the following active constituents which have previously been approved by the APVMA, *Clostridium perfringens* Type C, *Clostridium perfringens* Type D and *E. coli* K99 Pili. The purpose of the product is as an aid in the prevention of neonatal calf diarrhoea caused by enterotoxigenic, *E. coli* pilus type K99, bovine Group A Serotype G6 & G10 rotaviruses, enterotoxaemia caused by *Cl. perfringens* Types C&D, and as an aid in the control of neonatal calf diarrhoea caused by bovine coronaviruses.

### **PARTICULARS OF THE ACTIVE CONSTITUENT**

<b>Common Name:</b>	<i>Bovine rotavirus and Bovine coronavirus</i>
<b>Manufacturer:</b>	Intervet Inc. (Merck Animal Health) 21401 West Center Rd Elkhorn NEBRASKA 68022, USA
<b>Potency:</b>	Manufacturer's standard
<b>Appearance and Identity:</b>	As per 9 Code of Federal Regulations (CFR)
<b>Sterility:</b>	As per CFR
<b>Extraneous agents:</b>	As per CFR
<b>Mycoplasma:</b>	As per CFR
<b>Gene technology:</b>	Not applicable
<b>Mode of Action:</b>	Inducing immunological response

### **PARTICULARS OF THE APPLICATION**

<b>Proposed Product Name(s):</b>	Coopers Bovilis Rotavec Corona Calf Scours Vaccine
<b>Applicant Company:</b>	Intervet Australia Pty Ltd (MSD Animal Health) 91-105 Harpin Street Bendigo VIC 3550
<b>Manufacturer:</b>	Intervet Inc. (Merck Animal Health) 21401 West Center Rd Elkhorn NEBRASKA 68022, USA
<b>Name of Active Constituent:</b>	<i>Bovine rotavirus and Bovine coronavirus</i>

<b>Adjuvant:</b>	Oil adjuvant
<b>Signal Heading:</b>	Schedule 0
<b>Summary of Proposed Use:</b>	As an aid in the prevention of neonatal calf diarrhoea caused by enterotoxigenic <i>E. coli</i> pilus type K99, bovine Group A Serotype G6 & G10 rotaviruses, enterotoxaemia caused by <i>Cl. perfringens</i> Types C&D, and as an aid in the control of neonatal calf diarrhoea caused by bovine coronaviruses.
<b>Pack Sizes:</b>	20mL 10 doses and 100mL 50 doses vials.
<b>Amounts to be administered and route of administration:</b>	The product is to be used in pregnant cattle 10-12 weeks prior to calving, with a booster vaccine administered 4-6 weeks later, 2mL per dose subcutaneously. For subsequent calvings, cattle should be revaccinated with a single 2 mL dose, 4-6 weeks before calving. The purpose of this proposed vaccination schedule is to stimulate levels of immunity in pregnant animals that will result in protective levels of antibody to the constituent antigens being transferred in the colostrum. Calves receiving colostrum with adequate levels of maternally derived colostrum antibody will be passively protected against these agents for a period after birth
<b>Withholding Period:</b>	Nil

**SUMMARY OF THE APVMA'S EVALUATION OF COOPERS BOVILIS ROTAVEC CORONA CALF SCOURS VACCINE IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994**

The APVMA has assessed the chemistry and manufacturing aspects of Coopers Bovilis Rotavec Corona Calf Scours Vaccine and the product, including starting materials, master seed organism (source, isolation, identification, testing), culture media, vaccine production, storage, quality control and batch release analysis, and found them to meet APVMA standards. The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

The APVMA is satisfied that the proposed use of the new product Coopers Bovilis Rotavec Corona Calf Scours Vaccine containing the active constituents Bovine rotavirus and Bovine coronavirus, *Clostridium perfringens* Type C, *Clostridium perfringens* Type D, *E. coli* K99 Pili, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment. The excipients used in the product have been previously assessed and found to be safe. They are already present in several vaccines registered for use in Australia.

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.

**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 the approval for the active constituents' **Bovine rotavirus and Bovine**

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Notice – New Veterinary Chemical Products - Bovine rotavirus and Bovine coronavirus in the product Coopers Bovilis Rotavec Corona Calf Scours Vaccine (for Cattle)

**coronavirus** and the registration of Coopers Bovilis Rotavec Corona Calf Scours Vaccine 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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.

All personal and **confidential commercial information (CCI)**<sup>3</sup> 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:

Dr John Owusu  
Principal Evaluator  
Veterinary Medicines Program  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

**Phone:** (02) 6210 4736  
**Fax:** (02) 6210 4741  
**Email:** john.owusu@apvma.gov.au

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<sup>3</sup> A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

## 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 *MRL Standard* published by the APVMA. The *MRL Standard* lists MRLs of substances which 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, based on dietary exposure assessments and current health standards, that the limits are not harmful to public health.

The *MRL Standard* is accessible via the APVMA website, [www.apvma.gov.au](http://www.apvma.gov.au)

The APVMA has varied the *MRL Standard* as set out below with effect from the date of this notice.

For further information please contact:

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

**Phone:** (02) 6210 4837

**Fax:** (02) 6210 4840

**Email:** [residues@apvma.gov.au](mailto:residues@apvma.gov.au)



**AMENDMENT No. 60, 2011**

**Note:** ‘\*\*’ denotes that the maximum residue limit (MRL) has been set at or about the limit of analytical quantitation (see: Residue Guideline No.4, *Maximum Residue Limit Proposals ‘At or about the Limit of Analytical Quantitation’*, published in NRA Gazette No.9, p44, 5/9/95).

‘T’ denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out in Australia or overseas, and will be reconsidered at some future date.

**TABLE 1: MAXIMUM RESIDUE LIMITS OF PESTICIDES, AGRICULTURAL CHEMICALS, FEED ADDITIVES, VETERINARY MEDICINES AND ASSOCIATED SUBSTANCES IN FOOD COMMODITIES**

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

COMPOUND	FOOD	MRL (mg/kg)
<b>Buprofezin</b>		
DELETE:		
VC 0424	Cucumber	T0.5
VO 0440	Egg plant	T2
VC 0431	Squash, summer	T0.5
VO 0448	Tomato	T2
ADD:		
VC 0045	Fruiting vegetables, Cucurbits	T2
VO 0050	Fruiting vegetables, other than Cucurbits	T2
VL 0483	Lettuce, Leaf	T10
	Peppers, Chili, other cultivars	T2
<b>Imidacloprid</b>		
ADD:		
SO 0697	Peanut	T0.5

COMPOUND	FOOD	MRL (mg/kg)
<b>Trichlorfon</b>		
DELETE:		
	Vegetables [except beetroot; Brussels sprouts; cauliflower; celery; kale; peppers, pulses (dry); sugar beet; sweet corn (corn-on-the-cob)]	0.1
ADD:		
VO 4271	Cape gooseberry	T0.5
VO 0440	Egg plant	T0.5
VO 0443	Pepino	T0.5
	Vegetables [except Beetroot; Brussels sprouts; Cape gooseberry; Cauliflower; Celery; Egg plant; kale; Pepino; Peppers; Pulses (dry); Sugar beet; Sweet corn (corn-on-the-cob)]	0.1

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

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

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
<b>Dimethoate</b>		
DELETE:		
AL 0545	Lupin, forage	1
ADD:		
AB 0001	Citrus pulp, dry	10
	Cotton seed meal and hulls	T0.5
	Primary feed commodities	T30
	Tomato pomace, dry	0.02
<b>Imazapyr</b>		
ADD:		
AS 0645	Maize fodder (dry)	*0.05

### **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 (numbered 6O) 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 NO. 60

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.

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#### To commence: on gazettal of variation

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

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

<b>Buprofezin</b> Buprofezin	
Cucumber	T0.5
Egg plant	T2
Squash, summer	T0.5
Tomato	T2
<b>Trichlorfon</b> Trichlorfon	
Vegetables [except beetroot; Brussels sprouts; cauliflower; celery; kale; peppers; pulses; sugar beet; sweet corn (corn-on- the-cob)]	0.1

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

<b>Buprofezin</b> Buprofezin	
Fruiting vegetables, cucurbits	T2
Fruiting vegetables, other than cucurbits	T2
Lettuce, leaf	T10
Peppers, Chili, other cultivars	T2
<b>Imidacloprid</b> Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid	
Peanut	T0.5

<b>Trichlorfon</b> Trichlorfon	
Cape gooseberry	T0.5
Egg plant	T0.5
Pepino	T0.5
Vegetables [except beetroot; Brussels sprouts; cape gooseberry; cauliflower; celery; egg plant; kale; pepino; peppers; pulses; sugar beet; sweet corn (corn-on- the-cob)]	0.1

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## 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)<sup>4</sup> 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: 6pm (Canberra time) 6 January 2012**

### 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:

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

**Phone:** (02) 6210 4837  
**Fax:** (02) 6210 4840  
**Email:** residues@apvma.gov.au

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<sup>4</sup> 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 gazetted on 13 September 2011 (No. APVMA 18).

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, 2011) 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 <http://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) notifications 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:

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

**Phone:** (02) 6210 4837

**Fax:** (02) 6210 4840

**Email:** [residues@apvma.gov.au](mailto:residues@apvma.gov.au)

***Australia New Zealand***  
***Food Standards Code —***  
**Standard 1.4.2 — Maximum Residue Limits**  
**Amendment Instrument No. APVMA 5, 2011**

I, Rajumati Bhula, Program Manager, 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  
Program Manager  
Pesticides Program

Dated this 29<sup>th</sup> day of November 2011



## 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, 2011.

### 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 24 of 6 December 2011.

### 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<sup>5</sup>.

## 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.

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<sup>5</sup> Note An amendment history from 20 December 2000 appears at the beginning of the *Australia New Zealand Food Standard Code*.

# 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 –

<b>Azoxystrobin</b> Azoxystrobin	
Rice	T7
<b>Metsulfuron-methyl</b> Metsulfuron-methyl	
Poppy seed	T*0.01
<b>Triclopyr</b> Triclopyr	
Poppy seed	T*0.01

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

<b>Chlorothalonil</b> <i>Commodities of plant origin:</i> Chlorothalonil <i>Commodities of animal origin:</i> 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite expressed as chlorothalonil	
Papaya (pawpaw)	10
<b>Difenoconazole</b> Difenoconazole	
Papaya (pawpaw)	1
<b>Toltrazuril</b> Sum of toltrazuril, its sulfoxide and sulfone, expressed as toltrazuril	
Eggs	*0.03

## Cancellation of Product Registration at the Request of the Registrant

At the request of the registrant, the APVMA has cancelled the registration of the following product:

Product No.	Product Name	Registrant	Date of Effect
59303	SUCCESS2 NATURALYTE INSECT CONTROL	DOW AGROSCIENCES AUSTRALIA LIMITED	23/11/2011

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 23 November 2011 at wholesale and retail level, until the 23 November 2013.

After 23 November 2013 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 23 November 2013.

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 23 November 2013.

The supply and use of the product must be in accordance with the conditions of registration, 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:** (02) 6210 4749  
**Fax:** (02) 6210 4776  
**Email:** [chemicalreview@apvma.gov.au](mailto:chemicalreview@apvma.gov.au)

## Suspension of Products Containing Diuron and Label Approvals of Products Containing Diuron

The APVMA has suspended the following registrations and label approvals of products containing Diuron:

**Table 1: Registered products and label approvals containing Diuron**

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
31253	Dupont Krovar DF Herbicide	Du Pont (Australia) Ltd	31253/01^ 31253/0310 31253/4732
31275	Agspray Kill-All Total Herbicide	Agspray Chemical Co. Pty Ltd	31275/50432
31682	Agspray Die-It 800 Wettable Powder Diuron Herbicide	Agspray Chemical Co. Pty Ltd	Ψ
31685	Bayer Diuron 500 SC Liquid Herbicide	Lanxess Pty Ltd	31685/0399^ 31685/1103
31702	Nufarm Flowable Diuron Liquid Herbicide	Nufarm Australia Ltd	31702/0200^ 31702/0605^ 31702/1007
39201	Nufarm Diuron 900 DF Herbicide	Nufarm Australia Ltd	39201/1298^ 39201/0499^ 39201/0802^ 39201/0605^ 39201/0507
45177	Bayer Diuron 900 WG Herbicide	Lanxess Pty Ltd	45177/03^ 45177/0204
45441	Macspred Dymac G Granular Herbicide	Macspred Pty Ltd	45441/02
45772	Diurex WG Herbicide	Crop Care Australasia Pty Ltd	45772/1098^ 45772/0101^ 45772/1107
45909	Dupont Velpar K4 DF Herbicide	Du Pont (Australia) Ltd	45909/02^ 45909/0506
46812	Farmoz Diuron 900 WDG Herbicide	Farmoz Pty Ltd	46812/02^ 46812/0207^ 46812/0305^ 46812/0807
47661	Striker 500 SC Selective Herbicide by Sanonda	Sanonda (Australia) Pty Ltd	47661/02

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
47764	Macspred Kromac Industrial Herbicide	Macspred Pty Ltd	47764/02
48974	Zee-Uron 800 WP Herbicide	United Phosphorus Ltd	48974/01
49540	Zee-Uron 500 SC Herbicide	United Phosphorus Ltd	49540/01^ 49540/0705
49541	Zee-Uron 900 WG Herbicide	United Phosphorus Ltd	49541/01^ 49541/0108^ 49541/0508
50481	Agcare Biotech Flowable Diuron 500 SC Herbicide	Agcare Biotech Pty Ltd	50481/0398
52176	Farmoz Diuron 500 Flowable Herbicide	Farmoz Pty Ltd	52176/0100^ 52176/0305^ 52176/1106
52342	Chemag Diuron Liquid Herbicide	Imtrade Pty Ltd	52342/0100
52672	Sipcam Diuron 500 SC Herbicide	Sipcam Pacific Australia Pty Ltd	52672/0200^ 52672/0800
53046	Smart Diuron 500 Flowable Liquid Herbicide	Agcare Biotech Pty Ltd	53046/0600
53812	Imtrade Diuron 900WG Herbicide	Imtrade Pty Ltd	53812/0901 53812/52842
54182	Agricultural Product Services Diuron/Hexazinone DF Herbicide	Agricultural Product Services Pty Ltd	54182/0501
55094	Country Diuron 900 WG Herbicide	Accensi Pty Ltd	55094/0102
55561	Conquest Diuron 900 WG Herbicide	Conquest Agrochemicals Pty Ltd	55561/0302^ 55561/0106
55612	Kenso Agcare Diuron 500 Herbicide	Kenso Corporation (M) SDN BHD	55612/0102^ 55612/0402
56349	4 Farmers Diuron 500 SC Liquid Herbicide	4 Farmers Pty Ltd	56349/1002^ 56349/0204
56356*	4Farmers Diuron 900 DF Herbicide	4 Farmers Pty Ltd	56356/0405^ 56356/1207
56602*	Halley Diuron 500SC Herbicide	Halley International Enterprise (Australia) Pty Ltd	56602/0603
57823*	Echem Diuron 500 SC Herbicide	Echem (Aust) Pty Limited	57823/0204

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
57886*	Summit Diuron 900WG Herbicide	Sipcam Pacific Australia Pty Ltd	57886/1003^ 57886/0306
57934*	Runge Agrichems Diuron 900 WG Herbicide	Runge Agrichems Pty Ltd	57934/0104
58128*	4Farmers Diuron/Hexazinone WG Herbicide	4Farmers Pty Ltd	58128/1103
58440*	Tradewyns Diuron 500 Flowable Herbicide	Ospray Pty Ltd	58440/0304^ 58440/1206
58451*	Tradewyns Diuron 900 WG Herbicide	Ospray Pty Ltd	58451/0304^ 58451/0406
58455*	United Farmers Diuron 900 WG Herbicide	Ravensdown fertiliser Cooperative Limited	58455/0204^ 58455/0305
59120*	Farmoz Escalate Ultra Cotton Defoliant	Farmoz Pty Limited	59120/0505^ 59120/1108
59134*	Echem Thi-Ultra Cotton Defoliant	Echem (Aust) Pty Limited	59134/1004^ 59134/1208 59134/0210
59463*	Chemag Diuron/Hexazinone WG Herbicide	Imtrade Australia Pty Ltd	59463/0805
59557*	Barrage Herbicide	Crop Care Australasia Pty Ltd	59557/0105^
59777*	Dropp Ultramax Cotton Defoliant	Bayer Cropscience Pty Ltd	59777/1007^ 59777/1205
60152*	Agroreg Diuron 900 WG Herbicide	Agroreg Pty Limited	60152/0106^ 60152/0309
60286*	Genfarm Diuron 900WG Herbicide	Landmark Operations Limited	60286/0206^ 60286/1008
60768*	Farmoz Bobcat Combi WG Herbicide	Farmoz Pty Limited	60768/0806 50768/51116
60926*	Whitestar Hexon 900 WG herbicide	Agricultural Product Services Pty Ltd	60926/0506
61309*	CMS Diuron 900 WG Herbicide	CMS Trade Pty Ltd	61309/0906 61309/0309
61371*	Ospray Do-away Cotton Defoliant	Ospray Pty Ltd	61371/0407 61371/52252
62012*	Generex Sugarhex Herbicide	Macspred Pty Ltd	62012/0707

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS
62189*	Titan Diuron 900 WG Herbicide	Titan Ag Pty Ltd	62189/1108^ 62189/1207
62426*	Chemforce Diuron 900WG herbicide	Chemforce 2010 Pty Ltd	62426/1007
62700*	Ozcrop Diuron 900 WG Herbicide	CMS Trade Pty Ltd	62700/0108^ 62700/0309
62797*	Grandpar K4 Cane Herbicide	Sipcam Pacific Australia Pty Ltd	62797/0508
63571*	United Phosphorus Zee-uron 900 WG Herbicidee	United Phosphorus Ltd	63571/0210^ 63571/1108
63621*	Country Diuron 500SC Herbicide	Accensi Pty Ltd	63621/1108
63917*	Rygel Dihex 900 WG Herbicide	Rygel Australia Pty Ltd	63917/0409
64301*	Imtrade Velchem Dust Herbicide	Imtrade Australia Pty Ltd	64301/0909
64359*	Farmalinx Diuron 900 WG Herbicide	Farmalinx Pty Ltd	64359/0610^ 64359/52352
64727*	Agriron 900 WG Herbicide	Agri Environmental Pty Ltd	64727/0610
65037*	AC Vertex Herbicide	Axichem Pty Ltd	65037/0710
65161*	Titan Thidiazuron + Diuron Cotton Defoliant	Titan Ag Pty Ltd	65161/51714
65215*	AW Dethrone Herbicide	Agri West Pty Limited	65215/50428
65501*	Apparent Diuron 900 WG Herbicide	Apparent Pty Ltd	65501/51062
65536*	Sanonda Herbicide Diuron 900WG	Sanonda (Australia) Pty Ltd	65536/51149
65562*	Choice Dihex Cane Herbicide	Grow Choice Pty Limited	65562/51292
66184*	Apparent Diuron 500 Herbicide	Apparent Pty Ltd	66184/52944
66239	Rainbow Diuron 900 WG Herbicide	Shandong Rainbow International Co.Ltd	66239/53043

The suspensions are in effect from 28 November 2011 until 31 March 2012.

## REASONS

The reasons for the suspension are:

The APVMA has decided that the continued use of, or other dealings with products containing diuron may have an unintended harmful effect on the environment. In addition, the APVMA has decided that the instructions on approved labels associated with products affected by this finding may no longer be adequate.

In July 2011, the APVMA published the toxicology component of the report prepared by the Office of Chemical Safety (OCS) and the environmental component report prepared by the Department of Sustainability, Environment, Water, Populations and Communities (DSEWPaC) in connection with the APVMA's review of diuron. Comments addressing these reports were invited by 30 September 2011.

The APVMA has formed the view that the use of diuron in certain circumstances may have an unintended harmful effect on the environment. As such, the APVMA has decided to suspend product registrations and the associated label approvals for each of the products listed above

## **INSTRUCTIONS**

Subsections 45A(5) and 55(3) of the Agvet Code cease to apply in respect of the products identified in the table above.

During the period of suspension, a person may not possess, have custody of, use or deal with any of the products other than in accordance with:

- The instructions set out at the end of this Notice; and
- The permit issued by the APVMA for diuron (PER13198).

## **WARNING**

From 28 November 2011 a person may only possess, have custody of, use or otherwise deal with the products identified above in accordance with a permit issued by the APVMA and the instructions set out at the end of this Notice.

The APVMA may cancel the permit and issue a replacement permit at any time during the suspension period. Before using, supplying or otherwise dealing with products containing diuron, 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 <http://www.apvma.gov.au/permits/search.php>

Failure to comply with the instructions set out at the end of this Notice attracts a penalty under section 55(4) of the Agvet Code. The penalty is 300 penalty units (\$33,000).

It is also an offence to advertise or promote the use of the products during the period of suspension (other than for the purposes of advising users about the modified instructions for use).

## **INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH SUSPENDED, PRODUCT, OR PRODUCT CONTAINING THE SUSPENDED LABEL**

### **Possession and custody**

A person may possess, have custody of, use or otherwise deal with the suspended diuron products (bearing a suspended label) only in accordance with these instructions or permit PER13198, issued by the APVMA.

### **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 in full (currently PER 13198) setting out the conditions and instructions for use, and
- supply product with a copy of the instructions contained in the permit securely affixed to each container of product.



## Use

PERSONS who wish to use suspended products containing diuron (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 DURING SUSPENSION

The existing (suspended) label may include instructions for use in situations listed below. The use of diuron is no longer approved for these situations and the following restraints apply:

**DO NOT USE in banana, coffee, paw paws, pineapples, sugarcane or tea between 5 December 2011 and 31 March 2012**

**DO NOT USE around agricultural buildings**

**DO NOT USE on right-of-way areas**

**DO NOT USE on driveways, paths, lanes, drains, ditches, fence lines, car parks, tennis courts**

**DO NOT USE in factory sites, commercial and industrial areas UNLESS the area is adequately bunded to retain any runoff**

**DO NOT USE in irrigation channels or drains UNLESS ALL irrigation tailwater and rainfall can be captured and held on farm**

**DO NOT USE in non-crop areas**

### 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.

#### Restraints (All Crops):

DO NOT apply more than 1.8 kg ac/ha per year

DO NOT apply by air

DO NOT use in water-logged areas

DO NOT apply if greater than 50 mm rain fall is expected within 3 days of application

DO NOT irrigate within 3 days of application

DO NOT apply to fields where the slope exceeds 3%

DO NOT replant treated areas within 2 years of application of diuron except when otherwise stated on label

DO NOT use on very light sandy or gravelly soils as crop damage may occur

DO NOT apply within 20m of a down slope water body, unless a compliant minimum 5m wide effective vegetated treatment area (EVTA) between the edge of the down slope water body and any points where low flow runoff exits the inter-row furrows of the crop

DO NOT apply when there is non-target terrestrial vegetation within 130m downwind from the application area

Apply as a COARSE spray only

DO NOT spot spray greater than 5% of total farm area

Crop	Suspension recommendation
Asparagus	Continued use in accordance with current label rates but no more than 1.8 kg ac/ha per year  Subject to <u>restraints</u> above
Cotton	
Cotton defoliation	
Gladioli, Tulips, Daffodils, Liliium and Iris	
Lucerne (established for 1 year or more)	
Lupins (on light soils only)	
Peas	
Phalaris cultivars Sirolan and Sirosa	
Pulses (Including Chickpeas, Faba beans, Lentils, Narbon beans, Field peas and Vetch)	
Summer Fallow	
Wheat, Barley, Triticale, Cereal Rye, Oats	
Apples and pears (established at least 1 year)	Maximum rate of application 1.8 kg ac/ha per year  Subject to <u>restraints</u> above
Bore drains (Prickly Acacia, Mimosa Bush, Qld only)	
Citrus (established at least 1 year)	Tree crops: Apply under trees only as a directed band spray over a maximum of 50% of the area  DO NOT USE in factory sites, commercial and industrial areas UNLESS the area is adequately bunded to retain any runoff  DO NOT USE in irrigation channels or drains UNLESS ALL irrigation tailwater and rainfall can be captured and held on farm.
Duboisia	
Factory sites, commercial and industrial areas	
Grass seed crops established (at least 1 year old) fescue, phalaris and cocksfoot	
Irrigation channels and drains	
Vineyards	

Crop	Suspension recommendation
Bananas	DO NOT USE between 5 December 2011 and 31 March 2012  DO NOT apply more than 1.8 kg ac/ha per year outside the no-spray window.  Subject to <u>restraints</u> above  Tree crops: Apply as a directed band spray over a maximum of <b>50% of the area.</b>
Coffee	
Paw Paws (trees at least 9 months old)	
Pineapples	
Sugarcane	
Tea plantation	

### Warning

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

### APVMA CONTACT

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

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

**Phone:** (02) 6210 4749  
**Fax:** (02) 6210 4776  
**Email:** [chemicalreview@apvma.gov.au](mailto:chemicalreview@apvma.gov.au)

## Interim Pesticide and Veterinary Medicines Product Sales 10/11 Financial Year

This notice provides the collated interim product sales information provided to the APVMA for the 2010/11 financial year. The information includes product sales declarations received up until 25 November 2011. The interim information comprises 92.8% of all veterinary products and 96.2% of all agricultural products. In total the APVMA has received 94.5% of product sales / disposals declarations. A further and final notice of product sales data for the 2010/11 Financial Year will be gazetted in March 2012.

### AGRICULTURAL (PESTICIDES) PRODUCT SALES FOR THE 10/11 FINANCIAL YEAR

AGRICULTURAL PRODUCT TYPES	NO OF PRODUCTS	TOTAL \$
ADJUVANTS/SURFACTANTS	327	81,947,840.62
ANTIFOULING - BOAT	41	16,521,967.00
DAIRY CLEANSER	174	10,761,683.83
DISINFECTANT/SANITISER	87	8,204,881.46
FUNGICIDE	619	228,423,112.60
GROWTH PROMOTERS/REGULATORS	189	40,983,630.44
HERBICIDE	2130	1,238,291,241.95
HOUSEHOLD INSECTICIDE	529	143,731,529.64
INSECTICIDE	1098	355,333,087.11
MISC	56	5,804,407.87
MITICIDE	98	26,095,079.00
MIXED FUNCTION PESTICIDE	123	23,317,907.96
MOLLUSCICIDE	46	12,185,256.20
NEMATICIDE	17	1,587,412.00
POOL PRODUCTS/ALGICIDE	721	61,401,532.97
REPELLENT—DOGS/BIRDS ETC	25	1,299,398.00
SEED TREATMENTS	157	36,497,963.00
VERTEBRATE POISON	140	37,164,920.03
WOOD PRESERVATIVE	110	46,859,536.85
<b>GRAND TOTAL</b>	<b>6687</b>	<b>2,376,412,388.53</b>

**VETERINARY MEDICINES PRODUCT SALES FOR THE 10/11 FINANCIAL YEAR**

<b>VETERINARY PRODUCT TYPES</b>		<b>NO OF PRODUCTS</b>	<b>TOTAL \$</b>
ALIMENTARY SYSTEM	ANTI BLOAT	17	3,990,126.23
ALIMENTARY SYSTEM	ANTIDIARRHOEALS AND SCOUR TREATMENTS	18	1,539,898.94
ALIMENTARY SYSTEM	LAXATIVES, PURGATIVES, LUBICANTS, ANTISPASMODICS	14	3,037,864.37
ANAESTHETICS/ANALGESICS	ANAESTHETICS—LOCAL AND GENERAL	49	8,972,461.79
ANAESTHETICS/ANALGESICS	ANALGESICS	18	1,837,621.63
ANTIBIOTIC & RELATED	ANTIBIOTIC—INTRAMAMMARY	26	7,730,301.89
ANTIBIOTIC & RELATED	ANTIBIOTIC—ORAL	195	24,140,869.84
ANTIBIOTIC & RELATED	ANTIBIOTIC—PARENTERAL	86	19,174,943.27
ANTIBIOTIC & RELATED	OTHER ANTI-INFECTIVE AGENTS	51	1,917,387.12
ANTIBIOTIC & RELATED	SULFONAMIDES	43	2,675,160.39
ANTIDOTES	ANTIDOTES	12	1,267,753.66
CARDIOVASCULAR SYSTEM	CARDIAC REACTANTS, CLOTTING AGENTS	39	7,013,889.04
CENTRAL NERVOUS SYSTEM	HYPNOTICS, TRANQUILIZERS, EMETICS, ANTIEMETICS	43	3,180,998.30
DERMATOLOGICAL PREPS.	ANTIBIOTICS, ANTIFUNGALS, CORTICOSTEROID COMBINATIONS	36	1,777,671.29
DERMATOLOGICAL PREPS.	ANTISEPTICS (DERMATOLOGICAL AND GENERAL)	160	18,194,609.90
DERMATOLOGICAL PREPS.	GROOMING AIDS	8	190,174.00
DERMATOLOGICAL PREPS.	NONSTEROIDAL ANTIIPRURITICS, KERATOLYICS	40	6,257,686.84
EAR,NOSE,THROAT PREPS.	AURAL	33	4,562,557.27
ENDOCRINE SYSTEM	ANABOLIC STEROIDS	28	1,457,324.52
ENDOCRINE SYSTEM	CORTICOSTEROIDS AND ADRENAL COMPOUNDS	35	2,739,135.82
ENDOCRINE SYSTEM	SEX HORMONES	57	5,699,371.46

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL \$
ENDOCRINE SYSTEM	TROPIC HORMONES (PITUITARY) AND INSULIN PREPARATIONS	36	2,525,429.46
GENITOURINARY SYSTEM	DIURETICS, ACIDIFIERS, ALKALISERS	28	1,742,395.04
GENITOURINARY SYSTEM	UTERINE OR VAGINAL ACTING AGENTS	8	655,400.40
IMMUNOTHERAPY	ANTISERA, ANTIVENOM	11	2,899,704.78
IMMUNOTHERAPY	IMMUNOMODIFYING AGENTS	13	1,227,188.00
IMMUNOTHERAPY	INJECTABLE VACCINES	174	92,948,981.37
IMMUNOTHERAPY	NASAL, ORAL, OPHTHALMIC VACCINES	33	14,995,881.44
MISCELLANEOUS VETERINARY	MISCELLANEOUS	68	11,972,025.40
MUSCULOSKELETAL SYSTEM	ANTI-INFLAMMATORY AGENTS	205	26,388,650.56
MUSCULOSKELETAL SYSTEM	COUNTER-IRRITANTS, RUBEFACIENTS, POULTICES	23	1,700,813.87
NUTRITION & METABOLISM	ANTIBIOTIC AND ANTI-INFECTIVE SUPPLEMENTS	43	6,798,996.99
NUTRITION & METABOLISM	DIETARY/THERAPEUTIC PET FOODS	115	39,969,153.05
NUTRITION & METABOLISM	DIGESTIVE ENZYME SUPPLEMENTS	63	16,471,759.54
NUTRITION & METABOLISM	ELECTROLYTES	73	5,275,023.78
NUTRITION & METABOLISM	GROWTH PROMOTANTS	73	20,868,840.15
NUTRITION & METABOLISM	IRON AND HAEMOPOIETIC AGENTS	26	1,827,133.97
NUTRITION & METABOLISM	PROBIOTIC AND PREBIOTIC	23	775,693.29
NUTRITION & METABOLISM	TONICS, STIMULANTS	11	628,899.63
NUTRITION & METABOLISM	VITAMIN, MINERAL, AND NUTRITIONAL SUPPLEMENTS	247	21,360,412.78
OPHTHALMIC PREPARATIONS	OPHTHALMIC PREPARATIONS	24	1,375,414.35
PARASITICIDES	BIRDS—EXTERNAL	15	203,740.00
PARASITICIDES	BIRDS—INTERNAL	34	3,441,417.79
PARASITICIDES	LARGE & SMALL ANIMALS—EXTERNAL	21	2,056,939.14
PARASITICIDES	LARGE ANIMALS—EXTERNAL	172	80,692,445.06
PARASITICIDES	LARGE ANIMALS—INTERNAL	276	59,517,500.54

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL \$
PARASITICIDES	LARGE ANIMALS—INTERNAL AND EXTERNAL	75	47,026,336.65
PARASITICIDES	SMALL ANIMALS—EXTERNAL	198	99,686,116.40
PARASITICIDES	SMALL ANIMALS—INTERNAL	242	77,502,118.99
PARASITICIDES	SMALL ANIMALS—INTERNAL AND EXTERNAL	10	22,811,999.00
PARASITICIDES	SMALL ANIMALS AND BIRDS —EXTERNAL	7	21,606,430.36
RESPIRATORY SYSTEM	EXPECTORANTS, MUCOLYTICS, DECONGESTANTS, BRONCHODILATORS, RESP, STIMLANTS	28	1,230,931.24
	<b>GRAND TOTAL</b>	<b>3383</b>	<b>815,541,580.59</b>

#### APVMA CONTACT

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## Addendum to the Record of Approved Active Constituents

The current *Record of Approved Active Constituents for Registered Chemical Products* is also accessible from the APVMA website, [www.apvma.gov.au](http://www.apvma.gov.au)

### APPROVED SINCE GAZETTE NO. 23, 18 NOVEMBER 2011

For use in agricultural and/or veterinary chemical products:

Common Name	Approval Holder	Manufacturer Site	Approval No.
Triadimenol	SINON AUSTRALIA PTY LIMITED	NO 111, CHUNG SHAN RD CHUNG-HO VILLAGE TA-TU DISTRICT TAICHUNG HSIEN 432 TAIWAN REPUBLIC OF CHINA	66173
Ethephon	BAYER CROPSOURCE PTY LTD	2151 KING ST. EXT., CHARLESTON SOUTH CAROLINA 29405 USA	65808
N-coco alkyltrimethylenediamines	MISTRING P/L & NABONE P/L T/A INTEGRA WATER TREATMENT SOLUTIONS	STOCKVIKSVERKEN SE 850 13 SUNDSVALL SWEDEN	58607
Dimethoate	SINON AUSTRALIA PTY LIMITED	NO 111, CHUNG SHAN RD CHUNG-HO VILLIAGE TA-TU DISTRICT TAICHUNG HSIEN 432 TAIWAN REPUBLIC OF CHINA	65605

### APVMA CONTACT

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Application Management & Enquiries  
Australian Pesticides and Veterinary Medicines Authority  
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KINGSTON ACT 2604

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## Application Summaries

The APVMA publishes complete application summaries on the APVMA website, [www.apvma.gov.au](http://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. 23.

Application No.	Name
51545	IMTRADE BIFENTHRIN ULTRA 300 EC INSECTICIDE
52719	RAINBOW TRI-ALLATE 500 EC HERBICIDE
52930	IMTRADE GIBBER GROWTH REGULATOR
53301	PARAMECTIN INJECTION FOR CATTLE
53542	WSD ALBENDAZOLE BROAD SPECTRUM SHEEP, LAMB AND GOAT DRENCH
53856	FARMALINX GRAINPRO PLUS IGR GRAIN PROTECTOR
54070	BAYFIDAN 250 EC FUNGICIDE
54078	APPARENT SULFUR 800 WG FUNGICIDE AND MITICIDE
54084	AGRO-ESSENCE MCPA 500 HERBICIDE
54087	AGRO-ESSENCE TRIASULFURON 750 WG HERBICIDE
54102	MILBEKNOCK MITICIDE
54165	YATES MANCOZEB PLUS GARDEN FUNGICIDE
54327	THERMACELL MOSQUITO REPELLENT
54379	SEA MINERALS DERMAL SPRAY
54418	NEUTRADEX MILD DIURETIC AND URINARY BUFFER FOR GREYHOUNDS
54613	NOT AVAILABLE
54638	KENSO AGCARE CAPTAN 800 WG FUNGICIDE
54823	MORTEIN NATURGARD SURFACE SPRAY CRAWLING INSECT KILLER
54825	MORTEIN NATURGARD AUTOMATIC INDOOR INSECT CONTROL SYSTEM CITRONELLA HOUSEHOLD PROTECTION
54855	NOT AVAILABLE

<b>Application No.</b>	<b>Name</b>
54874	KENSO AGCARE PARA-KEN 334 HERBICIDE
54878	Q-DRENCH MULTI-COMBINATION DRENCH FOR SHEEP
54925	NOVA AGRO BENSULFURON 600 EG HERBICIDE
54945	BLADEX 900 WG HERBICIDE
54958	NOT AVAILABLE
54984	POOL ALGAECIDE POLYGARD CONCENTRATE
55026	CYDECTIN PLUS FLUKE ORAL SOLUTION FOR SHEEP
55093	NOT AVAILABLE
55094	NOT AVAILABLE
55133	NOVA AGRO LAMBDA 250 CS INSECTICIDE
55144	NOT AVAILABLE
55147	NOT AVAILABLE
52297	INTERNATIONAL CRUISER UNO HIGH STRENGTH POLISHING ANTIFOULING
52784	TERBYNE 750 WG HERBICIDE
53686	NOT AVAILABLE
53916	DESTINY SELECTIVE TURF HERBICIDE
54086	AGRO-ESSENCE PROPYZAMIDE 500 SC HERBICIDE
54090	ZUPREVO 40 MG/ML SOLUTION FOR INJECTION FOR PIGS
54113	CYDECTIN PLUS FLUKE POUR-ON FOR CATTLE
54133	KENSO AGCARE DIFLUKEN M SELECTIVE HERBICIDE
54354	BOXER GOLD HERBICIDE
54431	GLOBE POOL SERVICE CHLORINE 20G TABLETS
54444	FLORASULAM
54546	IMTRADE BOOST 250 SC PLANT GROWTH REGULATOR
54687	NOT AVAILABLE
54700	MORTEIN NATURGARD AUTOMATIC INDOOR INSECT CONTROL SYSTEM CITRONELLA
54701	MORTEIN NATURGARD AUTOMATIC INDOOR INSECT CONTROL SYSTEM EUCALYTPUS
54727	MISSION OMETHOATE 290 SC INSECTICIDE
54873	KDPC KANOLACIDE SPRAY ADJUVANT
54888	ZOOTER 600 SEED TREATMENT INSECTICIDE

Application No.	Name
54937	PYZAP INSECTICIDE BY C RUDDUCK
54966	APPARENT DICLOFOP-METHYL 375 SELECTIVE HERBICIDE
55022	ECHEM GLYPHOSATE 510 K HERBICIDE
55084	RAINBOW BROMOXYNIL 200 SELECTIVE HERBICIDE
55118	DOW AGROSCIENCES AMINE 625 HERBICIDE
55119	BITHOR GRANULAR INSECTICIDE
55127	TYLECO 250 GRANULAR
55132	TYLECO 50 GRANULAR
55170	NOT AVAILABLE
55182	NOT AVAILABLE
55197	NOVA AGRO CHLORSULFURON WG HERBICIDE
55209	SAKURA 850 WG HERBICIDE
55242	NOT AVAILABLE
54625	STOCK GUARD POUR-ON FOR CATTLE AND RED DEER

**APVMA CONTACT**

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