



**Commonwealth  
of Australia**

**Gazette**

No. APVMA 12, Tuesday, 17 June 2014

Published by The Australian Pesticides & Veterinary Medicines Authority

**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*. 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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The Manager, Public Affairs and Communications  
The Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Kingston ACT 2604

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

Website: [www.apvma.gov.au](http://www.apvma.gov.au).

## 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/](http://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.

## APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4870

For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

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### Erratum Notice

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, No. APVMA 11, June 3, 2014.

The Notice of Variation for Vetafarm Avian Insect Liquidator Ready To Use contained a typographical error. The product name (before the variation) was listed as 'ETAFARM AVIAN INSECT LIQUIDATOR RESIDUAL INSECTICIDE AND INSECT GROWTH REGULATOR READY TO USE' rather than 'VETAFARM AVIAN INSECT LIQUIDATOR RESIDUAL INSECTICIDE AND INSECT GROWTH REGULATOR READY TO USE'.

The correct entry for the Notice of Variation for Vetafarm Avian Insect Liquidator Ready To Use appears on page 10 of this Gazette.

## 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

<b>Product Name:</b>	Sinochem Seeker 200SC Insecticide
<b>Active Constituent/s:</b>	200 g/L fipronil
<b>Applicant Name:</b>	Sinochem Agro Co., Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of Use:</b>	For the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapes, mushrooms, pasture, potatoes, sorghum, sugarcane, swede and turnips
<b>Date of Registration:</b>	27 May 2014
<b>Label Approval No:</b>	69450/60817
<b>Product Name:</b>	Accensi Iprodione 365 SE Fungicide
<b>Active Constituent/s:</b>	365 g/L iprodione
<b>Applicant Name:</b>	Accensi Pty Ltd
<b>Applicant ACN:</b>	079 875 184
<b>Summary of Use:</b>	For the control of various fungal diseases in recreational turf as specified in the directions for use
<b>Date of Registration:</b>	28 May 2014
<b>Label Approval No:</b>	68088/57461
<b>Product Name:</b>	Perfenox Ant, Spider & Roach Killer
<b>Active Constituent/s:</b>	100 g/L permethrin 25:75
<b>Applicant Name:</b>	Biotis Life Science Pty Ltd
<b>Applicant ACN:</b>	103 118 887
<b>Summary of Use:</b>	For the control of ants, spiders, cockroaches, fleas and other household insects around the home
<b>Date of Registration:</b>	29 May 2014
<b>Label Approval No:</b>	69092/59964
<b>Product Name:</b>	Macro Protect 2,4-D Amine 625 AC Herbicide
<b>Active Constituent/s:</b>	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
<b>Applicant Name:</b>	Louis Dreyfus Commodities Australia Pty. Ltd
<b>Applicant ACN:</b>	004 088 000
<b>Summary of Use:</b>	For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures, and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas
<b>Date of Registration:</b>	29 May 2014
<b>Label Approval No:</b>	69835/61859

<b>Product Name:</b>	Tanalith E Wood Preservative Concentrate
<b>Active Constituent/s:</b>	161 g/L copper (Cu) as copper carbonate, 6.4 g/L tebuconazole
<b>Applicant Name:</b>	Arch Wood Protection (Aust) Pty Limited
<b>Applicant ACN:</b>	003 780 872
<b>Summary of Use:</b>	For the preservation of timber against fungal decay, wood borers and termites
<b>Date of Registration:</b>	30 May 2014
<b>Label Approval No:</b>	68552/58561
<b>Product Name:</b>	Macro Protect Glyphosate 700 SG Herbicide
<b>Active Constituent/s:</b>	700 g/kg glyphosate present as the mono-ammonium salt
<b>Applicant Name:</b>	Louis Dreyfus Commodities Australia Pty. Ltd
<b>Applicant ACN:</b>	004 088 000
<b>Summary of Use:</b>	For the control of many annual and perennial weeds in certain situations
<b>Date of Registration:</b>	2 June 2014
<b>Label Approval No:</b>	69839/61863
<b>Product Name:</b>	Job's Done Garden Weed Killer RTU
<b>Active Constituent/s:</b>	7.2 g/L glyphosate present as the isopropylamine salt
<b>Applicant Name:</b>	Agcare Pty Ltd
<b>Applicant ACN:</b>	159 778 757
<b>Summary of Use:</b>	For the control of grasses and broadleaf weeds applied as a spot treatment on rockeries, garden beds, paths, driveways, fence lines, lawn edges, firebreaks, around buildings and before planting new lawns and gardens
<b>Date of Registration:</b>	2 June 2014
<b>Label Approval No:</b>	69973/62203
<b>Product Name:</b>	Oztec Triclopyr 600 EC Herbicide
<b>Active Constituent/s:</b>	600 g/L triclopyr present as the butoxyethyl ester
<b>Applicant Name:</b>	Oztec Rural Pty Ltd
<b>Applicant ACN:</b>	056 693 095
<b>Summary of Use:</b>	For the control of a range of woody weeds and melons
<b>Date of Registration:</b>	2 June 2014
<b>Label Approval No:</b>	69922/62061
<b>Product Name:</b>	Turf Culture Columbus Insecticide
<b>Active Constituent/s:</b>	250 g/L thiamethoxam
<b>Applicant Name:</b>	Turf Culture Pty Ltd
<b>Applicant ACN:</b>	117 986 615
<b>Summary of Use:</b>	For control of African black beetle, Argentinian scarab and billbug in turf
<b>Date of Registration:</b>	3 June 2014
<b>Label Approval No:</b>	68967/59512
<b>Product Name:</b>	Sungod 360 Herbicide
<b>Active Constituent/s:</b>	360 g/L glyphosate
<b>Applicant Name:</b>	Alpha Crop Protection Pty Ltd
<b>Applicant ACN:</b>	165 653 047
<b>Summary of Use:</b>	For non-selective control of annual, aquatic and perennial weeds in certain situations
<b>Date of Registration:</b>	3 June 2014
<b>Label Approval No:</b>	69964/62187

<b>Product Name:</b>	Nufarm Maestro 200SC Insecticide
<b>Active Constituent/s:</b>	200 g/L fipronil
<b>Applicant Name:</b>	Nufarm Australia Limited
<b>Applicant ACN:</b>	004 377 780
<b>Summary of Use:</b>	For control of various insect pests in brassicas, cotton, wine grapevines, potatoes and sugar cane
<b>Date of Registration:</b>	4 June 2014
<b>Label Approval No:</b>	69919/62056

<b>Product Name:</b>	DuPont Altacor Hort Insecticide
<b>Active Constituent/s:</b>	350 g/kg chlorantraniliprole
<b>Applicant Name:</b>	Du Pont (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 716 469
<b>Summary of Use:</b>	For the control of certain species of insect pests in fruit crops
<b>Date of Registration:</b>	6 June 2014
<b>Label Approval No:</b>	69957/62169

<b>Product Name:</b>	Job's Done Ant Killer Granular
<b>Active Constituent/s:</b>	2 g/kg bifenthrin
<b>Applicant Name:</b>	Agcare Pty Ltd
<b>Applicant ACN:</b>	159 778 757
<b>Summary of Use:</b>	For the control of certain pests in turf and ants, fleas and ticks in external surrounds of buildings and structures
<b>Date of Registration:</b>	10 June 2014
<b>Label Approval No:</b>	69978/62215

## 2. VARIATIONS

<b>Product Name:</b>	Accensi Lawn Beetle & Grub Killer Granular Insecticide
<b>Applicant Name:</b>	Accensi Pty Ltd
<b>Applicant ACN:</b>	079 875 184
<b>Summary of Variation:</b>	To change the product name from 'COUNTRY LAWN BEETLE & GRUB KILLER GRANULAR INSECTICIDE' to 'ACCENSI LAWN BEETLE & GRUB 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
<b>Date of Variation:</b>	27 May 2014
<b>Label Approval No:</b>	63681/61711

<b>Product Name:</b>	Stag Herbicide
<b>Applicant Name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of Variation:</b>	To extend use to sugarcane and asparagus and to approve a pack size range of 5 kg to 1000 kg
<b>Date of Variation:</b>	27 May 2014
<b>Label Approval No:</b>	60874/59674

<b>Product Name:</b>	Yates Zaleton Dual Action Systemic Fungicide
<b>Applicant Name:</b>	Bayer CropScience Pty Ltd
<b>Applicant ACN:</b>	000 226 022
<b>Summary of Variation:</b>	To extend label claims to new diseases in roses and ornamentals under a general ornamental claim
<b>Date of Variation:</b>	27 May 2014
<b>Label Approval No:</b>	64474/61253
<b>Product Name:</b>	Cheminova Mepiquat Plant Growth Regulator
<b>Applicant Name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of Variation:</b>	To change the product name from 'OSPRAY MEPIQUAT PLANT GROWTH REGULATOR' to 'CHEMINOVA MEPIQUAT PLANT GROWTH REGULATOR'
<b>Date of Variation:</b>	2 June 2014
<b>Label Approval No:</b>	58425/62149
<b>Product Name:</b>	Cheminova Iprodione Liquid 250 Fungicide
<b>Applicant Name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of Variation:</b>	To change the product name from 'OSPRAY IPRODIONE LIQUID 250 FUNGICIDE' to 'CHEMINOVA IPRODIONE LIQUID 250 FUNGICIDE'
<b>Date of Variation:</b>	2 June 2014
<b>Label Approval No:</b>	60941/62071
<b>Product Name:</b>	Balance 750 WG Herbicide
<b>Applicant Name:</b>	Bayer CropScience Pty Ltd
<b>Applicant ACN:</b>	000 226 022
<b>Summary of Variation:</b>	To amend the summer fallow grazing withholding period statement
<b>Date of Variation:</b>	2 June 2014
<b>Label Approval No:</b>	49456/61047
<b>Product Name:</b>	Rustler Selective Herbicide
<b>Applicant Name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of Variation:</b>	To change the product name from 'OSPRAY RUSTLER SELECTIVE HERBICIDE' to 'RUSTLER SELECTIVE HERBICIDE', add uses in canola and oilseed poppies, to extend the use in buffalo grass to all states and to update the relevant label particulars
<b>Date of Variation:</b>	2 June 2014
<b>Label Approval No:</b>	61360/60305
<b>Product Name:</b>	Boxer Gold Herbicide
<b>Applicant Name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of Variation:</b>	To extend the use to include control of grass and broadleaf weeds in potatoes
<b>Date of Variation:</b>	4 June 2014
<b>Label Approval No:</b>	61234/58697

<b>Product Name:</b>	Cheminova Dicamba 500 SL Selective Herbicide
<b>Applicant Name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of Variation:</b>	To change the product name from 'OSPRAY DICAMBA 500 SL SELECTIVE HERBICIDE' to 'CHEMINOVA DICAMBA 500 SL SELECTIVE HERBICIDE'
<b>Date of Variation:</b>	4 June 2014
<b>Label Approval No:</b>	60348/62177
<b>Product Name:</b>	Cheminova Diuron 500 Flowable Herbicide
<b>Applicant Name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of Variation:</b>	To change the product name from 'OSPRAY DIURON 500 FLOWABLE HERBICIDE' to 'CHEMINOVA DIURON 500 FLOWABLE HERBICIDE'
<b>Date of Variation:</b>	4 June 2014
<b>Label Approval No:</b>	58440/62163
<b>Product Name:</b>	Apparent Devour 1020 Penetrant
<b>Applicant Name:</b>	Apparent Pty. Ltd
<b>Applicant ACN:</b>	143 724 136
<b>Summary of Variation:</b>	To change the product name from 'APPARENT POLYSILOXANE 1020 PENETRANT' to 'APPARENT DEVOUR 1020 PENETRANT'
<b>Date of Variation:</b>	4 June 2014
<b>Label Approval No:</b>	68848/62155
<b>Product Name:</b>	Sumitomo Samurai Systemic Insecticide
<b>Applicant Name:</b>	Sumitomo Chemical Australia Pty Limited
<b>Applicant ACN:</b>	081 096 255
<b>Summary of Variation:</b>	To add application through micro-irrigation systems to control a range of pests in apples and grapes
<b>Date of Variation:</b>	4 June 2014
<b>Label Approval No:</b>	60687/60863
<b>Product Name:</b>	Nominee Herbicide
<b>Applicant Name:</b>	Sumitomo Chemical Australia Pty Limited
<b>Applicant ACN:</b>	081 096 255
<b>Summary of Variation:</b>	To extend the use in sports field situations to control winter grass
<b>Date of Variation:</b>	11 June 2014
<b>Label Approval No:</b>	63233/60931
<b>Product Name:</b>	Salvation Herbicide
<b>Applicant Name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	100 199 169
<b>Summary of Variation:</b>	To change the product name from 'OSPRAY SALVATION HERBICIDE' to 'SALVATION HERBICIDE'
<b>Date of Variation:</b>	11 June 2014
<b>Label Approval No:</b>	61800/62110



## 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>	PAW Pure Animal Wellbeing by Blackmores NutriDerm Replenishing Shampoo
<b>Active Constituent/s:</b>	20 g/L colloidal oatmeal
<b>Applicant Name:</b>	Blackmores Limited
<b>Applicant ACN:</b>	009 713 437
<b>Summary of Use:</b>	For use as an aid in soothing and cleansing dry, itchy skin in dogs and cats
<b>Date of Registration:</b>	13 May 2014
<b>Label Approval No:</b>	65958/52383
<b>Product Name:</b>	Econase XT P
<b>Active Constituent/s:</b>	4,000,000 BXU / g Endo—1,4—B—D—xylanase (EC 3.2.1.8)
<b>Applicant Name:</b>	Roal Oy
<b>Applicant ACN:</b>	N/A
<b>Summary of Use:</b>	For use as an enzyme supplement for poultry and pigs to enhance digestion of non-starch polysaccharides in feed
<b>Date of Registration:</b>	27 May 2014
<b>Label Approval No:</b>	65965/52406
<b>Product Name:</b>	Doxalino 120G Granulated Feed Additive
<b>Active Constituent/s:</b>	Salinomycin sodium (minimum 120 mg/g as the sodium salt)
<b>Applicant Name:</b>	Dox-al Italia S.P.A.
<b>Applicant ACN:</b>	N/A
<b>Summary of Use:</b>	For use in control of coccidiosis in chickens and enhancement of productivity in grower finisher pigs and feedlot beef cattle
<b>Date of Registration:</b>	27 May 2014
<b>Label Approval No:</b>	67987/57228
<b>Product Name:</b>	BioRelease Deslorelin (BRD)
<b>Active Constituent/s:</b>	Each mL contains 1.25 mg deslorelin as deslorelin acetate
<b>Applicant Name:</b>	Caledonian Holdings Distribution Pty Ltd
<b>Applicant ACN:</b>	122 162 190
<b>Summary of Use:</b>	For the induction of ovulation in mares
<b>Date of Registration:</b>	30 May 2014
<b>Label Approval No:</b>	64329/48064

<b>Product Name:</b>	Eclipse Combination Oral Drench For Sheep
<b>Active Constituent/s:</b>	1 g/L abamectin, 40 g/L levamisole hydrochloride, 2.2 g/L cobalt (as cobalt disodium EDTA), 0.5 g/L selenium (as sodium selenate)
<b>Applicant Name:</b>	Merial Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of Use:</b>	For use in the treatment and control of susceptible strains of adult and immature gastrointestinal parasites in sheep
<b>Date of Registration:</b>	2 June 2014
<b>Label Approval No:</b>	69963/62183

<b>Product Name:</b>	Apex Thyroxine Oral Solution
<b>Active Constituent/s:</b>	1m g/mL levothyroxine sodium
<b>Applicant Name:</b>	Apex Laboratories Pty Ltd
<b>Applicant ACN:</b>	000 397 240
<b>Summary of Use:</b>	For the treatment of hypothyroidism in dogs
<b>Date of Registration:</b>	4 June 2014
<b>Label Approval No:</b>	67226/55526

## 2. VARIATIONS

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

<b>Product Name:</b>	Aristopet Animal Health Flea and Tick Spray Plus Insect Growth Regulator for Dogs and Cats
<b>Applicant Name:</b>	Aristopet Pty Ltd
<b>Applicant ACN:</b>	145 418 882
<b>Summary of Variation:</b>	To change the product name from 'BEAPHAR BOUQUET FLEA & TICK SPRAY PLUS IGR FOR DOGS, CATS, PUPPIES, KITTENS & HOUSEHOLDS' to 'ARISTOPET ANIMAL HEALTH FLEA AND TICK SPRAY PLUS INSECT GROWTH REGULATOR FOR DOGS AND CATS'
<b>Date of Variation:</b>	22 May 2014
<b>Label Approval No:</b>	64035/54033

## OTHER NOTICES

### Licensing of Veterinary Chemical Manufacturers

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Pursuant to Part 8 of the Agricultural and Veterinary Chemical Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action, with respect to the licensing of the following veterinary chemical manufacturers, with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the APVMA's website [www.apvma.gov.au](http://www.apvma.gov.au).

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#### 1. NEW LICENCES

**PADULA SERUMS PTY. LTD.**      **LICENCE NO:** 1105

**ACN:** 167 348 610

26 Howitt Ave

BAIRNSDALE VIC 3875

**Product Types:\***

- *Category 1:* immunobiologicals (snake antivenom, tetanus antitoxin and equine plasma products)

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, blood collection, plasma separation, management and immunisation of donor animals, labelling, analysis and testing (physical, chemical, serological, immunobiological, mouse bioassay for potency), storage and release for supply.

**Licence Issued:** 8 May 2014

Licence issued with special conditions

#### 2. CHANGES TO EXISTING LICENCES

**CHEMINOVA (MFG) PTY  
LIMITED**

**LICENCE NO:** 2204

**ACN:** 132 767 956

16 Lucca Road

WYONG NSW 2259

**Product Types: \***

- *Category 2:* powders, liquids, tablets (mineral supplements) and capsules (intra-ruminal slow release)
- *Category 3:* powders and liquids

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, filling, tableting, capsule filling from bulk, oxidation of metal, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply

**Amended Licence Issued:** 6 May 2014

Amended product types, steps of manufacture and conditions

**ASUREQUALITY AUSTRALIA  
PTY LTD**

**ACN:** 106 787 704

28 Mareno Road

TULLAMARINE VIC 3043

**LICENCE NO:** 1085

**Product Types:** \*

- *Category 1:* immunobiologicals

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, aseptic filling, sterilisation (heat), secondary packaging, labelling, storage and release for supply

**Amended Licence Issued:** 13 May 2014

Amended product types and conditions

**BEC FEED SOLUTIONS PTY  
LTD**

**ACN:** 010 345 150

50 Antimony Street

CAROLE PARK QLD 4300

**LICENCE NO:** 4016

**Product Types:** \*

- *Category 4:* Premixes

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, storage and release for supply

**Amended Licence Issued:** 14 May 2014

Change of key personnel

### 3. LICENCE CANCELLATIONS

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

**PHOENIX ANALYTICAL  
SERVICES PTY LTD**

**ACN:** 119 847 871

Units 2-3

54 Smallwood Street

UNDERWOOD QLD 4119

**LICENCE NO:** 6151

**Date Cancelled:** 12 May 2014

**Reason for Cancellation:** Section 127(1)(e)

**DFC PHARMAMED PTY  
LIMITED**

**ACN:** 075 718 302

23-25 Sefton Road

THORNLEIGH NSW 2120

**LICENCE NO:** 2041

**Date Cancelled:** 12 May 2014

**Reason for Cancellation:** Section 127(1)(e)

**TRENWELL AGRICULTURE  
PTY LTD**

**ACN:** 096 511 045

25 Brassey Court

MICKLEHAM VIC 3064

**LICENCE NO:** 1065

**Date Cancelled:** 12 May 2014

**Reason for Cancellation:** Section 127(1)(f)

**APVMA CONTACT**

MQL Officer

Manufacturing, Quality and Licensing

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

**Phone:** +61 2 6210 4899

**Fax:** +61 2 6210 4741

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

## Dimethoate Review: Cancellation of Certain Label Approvals following Approval of new Labels

On 6 June 2014, the APVMA cancelled certain label approvals of the dimethoate products identified in the table below. The decision to cancel these label approvals was made under subsection 41(3) of the *Agricultural and Veterinary Chemicals Code Act 1994*. This action follows the approval of new labels for these products.

All products containing dimethoate and their associated labels were suspended by the APVMA on 6 October 2011 under subsections 41(1) and 41(3) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) due to unacceptable dietary risks identified in the *Dimethoate Residues and Dietary Risk Assessment Report* published by the APVMA in August 2011. Suspended products and products bearing suspended labels may currently only be used in accordance with the suspension instructions issued by the APVMA and also included in permit PER 13155 (agricultural products).

The suspensions of these three products were revoked in January and February 2014 to allow approval of new labels (as listed in Column 6 of Table 1) that carry instructions that mitigate the identified dietary risks.

Label approvals listed in Column 4 of Table 1 do not have instructions that mitigate the identified dietary risks. The APVMA has cancelled these label approvals and issued instructions for the use of product bearing these labels that are consistent with suspension instructions issued by the APVMA and also included in permit PER 13155 (agricultural products).

**TABLE 1**

1. Registered Product No	2. Registered Product Name	3. Registrant	4. Cancelled Label Approval Numbers	5. Date of Effect of cancellation	6. New Label Approval number
32962	Nufarm Dimethoate Systemic Insecticide	Nufarm Australia Limited	32962/0401, 32962/0402, 32962/0701, 32962/0998, 32962/1299, 32962/0704, 32962/0104, 32962/1203, 32962/1006, 32962/53189	6 June 2014	32962/59912
39239	Farmoz Dimethoate 400 Systemic Insecticide	Farmoz Pty Limited	39239/0402, 39239/0897, 39239/4252, 39239/0708, 39239/0809, 39239/0108, 39239/0405	6 June 2014	39239/61011
55704	Conquest Dimethoate 400 Systemic Insecticide	Conquest Crop Protection Pty Ltd	55704/0502	6 June 2014	55704/60954

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

The following instructions set out how a person can deal with any product bearing a cancelled label approval as listed in Column 4 of Table 1 above.

## INSTRUCTIONS

Subsections 45A(5) and 55(3) of the Agvet Code cease to apply in respect of the cancelled label approvals identified in Column 4 of Table 1 above. A person may not possess, have custody of, use or deal with products bearing cancelled labels from 16 October 2013 until 5 October 2014 other than in accordance with:

- The instructions set out at the end of this Notice; and
- A permit issued by the APVMA.

Permits, with modified instructions for use of dimethoate products, have been issued under section 114 of the Agvet Code (PER 13155 for agricultural products and PER 13156 for home garden products). The instructions for use have been reproduced at the end of this Notice. These permits still apply to products bearing these cancelled labels.

## WARNING

The label approvals listed in Column 4 of Table 1 above have been cancelled. Prior to the cancellation of these labels they were suspended with new instructions for use issued during the period of suspension. These instructions also apply during this period of phase out. Since 6 October 2011, when these product labels were first suspended and new instructions issued, a person can only possess, have custody of, use or otherwise deal with products bearing the label approvals identified above in accordance with a permit issued by the APVMA and the instructions set out at the end of this Notice.

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

## APVMA CONTACT

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

Contact Officer  
Chemical Review 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](mailto:chemicalreview@apvma.gov.au)

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

### **Possession and custody**

A person may possess, have custody of, use or otherwise deal with registered dimethoate products, bearing a cancelled label, only in accordance with these instructions or the relevant permit (permits PER 13155 for agricultural products or PER 13156 for home garden products) issued by the APVMA.

### **Supply**

A person may supply or cause to be supplied product bearing a cancelled label at wholesale and retail level, until 5 October 2014.

After 5 October 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.

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

- a copy of the relevant permit (PER 13155 for agricultural products or PER 13156 for home garden products) in full setting out the conditions and instructions for use, and
- supply product with a copy of the instructions contained in the relevant permit securely affixed to each container of product.

### **Use**

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

**READ THESE INSTRUCTIONS** before using or otherwise handling the product.

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

#### **PROHIBITED CROP USES: HOME GARDEN PRODUCTS**

The current (suspended) label may include instructions for use on fruit trees and vegetables. The use of dimethoate on these crops is no longer approved and the following restraint applies.

#### **DO NOT apply to food producing plants in the home garden**

#### **PROHIBITED CROP USES: AGRICULTURAL PRODUCTS**

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

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

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

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

**DO NOT USE** on cherry, grape or mini tomatoes



**DO NOT USE as a foliar, post-harvest or quarantine treatment on:**

- Tropical or subtropical edible peel fruit [babacos, carambolas (Five Corner), figs and edible peel varieties of guavas, kiwifruit and persimmons].
- Pome fruit [apples, loquats, pears, quinces],
- Stone fruit after petal fall [apricots, cherries, nectarines, peaches, plums, apricot],
- Grapes after commencement of flowering,
- Berry fruit, (other than blackberries, raspberries, bilberries, blueberries and other vaccinium berries)
- Strawberries (except strawberry runners—vegetative planting material only)
- Vegetables, other than those listed below
  - Dimethoate may be used on artichoke (globe), asparagus, beans, beetroot, broccoli, cabbage (drumhead varieties only), capsicums, carrot, cauliflower, celery, chilli (peppers), peas, potatoes and sweet potatoes, onion, parsnips, radish, rhubarb, sweetcorn, tomatoes for processing, tomatoes (large field grown for fresh consumption) prior to fruit set, turnip and zucchini,
- Cucurbits (other than melons, watermelons and zucchini)

**Directions for Use:**

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

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

<b>Fruit crops</b>	<b>Vegetable crops</b>	<b>Non-food crops</b>
Abius Avocado Banana Blackberries Cactus fruit Casimiroas (white sapote) Chinese Gooseberries (kiwifruit) (inedible peel varieties ONLY) Citrus Fruit Custard Apple and cherimoya Feijoa Granadillas Guavas (inedible peel varieties only) Litchis (lychee) Mangoes Passionfruit and banana passionfruit Pawpaw (papaya) Persimmons (American -inedible peel varieties ONLY) Pomegranates Raspberries Santols Sapodillas (chikus) Tamarillos Wax jambus	<i>Existing labels include preharvest uses only</i> Asparagus Melons and watermelons Onions Rhubarb Watermelons Zucchini Seed dressings (vetches, lupins, peas, lucerne, clover, linseed, canola)	Duboisia, Farm and forest trees Eucalyptus Kurrajongs Oil tea-tree Ornamentals, protea Shrubs Umbrella trees Wildflowers

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

<b>Crop</b>	<b>Additional use restrictions</b>
Blueberries, bilberries and other vaccinium berries	<b>DO NOT</b> exceed a maximum number of 7 applications per crop per season with a minimum retreatment interval of 21 days between consecutive applications  <b>DO NOT</b> harvest for 1 day after final application
Grapes	<b>DO NOT</b> use after flowering commences
Stone fruit	<b>DO NOT</b> use after petal fall
Artichoke, globe	<b>DO NOT</b> harvest for 14 days after final application
Beetroot	
Beans	<b>DO NOT</b> harvest for 7 days after application <b>DO NOT</b> graze or cut for stockfood for 7 days after application
Broccoli	<b>DO NOT</b> harvest for 21 days after final application
Cabbage specified drumhead varieties only when grown to maturity to be harvested as head cabbages (see Table 3 below)	<b>DO NOT</b> harvest for 21 days after final application
Capsicum	<b>DO NOT USE</b> as a post-harvest treatment for capsicums. <b>DO NOT USE</b> as a post-harvest quarantine treatment for capsicums
Chilli	<b>Preharvest uses</b> <b>DO NOT</b> harvest for 3 days after application
Carrots	<b>DO NOT</b> harvest for 14 days after final application
Cauliflower	<b>DO NOT</b> harvest for 21 days after final application
Celery	
Peas	<b>DO NOT</b> harvest for 7 days after application <b>DO NOT</b> graze or cut for stockfood for 7 days after application
Parsnips	<b>DO NOT</b> harvest for 14 days after final application

<b>Crop</b>	<b>Additional use restrictions</b>
Potatoes	<b>DO NOT</b> harvest for 14 days after final application
Sweet potatoes	
Radishes	<b>DO NOT</b> harvest for 14 days after application
Strawberry (runner production—vegetative planting material only)	<b>DO NOT</b> use on fruiting strawberries
Sweet corn	<b>DO NOT</b> harvest for 7 days after application <b>DO NOT</b> graze or cut for stockfood for 7 days after application
Tomatoes for processing only	<b>DO NOT</b> harvest for 21 days after final application <b>DO NOT USE</b> as a post-harvest treatment for tomatoes <b>DO NOT USE</b> as a post-harvest quarantine treatment for tomatoes. <b>DO NOT USE</b> on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels <b>DO NOT USE</b> on cherry, grape or mini tomatoes
Tomatoes, large, field grown for fresh consumption	<b>DO NOT</b> apply after commencement of flowering <b>DO NOT USE</b> on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels <b>DO NOT USE</b> as a post-harvest treatment for tomatoes <b>DO NOT USE</b> as a post-harvest quarantine treatment for tomatoes <b>DO NOT USE</b> on cherry, grape or mini tomatoes
Turnips	<b>DO NOT</b> harvest for 14 days after final application
Cereals, (including maize, sorghum)	<b>DO NOT</b> harvest for 4 weeks after application <b>DO NOT</b> graze or cut for stockfood for 14 days after application
Cotton	<b>DO NOT</b> harvest for 14 days after application <b>DO NOT</b> Feed cotton fodder, stubble or trash to livestock
Oilseeds, pulses (grain legumes)	<b>DO NOT</b> harvest for 14 days after application <b>DO NOT</b> graze or cut for stockfood for 14 days after application
Pastures, forage crops and leucaena	<b>DO NOT</b> graze or cut for stockfood for 14 days after application

**WITHHOLDING PERIODS (see additional use restrictions above)**

Citrus

**DO NOT** harvest for 7 days after application

Blueberries (and other vaccinium berries including bilberries)

**DO NOT** harvest for 1 day after application

Blackberries, raspberries

**DO NOT** harvest for 7 days after application

Grapes, Stone fruit

Harvest withholding period: Not required when used as directed

Assorted sub-tropical and tropical fruit – inedible peel (other than mango and pineapple), including abui, avocado, banana, banana passionfruit, casimiroas (white sapote), cherimoya, custard apple, granadillas, litchi/lychee, passionfruit, paw paw, santols, sapodillas (chikus), wax jambus

**DO NOT** harvest for 7 days after application

Mango

**DO NOT** harvest for 3 days after application

Post harvest dipping (avocados, bananas, cactus fruit, chilli, custard apples, feijoas, guavas, kiwifruit (chinese gooseberries inedible peel varieties), litchis (lychees), mangoes, melons, passionfruit, banana passionfruit, pawpaws, persimmons (inedible peel varieties), pomegranates, tamarillos, watermelons) **NOT REQUIRED WHEN USED AS DIRECTED (dip uses only)**

Litchis (lychees) (pre-planting dip)

Harvest withholding period: Not required when used as directed

Asparagus, onions, rhubarb, sweet corn

**DO NOT** harvest for 7 days after application

Sweetcorn:

**DO NOT** graze or cut for stockfood for 7 days after application

Beans, peas (green vegetables)

**DO NOT** harvest for 7 days after application

**DO NOT** graze or cut for stockfood for 7 days after application

Beetroot, carrot, globe artichoke, parsnips potatoes, radish, sweet potatoes, turnip

**DO NOT** harvest for 14 days after application

Broccoli, cauliflower, celery

**DO NOT** harvest for 21 days after application

Strawberry plants (runner production—vegetative planting material only)

**NOT REQUIRED WHEN USED AS DIRECTED**

Tomatoes (for processing)

**DO NOT** harvest for 21 days after application

Tomatoes, large, field grown for fresh consumption

Harvest withholding period: **NOT REQUIRED WHEN USED AS DIRECTED**

(ie. **DO NOT** apply after commencement of flowering)

Drumhead cabbage (specified varieties only)

**DO NOT** harvest for 21 days after application

Capsicums, chilli peppers

**DO NOT** harvest for 3 days after application

Melons (including watermelons), zucchini

**DO NOT** harvest for 1 day after application

Cereals, (including maize, sorghum)

**DO NOT** harvest for 4 weeks after application

**DO NOT** graze or cut for stockfood for 14 days after application

Cotton

**DO NOT** harvest for 14 days after application

**DO NOT** Feed cotton fodder, stubble or trash to livestock

Oilseeds, pulses (grain legumes)

**DO NOT** harvest for 14 days after application

**DO NOT** graze or cut for stockfood for 14 days after application

Pastures, forage crops and leucaena

**DO NOT** graze or cut for stockfood for 14 days after application

Seed dressings (vetches, lupins, peas, lucerne, clover, linseed canola), **NOT REQUIRED WHEN USED AS DIRECTED**

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

<b>Seed company</b>	<b>Drumhead Cabbage varieties</b>
Fairbanks seed	Avachat F <sub>1</sub> , Grandslam F <sub>1</sub> , Superba
Terranova	Neptune, Winterhead, Red queen, Green coronet, Eureka
Lefroy valley seeds	Conquistador, Burton, Landini
Rijk zwaan	Racoma RZ F <sub>1</sub>
Ace	Major F <sub>1</sub> , Red gem
S&G seeds	Maxfield
SPS	Arixos, Asia, Kameron, Red jewel
Bejo seeds	Ducat F <sub>1</sub> , Gazelle F <sub>1</sub> , Megaton F <sub>1</sub> , Benelli F <sub>1</sub> , Gonzales F <sub>1</sub> , Mandy F <sub>1</sub> , Field Glory F <sub>1</sub> , Score F <sub>1</sub>
Eden seeds	Golden acre, Mammoth red rock
King seeds	Campra F1, Sunta
Yates	Racer drumhead, Red dutch
Australian seed	Mammoth red rock, All seasons

## Inactivated West Nile Virus, Strain VM—2 in the product: EQUIVAC WNV

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Zoetis Australia Pty Limited, for the approval of the new active constituent, Inactivated West Nile virus, strain VM—2. The APVMA also has before it an application from the same applicant, for the registration of a new product, EQUIVAC WNV ('the product').

### Particulars of the active constituent

Applicant company:	ZOETIS AUSTRALIA PTY LTD 38-42 Wharf Road WEST RYDE NSW 2114
Name of active constituent:	Inactivated West Nile virus, strain VM—2
Manufacturer:	Boehringer Ingelheim Vetmedica Inc., 800 Fifth Street, N.W. / 141 East Riverside Drive Fort Dodge, Iowa 50501 USA, Or Zoetis Inc, 2000 Rockford Road, Charles City, Iowa, USA
Appearance:	As per European Pharmacopoeia
Sterility:	As per European Pharmacopoeia
Extraneous agents:	As per European Pharmacopoeia
Mycoplasma:	As per European Pharmacopoeia
Gene technology:	Not applicable
Mode of action:	Inducing immunological response

## **Particulars of the Product**

### **Proposed name**

EQUIVAC WNV

### **Active constituent**

Inactivated West Nile virus, strain VM—2

### **Adjuvant**

MetaStim (SP oil)

### **Pharmaceutical form**

Emulsion for injection

### **Pack sizes**

5 single-dose syringes.

10 single-dose syringes.

25 single-dose syringes

### **Target species**

Horses

### **Amounts to be administered and administration route**

Administer one dose (1 mL), by deep intramuscular injection in the neck region.

### **Vaccination schedule**

Primary vaccination course: first injection from 6 months of age, second injection 3–5 weeks later.

Revaccination: a sufficient degree of protection should be achieved after an annual booster injection with a single 1 mL dose.

### **Indications for use**

For the active immunisation of horses 6 months of age or older against West Nile virus (formerly Kunjin virus) disease by reducing the number of viraemic horses.

Onset of immunity: 3 weeks after primary vaccination course.

Duration of immunity: 12 months after primary vaccination course

### **Side effects:**

Transient local reactions in the form of a mild, local swelling at the injection site post vaccination (maximum 1 cm in diameter) that resolve spontaneously within 1 to 2 days and that are sometimes associated with pain and mild depression were reported in very rare cases. In very rare cases transient hyperthermia may occur for up to 2 days.

### **Withholding period**

Zero Days

### **Manufacturer**

Zoetis Inc, 2000 Rockford Road,

Charles City, Iowa, USA

Or

Elanco Animal Health Ireland Limited

Finisklin Industrial Estate Sligo, Ireland

### **Applicant name**

ZOETIS AUSTRALIA PTY LTD

38-42 Wharf Road

WEST RYDE NSW 2114

**Summary of the APVMA's evaluation of Equivac WNV 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 inactivated West Nile virus, strain VM—2 (active constituent) and the product and found them to meet APVMA standard. The assessment included starting materials, master seeds (source, identity, and purity), culture media, vaccine production, quality control, shelf life and batch release analysis.

The APVMA is satisfied that the proposed use of inactivated West Nile virus, strain VM—2 in the product, for the active immunisation of horses 6 months of age or older against West Nile virus (formerly Kunjin virus) disease, by reducing the number of viraemic horses, would not be likely to have an effect that is harmful to human beings, environment or trade. The adjuvant has been assessed and is already present in registered vaccines in Australia and the excipients are already present in several vaccines registered for use in Australia. They have been previously assessed and found to be safe.

In relation to its assessment of efficacy and safety in target animal the APVMA is satisfied that the data supporting the efficacy and safety of the product adequately demonstrate that this product is likely to be safe and effective under Australian conditions when used according to label instructions.

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 APVMA should grant the application for approval of the active constituent inactivated West Nile virus, strain VM—2 and registration of the product.

Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined above that the APVMA is required to take into account in deciding whether to grant the application.

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.

When making a submission please include a:

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

Written submissions on the APVMA's proposal to grant approval for the active inactivated West Nile virus, strain VM—2, and registration of the product that relate to the grounds for approval should be addressed to:

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

Phone: +61 2 6210 4730

Fax: +61 2 6210 4736

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



## **G-PROTEIN (sG) of Hendra Virus in the product: Equivac HeV Hendra Virus Vaccine For Horses**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Zoetis Australia Pty Limited, for the approval of the new active constituent, G-Protein (sG) of Hendra Virus. The APVMA also has before it an application from the same applicant, for the registration of a new product, Equivac HeV Hendra Virus Vaccine for Horses ('the product').

### **Particulars of the active constituent**

Applicant company:	Zoetis Australia Pty Ltd 38-42 Wharf Road WEST RYDE NSW 2114
Name of active constituent:	G-Protein (sG) of Hendra Virus
Manufacturer:	Zoetis Australia Australia Research And Manufacturing Pty Ltd 45 Popular Road Parkvile VICTORIA 3052
Potency:	As per Manufacturer's specification
Appearance:	As per European Pharmacopoeia
Sterility:	As per European Pharmacopoeia
Extraneous agents:	As per European Pharmacopoeia
Mycoplasma:	As per European Pharmacopoeia
Gene technology:	Not applicable
Mode of action:	Inducing immunological response

## **Particulars of the Product**

### **Proposed name**

Equivac HeV Hendra Virus Vaccine for Horses

### **Active constituent**

G-Protein (sG) of Hendra Virus

### **Adjuvant**

Immune Stimulating Complex

### **Pharmaceutical form**

Emulsion for injection

### **Pack sizes**

1 mL syringe  
10 mL vial

### **Target species**

Horses

### **Amounts to be administered and administration route**

Administer one dose (1 mL), by deep intramuscular injection in the neck region.

### **Vaccination schedule**

Primary vaccination course: first injection from 4 months of age or above, second injection 3 weeks later.  
Revaccination: a sufficient degree of protection should be achieved after 6 month booster injection with a single 1 mL dose.

### **Indications for use**

As an aid in the prevention of clinical disease caused by Hendra virus in horses 4 months of age or older.

Onset of immunity: 3 weeks after primary vaccination course.

Duration of immunity: 6 months after primary vaccination course.

### **Side effects:**

Transient swelling may develop at the site of vaccination in some horses but should resolve within one week without treatment.

In a small proportion of horses transient post-vaccination reactions including injection site pain, increase in body temperature, lethargy, inappetance, and muscle stiffness have also been observed. Very rarely reported symptoms have included urticaria, mild peripheral oedema and mild transient colic. Symptoms may vary in severity and on rare occasions may require veterinary intervention.

Systemic allergic reactions such as anaphylaxis are thought to occur rarely with all vaccines and may require parenteral treatment with adrenaline, corticosteroid and antihistamine as appropriate and should be followed with appropriate supportive therapy.

### **Withholding period**

Zero Days

### **Manufacturer**

Zoetis Australia Australia  
Research And Manufacturing Pty Ltd  
45 Popular Road  
Parkville  
VICTORIA 3052

### **Applicant name**

ZOETIS AUSTRALIA PTY LTD  
38-42 Wharf Road  
WEST RYDE NSW 2114

**Summary of the APVMA's evaluation of Equivac HeV Hendra Virus Vaccine for Horses 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 G-Protein (sG) of Hendra Virus (active constituent) and the product and found them to meet APVMA standard. The assessment included starting materials, master seeds (source, identity, and purity), culture media, vaccine production, quality control, shelf life and batch release analysis.

The APVMA is satisfied that the proposed use of G-Protein (sG) of Hendra Virus in the product, for the active immunisation of horses 4 months of age or older as an aid in the prevention of clinical disease caused by Hendra virus in horses, would not be likely to have an effect that is harmful to human beings, environment or trade. The adjuvant has been assessed and is already present in registered vaccines in Australia and the excipients are already present in several vaccines registered for use in Australia. They have been previously assessed and found to be safe.

In relation to its assessment of efficacy and safety in target animal the APVMA is satisfied that the data supporting the efficacy and safety of the product adequately demonstrate that this product is likely to be safe and effective under Australian conditions when used according to label instructions.

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 APVMA should grant the application for approval of the active constituent G-Protein (sG) of Hendra Virus and registration of the product.

Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined above that the APVMA is required to take into account in deciding whether to grant the application.

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.

When making a submission please include a:

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

Written submissions on the APVMA's proposal to grant approval for the active G-Protein (sG) of Hendra Virus, and registration of the product that relate to the grounds for approval should be addressed to:

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

Phone: +61 2 6210 4730

Fax: +61 2 6210 4736

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

## 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. 4)*) gazetted on 8 April 2014 (No. APVMA 8).

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 6, 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](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) 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 has 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](mailto:residues@apvma.gov.au)

***Australia New Zealand***  
***Food Standards Code —***  
**Standard 1.4.2—Maximum Residue Limits**  
**Amendment Instrument No. APVMA 6, 2014**

I, Rajumati Bhula, Executive Director, Pesticides Program and delegate of the Australian Pesticides and Veterinary Medicines Authority for the relevant purposes pursuant to 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 eleventh day of June 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 6, 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 12 of 17 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 –

<b>Abamectin</b>	
Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Peanut	T*0.002
<b>Chlorantraniliprole</b>	
<i>Plant commodities and animal commodities other than milk:</i> Chlorantraniliprole	
<i>Milk:</i> Sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole	
Strawberry	T0.5
<b>Cypermethrin</b>	
Cypermethrin, sum of isomers	
Onion, Welsh	T0.5
<b>Fipronil</b>	
Sum of fipronil, the sulphenyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulphenyl]-1H-pyrazole-3-carbonitrile), the sulphonyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulphonyl]-1H-pyrazole-3-carbonitrile), and the trifluoromethyl metabolite (5-amino-4-trifluoromethyl-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1H-pyrazole-3-carbonitrile)	
Celery	T0.3
Lettuce, head	T0.1
Lettuce, leaf	T0.1
<b>Flonicamid</b>	
Flonicamid [ <i>N</i> -(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [ <i>N</i> -(4-trifluoromethylnicotinoyl)glycine]	
Cotton seed	T1
Edible offal (mammalian)	T*0.02
Eggs	T*0.02
Meat (mammalian)	T*0.02
Milks	T*0.02
Poultry, edible offal of	T*0.02
Poultry meat	T*0.02
<b>Haloxypop</b>	
Sum of haloxypop, its esters and conjugates, expressed as haloxypop	
Chia	T3

<b>Metalaxyl</b> Metalaxyl	
Herbs [except chives, thyme]	T0.3
Kaffir lime leaves	T0.3
Lemon grass	T0.3
Lemon verbena (dry leaves)	T0.3
Rose and dianthus (edible flowers)	T0.3
Thyme	T0.5
Turmeric, root	T0.1
<b>Naphthalene acetic acid</b> 1-Naphthelene acetic acid	
Rambutan	T*0.05
<b>Prometryn</b> Prometryn	
Turmeric, root	T*0.01
<b>Pyroxasulfone</b> <i>Commodities of plant origin:</i> Sum of pyroxasulfone and (5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-yl)methanesulfonic acid, expressed as pyroxasulfone <i>Commodities of animal origin:</i> 5-Difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid, expressed as pyroxasulfone	
Pulses	T*0.01
<b>Spirotetramat</b> Sum of spirotetramat, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat	
Kiwifruit	T0.1
<b>Tebuconazole</b> Tebuconazole	
Radish	T0.3
Radish leaves	T2
<b>Tolclofos-methyl</b> Tolclofos-methyl	
Lettuce, head	T*0.01
Lettuce, leaf	T*0.01

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

<b>Metalaxyl</b> Metalaxyl	
Dill	T0.3
Parsley	0.3



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

<b>Azoxystrobin</b>	
Azoxystrobin	
Lettuce, head	T15
Lettuce, leaf	T15
<b>Bifenazate</b>	
Sum of bifenazate and bifenazate diazene (diazene-carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl-3-yl] 1-methylethyl ester), expressed as bifenazate	
Blackberries	T7
Cloudberry	T7
Dewberries (including boysenberry and loganberry)	T7
Raspberries, red, black	T7
<b>Ethephon</b>	
Ethephon	
Walnuts	T5
<b>Iprodione</b>	
Iprodione	
Celeriac	T0.7
Peppers	T3
<b>Metalaxyl</b>	
Metalaxyl	
Peppers	T0.1
<b>Pyrimethanil</b>	
Pyrimethanil	
Podded pea (young pods) (snow and sugar snap)	T10
<b>Tebuconazole</b>	
Tebuconazole	
Beetroot	T0.3
Beetroot leaves	T2
Chard (silver beet)	T2
Chicory leaves	T2
Endive	T2
Spinach	T2

## 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. 11, 3 JUNE 2014

For use in agricultural and/or veterinary chemical products:

Common Name	Approval Holder	Manufacturer and Site of Manufacture	Approval No.
<i>Bacillus thuringiensis</i> — subsp. <i>Israelensis</i> Strain HKA1999	EUREKA ! AGRESEARCH (VIC) PTY. LTD.	HUBEI KANGXIN AGRO-INDUSTRY CO., LTD NO. 8, NANHU AVENUE, HONGSHAN DISTRICT WUHAN 430064 P.R. CHINA	68890

### APVMA CONTACT

For further information please contact:

Case management and administration unit  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

**Phone:** +61 6 6210 4701

**Fax:** +61 6 6210 4721

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

## 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. 11, 3 JUNE 2014.

Application No.	Name
58981	DITHIANON
59727	WET & FORGET RAPID APPLICATION
60829	NOT AVAILABLE
60830	NOT AVAILABLE
60832	NOT AVAILABLE
61270	TERMINADE RESIDUAL TERMITICIDE
61541	YATES NATURE'S WAY VEGIE & HERB SPRAY CONCENTRATE
61544	YATES NATURE'S WAY VEGIE & HERB SPRAY
61735	RAPIDOL FUNGICIDE
61739	MANDESTROBIN
61979	NOT AVAILABLE
62225	OPTIPHOS 5000 LIQUID
62227	OPTIPHOS 20000 LIQUID
62229	OPTIPHOS 10000 LIQUID
62332	NOT AVAILABLE
62344	PAW PURE ANIMAL WELLBEING BY BLACKMORES DERMEGA OMEGA 3 & 6 ORAL SUPPLEMENT
62346	CARPRIEVE 75 MG CHEWABLE TABLETS FOR DOGS
62347	CARPRIEVE 25 MG CHEWABLE TABLETS FOR DOGS
62350	MELOXIMAV ORAL SUSPENSION FOR DOGS
62370	APOLLINI 510 K HERBICIDE
62405	Q-DRENCH MINERALISED MULTI-COMBINATION DRENCH FOR SHEEP
62412	SYSTIVA SEED TREATMENT FUNGICIDE
62616	TEBUCONAZOLE

Application No.	Name
62648	WELLFARM SIMAZINE 900 WG HERBICIDE
62664	WELLFARM 2,4-D AMINE 625 SL HERBICIDE
62666	WELLFARM PROPYZAMIDE 500 SC HERBICIDE
62677	WELLFARM TEBUCONAZOLE 430 SC FUNGICIDE
62688	HYMENOPHTHOR ULTRA GRANULAR COCKROACH BAIT
62690	WELLFARM TRIFLURALIN 480 EC HERBICIDE
62692	WELLFARM DIFLUFENICAN 25 + MCPA ISO-OCTYL ESTER 250 EC HERBICIDE
62707	ZODIAC STABILISED POOL CHLORINE
62711	ZODIAC POOL EZY SANITISER
62712	WELLFARM MCPA AMINE 500 SL HERBICIDE
62716	FENAMIPHOS
62727	FARMALINX BOMOXAPAC HERBICIDE
62804	WELLFARM BROMOXYNIL 200 EC HERBICIDE
58104	KENDON CARBARYL WETTABLE GRANULE INSECTICIDE
61138	NOT AVAILABLE
61761	NUFARM TAZER EXPERT FUNGICIDE
61781	INDOXACARB
61814	YATES ZERO RAPID 1-HR ACTION WEEDKILLER CONCENTRATE
61906	SELECT 3 IN 1 OUTDOOR, INDOOR & GARDEN SURFACE SPRAY
61909	SELECT PERMETHRIN ANT KILLER
62088	RAMETIN COMBO SHEEP DRENCH MIX PACK
62089	COMBO LV ORAL ANTHELMINTIC FOR SHEEP AND LAMBS
62091	OMETHOATE
62094	NUFARM RIFLE 440 HERBICIDE
62191	CONQUEST GUNNER 750 WG HERBICIDE
62194	NOT AVAILABLE
62249	MUSKIL DUAL ACTIVE RODENTICIDE BLOCKS WITH FLUO-NP TECHNOLOGY
62322	OZTEC 2,4-D AMINE 625 HERBICIDE
62382	KELPIE GFOS 200 HERBICIDE
62467	FARMALINX BINGO 250 YIELD AND QUALITY ENHANCER
62529	MORTEIN CRAWLING INSECT SURFACE SPRAY KILL & PROTECT HIGH PERFORMANCE EASY REACH FAST DIRECT KILL
62575	METALAXYL

Application No.	Name
62602	FARMALINX POWERQUAT 300 SL HERBICIDE
62675	PILARSATO 450 SL HERBICIDE

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

Application No.	Product/Active Constituent Name
61818	YATES CONFIDOR READY TO USE INSECTICIDE
60758	PIRANHA DIP FOR SHEEP

#### APVMA CONTACT

For further information please contact:

Case management and administration unit  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

**Phone:** +61 2 6210 4701

**Fax:** +61 2 6210 4721

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