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**Gazette**

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**AGRICULTURAL AND  
VETERINARY CHEMICALS**



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**

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

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## GENERAL INFORMATION

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

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

## DISTRIBUTION AND SUBSCRIPTION

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

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## Agricultural Chemical Products and Approved Labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

### 1. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

<b>Application no.:</b>	60731
<b>Product name:</b>	Starkle 200 SG Insecticide
<b>Active constituent/s:</b>	200 g/kg dinotefuran
<b>Applicant name:</b>	Agnova Technologies Pty Ltd
<b>Applicant ACN:</b>	097 705 158
<b>Summary of use</b>	For the control of silverleaf, whitefly and green mirid in cotton.
<b>Date of registration/approval:</b>	22 December 2015
<b>Product registration no.:</b>	69398
<b>Label approval no.:</b>	69398/60731

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

<b>Application no.:</b>	104066
<b>Product name:</b>	Relyon Paraquick 250 Herbicide
<b>Active constituent/s:</b>	250 g/L paraquat present as paraquat dichloride
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the control of a wide range of grasses and broadleaf weeds.
<b>Date of registration/approval:</b>	21 December 2015
<b>Product registration no.:</b>	81797
<b>Label approval no.:</b>	81797/104066

<b>Application no.:</b>	102522
<b>Product name:</b>	Weed Force Weed Stop Herbicide
<b>Active constituent/s:</b>	880 g/kg terbacil, 40 g/kg sulfometuron methyl
<b>Applicant name:</b>	Weed Force Pty Ltd
<b>Applicant ACN:</b>	602 207 152
<b>Summary of use</b>	For the control of certain annual and perennial weeds in commercial and industrial areas, around agricultural buildings, fence lines and rights of way and the control of certain annual and perennial weeds pre-plant in <i>E. globulus</i> and <i>E. nitens</i> plantations.
<b>Date of registration/approval:</b>	21 December 2015
<b>Product registration no.:</b>	81190
<b>Label approval no.:</b>	81190/102522

<b>Application no.:</b>	103786
<b>Product name:</b>	Rotam Shamal 500 SC Herbicide
<b>Active constituent/s:</b>	500 g/L propyzamide
<b>Applicant name:</b>	Rotam Agrochemical CO., LTD.
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For selective control of certain grasses and broadleaf weeds in lettuce, sports turf, lawn, legume seed crops and pastures.
<b>Date of registration/approval:</b>	21 December 2015
<b>Product registration no.:</b>	81711
<b>Label approval no.:</b>	81711/103786
<b>Application no.:</b>	103454
<b>Product name:</b>	Brunnings Ready to Use Wasp & Ant Dust Puffer Pack
<b>Active constituent/s:</b>	10 g/kg permethrin 25:75
<b>Applicant name:</b>	STV International Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For effectively controlling ants and wasps for domestic and home garden use.
<b>Date of registration/approval:</b>	22 December 2015
<b>Product registration no.:</b>	81610
<b>Label approval no.:</b>	81610/103454
<b>Application no.:</b>	104206
<b>Product name:</b>	Eureka! Clopyralid 750 SG Herbicide
<b>Active constituent/s:</b>	750 g/kg clopyralid present as the potassium salt
<b>Applicant name:</b>	Eureka! Agresearch Pty Ltd
<b>Applicant ACN:</b>	086 194 738
<b>Summary of use</b>	For the control of a wide range of broadleaf weeds in wheat, barley, oats, triticale, canola, pastures and fallow land.
<b>Date of registration/approval:</b>	22 December 2015
<b>Product registration no.:</b>	81866
<b>Label approval no.:</b>	81866/104206
<b>Application no.:</b>	102332
<b>Product name:</b>	Fullguard 240 Herbicide
<b>Active constituent/s:</b>	240 g/L carfentrazone-ethyl
<b>Applicant name:</b>	Shandong Rainbow International Co., Ltd.
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For the control of marshmallow and certain other broadleaf weeds prior to establishment of crops, fallows or forest plantations, in commercial, industrial and public service areas, around agricultural buildings and yards, in tree fruits, nuts, grapevines in tank mixture with knockdown herbicides; control of marshmallow and annual nettles in grass pastures and rough grass/turf areas; and control of volunteer cotton seedlings and desiccation of cotton re-growth.
<b>Date of registration/approval:</b>	23 December 2015
<b>Product registration no.:</b>	81110
<b>Label approval no.:</b>	81110/102332

<b>Application no.:</b>	103484
<b>Product name:</b>	Sinon Eco Surfactant
<b>Active constituent/s:</b>	1020 g/L polyether modified polysiloxane
<b>Applicant name:</b>	Sinon Australia Pty Limited
<b>Applicant ACN:</b>	102 741 024
<b>Summary of use</b>	For use as a spray additive for improved penetration of several agricultural pesticides.
<b>Date of registration/approval:</b>	6 January 2016
<b>Product registration no.:</b>	81627
<b>Label approval no.:</b>	81627/103484
<b>Application no.:</b>	101261
<b>Product name:</b>	Nozomi Herbicide
<b>Active constituent/s:</b>	500 g/kg flumioxazin
<b>Applicant name:</b>	Sumitomo Chemical Australia Pty Limited
<b>Applicant ACN:</b>	081 096 255
<b>Summary of use</b>	For knockdown and residual control of various grass and broadleaf weeds in sugarcane.
<b>Date of registration/approval:</b>	8 January 2016
<b>Product registration no.:</b>	80606
<b>Label approval no.:</b>	80606/101261
<b>Application no.:</b>	104058
<b>Product name:</b>	Relyon Sprayquick Herbicide
<b>Active constituent/s:</b>	135 g/L paraquat present as paraquat dichloride, 115g/L diquat present as diquat dibromide
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the control of a wide range of grasses and broadleaf weeds.
<b>Date of registration/approval:</b>	11 January 2016
<b>Product registration no.:</b>	81790
<b>Label approval no.:</b>	81790/104058
<b>Application no.:</b>	104130
<b>Product name:</b>	Relyon Circus 520 EC Herbicide
<b>Active constituent/s:</b>	520 g/L haloxyfop present as the haloxyfop-r-methyl ester
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the post-emergent control of a wide range of annual and perennial grass weeds in grain legume and oilseed crops, lucerne, medic and clove pasture and seeds crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops.
<b>Date of registration/approval:</b>	11 January 2016
<b>Product registration no.:</b>	81829
<b>Label approval no.:</b>	81829/104130

<b>Application no.:</b>	104127
<b>Product name:</b>	Alpha Glufosinate 200SL Herbicide
<b>Active constituent/s:</b>	200 g/L glufosinate-ammonium
<b>Applicant name:</b>	Alpha Crop Protection Pty Ltd
<b>Applicant ACN:</b>	165 653 047
<b>Summary of use</b>	For the non-residual control of broadleaf and grass weeds in various situations.
<b>Date of registration/approval:</b>	11 January 2016
<b>Product registration no.:</b>	81825
<b>Label approval no.:</b>	81825/104127
<b>Application no.:</b>	103798
<b>Product name:</b>	Rotam Proten 250 EC Fungicide
<b>Active constituent/s:</b>	250 g/L propiconazole.
<b>Applicant name:</b>	Rotam Agrochemical Co., Ltd.
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For the control of certain fungal diseases of bananas, peanuts, pineapples, stone fruit, sugar cane, wheat and other crops.
<b>Date of registration/approval:</b>	12 January 2016
<b>Product registration no.:</b>	81714
<b>Label approval no.:</b>	81714/103798
<b>Application no.:</b>	104139
<b>Product name:</b>	Alpha Tebuconazole 430SC Fungicide
<b>Active constituent/s:</b>	430 g/L tebuconazole
<b>Applicant name:</b>	Alpha Crop Protection Pty Ltd
<b>Applicant ACN:</b>	165 653 047
<b>Summary of use</b>	For the control of leaf spot and leaf speckle on bananas; rust, leaf spot and net blotch of peanuts; foliar diseases on cereal crops; and other diseases on beans, peas, onions, pawpaw, pyrethrum and ryegrass and fescue seed crops.
<b>Date of registration/approval:</b>	12 January 2016
<b>Product registration no.:</b>	81836
<b>Label approval no.:</b>	81836/104139
<b>Application no.:</b>	104055
<b>Product name:</b>	Relyon Optane LV 680 Herbicide
<b>Active constituent/s:</b>	680 g/L 2,4-D present as the 2-ethylhexyl ester
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For selective control of various weeds in crops, pastures and non-agricultural areas.
<b>Date of registration/approval:</b>	12 January 2016
<b>Product registration no.:</b>	81788
<b>Label approval no.:</b>	81788/104055

<b>Application no.:</b>	102322
<b>Product name:</b>	Metsuram 600 WG Herbicide
<b>Active constituent/s:</b>	600 g/kg metsulfuron methyl
<b>Applicant name:</b>	Rotam Agrochemical Co., Ltd.
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For use in native pastures, rights of way, commercial and industrial areas to control brush and broadleaf weeds and in winter cereal crops for the control of certain broadleaved weeds.
<b>Date of registration/approval:</b>	13 January 2016
<b>Product registration no.:</b>	81100
<b>Label approval no.:</b>	81100/102322
<b>Application no.:</b>	104138
<b>Product name:</b>	Alpha Glyphosate Dry 700SG Herbicide
<b>Active constituent/s:</b>	700 g/kg glyphosate present as the mono-ammonium salt
<b>Applicant name:</b>	Alpha Crop Protection Pty Ltd
<b>Applicant ACN:</b>	165 653 047
<b>Summary of use</b>	For the control of many annual and perennial weeds in certain situations.
<b>Date of registration/approval:</b>	13 January 2016
<b>Product registration no.:</b>	81835
<b>Label approval no.:</b>	81835/104138
<b>Application no.:</b>	101678
<b>Product name:</b>	Bronco 400 Herbicide
<b>Active constituent/s:</b>	400 g/L bromoxynil present as the n-octanoyl ester
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use</b>	For control of a range of broadleaf weeds in cereals, linseed, clover, lucerne, turf, fallow and non-crop situations.
<b>Date of registration/approval:</b>	13 January 2016
<b>Product registration no.:</b>	80801
<b>Label approval no.:</b>	80801/101678
<b>Application no.:</b>	62931
<b>Product name:</b>	Imtrade Noscllex 800 WG Fungicide
<b>Active constituent/s:</b>	800 g/kg procymidone
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of use</b>	For the control of certain fungal diseases on various crops as specified in the directions for use table.
<b>Date of registration/approval:</b>	13 January 2016
<b>Product registration no.:</b>	70284
<b>Label approval no.:</b>	70284/62931
<b>Application no.:</b>	102499
<b>Product name:</b>	Rotam Picloram + Triclopyr (100 + 300) Herbicide
<b>Active constituent/s:</b>	100 g/L picloram present as hexyloxypropylamine salt, 300 g/L triclopyr present as the butoxyethyl ester.
<b>Applicant name:</b>	Rotam Agrochemical Co., Ltd.
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For control of a range of environmental and noxious woody and herbaceous weeds.
<b>Date of registration/approval:</b>	14 January 2016
<b>Product registration no.:</b>	81179
<b>Label approval no.:</b>	81179/102499



<b>Application no.:</b>	102757
<b>Product name:</b>	Hovex Fly & Mosquito Coils
<b>Active constituent/s:</b>	4 g/kg d-allethrin, 0.5 g/kg citronella oil
<b>Applicant name:</b>	Pascoe's Pty Ltd
<b>Applicant ACN:</b>	055 220 463
<b>Summary of use</b>	To control flies and mosquitoes around the home.
<b>Date of registration/approval:</b>	14 January 2016
<b>Product registration no.:</b>	81293
<b>Label approval no.:</b>	81293/102757
<b>Application no.:</b>	103277
<b>Product name:</b>	Hovex Outdoor Fogger
<b>Active constituent/s:</b>	1.1 g/kg esbiothrin, 0.5 g/kg permethrin
<b>Applicant name:</b>	Pascoe's Pty Ltd
<b>Applicant ACN:</b>	055 220 463
<b>Summary of use</b>	For use against flying insects in the home and garden.
<b>Date of registration/approval:</b>	14 January 2016
<b>Product registration no.:</b>	81517
<b>Label approval no.:</b>	81517/103277
<b>Application no.:</b>	103594
<b>Product name:</b>	Hovex Indoor Automatic Insect Control System
<b>Active constituent/s:</b>	9 g/kg pyrethrins, 45 g/kg piperonyl butoxide
<b>Applicant name:</b>	Pascoe's Pty Ltd
<b>Applicant ACN:</b>	055 220 463
<b>Summary of use</b>	For the control of crawling and flying insects in and around the home.
<b>Date of registration/approval:</b>	14 January 2016
<b>Product registration no.:</b>	81672
<b>Label approval no.:</b>	81672/103594
<b>Application no.:</b>	103598
<b>Product name:</b>	Hovex Outdoor Automatic Insect Control System
<b>Active constituent/s:</b>	9 g/kg pyrethrins, 45 g/kg piperonyl butoxide
<b>Applicant name:</b>	Pascoe's Pty Ltd
<b>Applicant ACN:</b>	055 220 463
<b>Summary of use</b>	For the control of crawling and flying insects in and around the home.
<b>Date of registration/approval:</b>	14 January 2016
<b>Product registration no.:</b>	81674
<b>Label approval no.:</b>	81674/103598
<b>Application no.:</b>	101813
<b>Product name:</b>	Fist Hydrocap Herbicide
<b>Active constituent/s:</b>	456 g/L pendimethalin
<b>Applicant name:</b>	UPL Australia Limited
<b>Applicant ACN:</b>	066 391 384
<b>Summary of use</b>	For the control of wireweed, annual grasses (including annual ryegrass) and certain broadleaf weeds in various crops.
<b>Date of registration/approval:</b>	15 January 2016
<b>Product registration no.:</b>	80856
<b>Label approval no.:</b>	80856/101813

<b>Application no.:</b>	104128
<b>Product name:</b>	Alpha Atrazine 900WG Herbicide
<b>Active constituent/s:</b>	900 g/kg atrazine
<b>Applicant name:</b>	Alpha Crop Protection Pty Ltd
<b>Applicant ACN:</b>	165 653 047
<b>Summary of use</b>	For the control of weeds and grasses in sorghum, maize, sugar cane, TT canola, lucerne and fallow area maintenance.
<b>Date of registration/approval:</b>	18 January 2016
<b>Product registration no.:</b>	81826
<b>Label approval no.:</b>	81826/104128
<b>Application no.:</b>	104199
<b>Product name:</b>	Relyon Prozam 500 WG Herbicide
<b>Active constituent/s:</b>	500 g/kg propyzamide
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For selective control of certain grasses and broadleaf weeds in lettuce, sports turf, home lawns and legumes, seed crops and pastures.
<b>Date of registration/approval:</b>	18 January 2016
<b>Product registration no.:</b>	81862
<b>Label approval no.:</b>	81862/104199
<b>Application no.:</b>	104122
<b>Product name:</b>	Alpha Trifluralin 480EC Herbicide
<b>Active constituent/s:</b>	480 g/L trifluralin
<b>Applicant name:</b>	Alpha Crop Protection Pty Ltd
<b>Applicant ACN:</b>	165 653 047
<b>Summary of use</b>	For use as a pre-emergence herbicide for the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops.
<b>Date of registration/approval:</b>	18 January 2016
<b>Product registration no.:</b>	81821
<b>Label approval no.:</b>	81821/104122
<b>Application no.:</b>	104146
<b>Product name:</b>	Relyon Insight 300 Herbicide
<b>Active constituent/s:</b>	300 g/L clopyralid present as the triisopropanolamine salt
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the control of a wide range of broadleaf weeds in wheat, barley, triticale, oats, pastures, canola, fallow land, forests and industrial situations.
<b>Date of registration/approval:</b>	19 January 2016
<b>Product registration no.:</b>	81843
<b>Label approval no.:</b>	81843/104146

<b>Application no.:</b>	104335
<b>Product name:</b>	Relyon Omethon 290 Insecticide
<b>Active constituent/s:</b>	290 g/L omethoate (an anticholinesterase compound)
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the control of redlegged earth mite, blue oat mite and lucerne flea on pastures, cereals, oilseed and legume crops, and bluegreen aphid and cowpea aphid on pasture legumes, lucerne, faba beans and vetch.
<b>Date of registration/approval:</b>	19 January 2016
<b>Product registration no.:</b>	81882
<b>Label approval no.:</b>	81882/104335

<b>Application no.:</b>	104338
<b>Product name:</b>	Relyon Samba 500 Herbicide
<b>Active constituent/s:</b>	500 g/L dicamba (present as the dimethylamine salt)
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the control of certain broadleaf weeds in winter cereals, pastures, conservation tillage, sugar cane, turf, rice, grain sorghum and non-crop areas.
<b>Date of registration/approval:</b>	19 January 2016
<b>Product registration no.:</b>	81884
<b>Label approval no.:</b>	81884/104338

### 3. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	105069
<b>Product name:</b>	Hortico Insect & Disease Control Ready To Spray Roses & Flowers
<b>Active constituent/s:</b>	0.1 g/L tau-fluvalinate, 0.05 g/L myclobutanil
<b>Applicant name:</b>	Duluxgroup (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 049 427
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'HORTICO ROSE SPRAY READY TO USE' to 'HORTICO INSECT & DISEASE CONTROL READY TO SPRAY ROSES & FLOWERS'.
<b>Date of variation:</b>	1 December 2015
<b>Product no.:</b>	60756
<b>Label approval no.:</b>	60756/105069

<b>Application no.:</b>	105081
<b>Product name:</b>	AC Fearsome 500 Fungicide
<b>Active constituent/s:</b>	500 g/L flutriafol
<b>Applicant name:</b>	Axichem Pty Ltd
<b>Applicant ACN:</b>	131 628 594
<b>Summary of variation:</b>	To add a 1 L-1000 L pack size range.
<b>Date of variation:</b>	2 December 2015
<b>Product registration no.:</b>	68744
<b>Label approval no.:</b>	68744/105081

<b>Application no.:</b>	105083
<b>Product name:</b>	AC Impressor 600 Seed Dressing
<b>Active constituent/s:</b>	600 g/L imidacloprid
<b>Applicant name:</b>	Axichem Pty Ltd
<b>Applicant ACN:</b>	131 628 594
<b>Summary of variation:</b>	To add a 1 L-1000 L pack size range.
<b>Date of variation:</b>	2 December 2015
<b>Product registration no.:</b>	65197
<b>Label approval no.:</b>	65197/105083
<b>Application no.:</b>	105086
<b>Product name:</b>	Hortico Insect Killer Ready To Spray Trees & Shrubs
<b>Active constituent/s:</b>	0.125 g/L imidacloprid
<b>Applicant name:</b>	Duluxgroup (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 049 427
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'HORTICO IMIDACLOPRID SYSTEMIC INSECT KILLER' to 'HORTICO INSECT KILLER READY TO SPRAY TREES & SHRUBS'.
<b>Date of variation:</b>	2 December 2015
<b>Product no.:</b>	67089
<b>Label approval no.:</b>	67089/105086
<b>Application no.:</b>	105115
<b>Product name:</b>	Family Protection Aerogard Odourless Protection 4 Hours Protection Low Irritant*Great For Kids 12 Months + Insect Repellent Roll On
<b>Active constituent/s:</b>	99.6 g/L picaridin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'FAMILY PROTECTION AEROGARD LOW IRRITANT* ODOURLESS 4 HOURS PROTECTION GREAT FOR KIDS 12 MONTHS + INSECT REPELLENT ROLL ON' to 'FAMILY PROTECTION AEROGARD ODOURLESS PROTECTION 4 HOURS PROTECTION LOW IRRITANT* GREAT FOR KIDS 12 MONTHS + INSECT REPELLENT ROLL ON'.
<b>Date of variation:</b>	4 December 2015
<b>Product no.:</b>	61363
<b>Label approval no.:</b>	61363/105115
<b>Application no.:</b>	105116
<b>Product name:</b>	Family Protection Aerogard Odourless Protection 4 Hours Protection Low Irritant* Great For Kids 12 Months + Insect Repellent Spray
<b>Active constituent/s:</b>	92.8 g/L picaridin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'FAMILY PROTECTION AEROGARD LOW IRRITANT* ODOURLESS 4 HOURS PROTECTION GREAT FOR KIDS 12 MONTHS + INSECT REPELLENT SPRAY' to 'FAMILY PROTECTION AEROGARD ODOURLESS PROTECTION 4 HOURS PROTECTION LOW IRRITANT* GREAT FOR KIDS 12 MONTHS + INSECT REPELLENT SPRAY'.
<b>Date of variation:</b>	4 December 2015
<b>Product no.:</b>	61365
<b>Label approval no.:</b>	61365/105116

<b>Application no.:</b>	105183
<b>Product name:</b>	Enviromax Fipronil 200SC Insecticide
<b>Active constituent/s:</b>	200 g/L fipronil
<b>Applicant name:</b>	Enviromax Technologies Pty Ltd
<b>Applicant ACN:</b>	132 643 577
<b>Summary of variation:</b>	To add a 1 L – 200 L pack size range.
<b>Date of variation:</b>	17 December 2015
<b>Product registration no.:</b>	65313
<b>Label approval no.:</b>	65313/105183
<b>Application no.:</b>	105206
<b>Product name:</b>	Sabakem Chlorpyrifos 500EC Insecticide
<b>Active constituent/s:</b>	500 g/L chlorpyrifos
<b>Applicant name:</b>	Sabakem Pty Ltd
<b>Applicant ACN:</b>	151 682 138
<b>Summary of variation:</b>	To add a 110 L pack size
<b>Date of variation:</b>	17 December 2015
<b>Product registration no.:</b>	67451
<b>Label approval no.:</b>	67451/105206
<b>Application no.:</b>	105219
<b>Product name:</b>	Imtrade Metakill Snail & Slug Bait
<b>Active constituent/s:</b>	50 g/kg metaldehyde
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of variation:</b>	To add a 500 g – 1000 kg pack size range.
<b>Date of variation:</b>	18 December 2015
<b>Product registration no.:</b>	64990
<b>Label approval no.:</b>	64990/105219
<b>Application no.:</b>	105236
<b>Product name:</b>	Green Guard SC Premium Biological Insecticide
<b>Active constituent/s:</b>	100 g/L metarhizium anisopliae var acridum spores
<b>Applicant name:</b>	BASF Agricultural Specialties Pty Ltd
<b>Applicant ACN:</b>	107 914 563
<b>Summary of variation:</b>	To add a 1 L and 6 x 1 L pack size.
<b>Date of variation:</b>	21 December 2015
<b>Product registration no.:</b>	61596
<b>Label approval no.:</b>	61596/105236
<b>Application no.:</b>	102794
<b>Product name:</b>	AW Trifluralin 480 Selective Herbicide
<b>Active constituent/s:</b>	480 g/L trifluralin
<b>Applicant name:</b>	Agri West Pty Limited
<b>Applicant ACN:</b>	108 899 181
<b>Summary of variation:</b>	To add additional 20 L and 200 L pack sizes.
<b>Date of variation:</b>	12 January 2016
<b>Product registration no.:</b>	59247
<b>Label approval no.:</b>	59247/102794

<b>Application no:</b>	102557
<b>Product name:</b>	SAS Mothballs
<b>Active constituent/s:</b>	990 g/kg naphthalene
<b>Applicant name:</b>	PJ SAS Trading Pty Limited
<b>Applicant ACN:</b>	088 137 017
<b>Summary of variation:</b>	To add an additional 3 x 9 g pack size.
<b>Date of variation:</b>	15 January 2016
<b>Product registration no.:</b>	63747
<b>Label approval no.:</b>	63747/102557
<b>Application no:</b>	102935
<b>Product name:</b>	Weed Force Renovate Herbicide
<b>Active constituent/s:</b>	600 g/kg metsulfuron-methyl
<b>Applicant name:</b>	Weed Force Pty Ltd
<b>Applicant ACN:</b>	602 207 152
<b>Summary of variation:</b>	To add new pack size range of 40 g - 1.5 kg.
<b>Date of variation:</b>	18 January 2016
<b>Product registration no.:</b>	80776
<b>Label approval no.:</b>	80776/102935
<b>Application no:</b>	102830
<b>Product name:</b>	Weed Force Gusto Herbicide
<b>Active constituent/s:</b>	750 g/kg sulfometuron methyl
<b>Applicant name:</b>	Weed Force Pty Ltd
<b>Applicant ACN:</b>	602 207 152
<b>Summary of variation:</b>	To add pack size range of 200 g - 1.5 kg.
<b>Date of variation:</b>	18 January 2016
<b>Product registration no.:</b>	80733
<b>Label approval no.:</b>	80733/102830
<b>Application no.:</b>	100679
<b>Product name:</b>	Couraze Classic Insecticide
<b>Active constituent/s:</b>	350 g/L imidacloprid
<b>Applicant name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of variation:</b>	To extend uses to include potatoes.
<b>Date of variation:</b>	18 December 2015
<b>Product registration no.:</b>	61591
<b>Label approval no.:</b>	61591/100679
<b>Application no.:</b>	103425
<b>Product name:</b>	Permatek 100 Encaps Timber Insecticide
<b>Active constituent/s:</b>	100 g/L bifenthrin
<b>Applicant name:</b>	Zelam Pty Ltd
<b>Applicant ACN:</b>	082 428 028
<b>Summary of variation:</b>	To extend uses to include H2 S glueline treatment for hardwood, plywood and LVL.
<b>Date of variation:</b>	19 January 2016
<b>Product registration no.:</b>	60241
<b>Label approval no.:</b>	60241/103425

<b>Application no.:</b>	102645
<b>Product name:</b>	Loveland Products MSO with Leci-Tech Spray Adjuvant
<b>Active constituent/s:</b>	630 g/L methyl esters of vegetable oil
<b>Applicant name:</b>	Loveland Products, Inc.
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	To add certain companion products to the registered label and to increase the application rate to control difficult weeds.
<b>Date of approval:</b>	24 December 2015
<b>Label approval no.:</b>	70101/102645

<b>Application no.:</b>	104879
<b>Product name:</b>	Nufarm Dimethoate Systemic Insecticide
<b>Active constituent/s:</b>	400 g/L dimethoate (an anti-cholinesterase compound)
<b>Applicant name:</b>	Nufarm Australia Limited
<b>Applicant ACN:</b>	004 377 780
<b>Summary of use:</b>	To vary the label in accordance with the review of dimethoate.
<b>Date of approval:</b>	18 January 2016
<b>Label approval no.:</b>	32962/104879

#### 4. LABEL APPROVAL

<b>Application no.:</b>	104438
<b>Product name:</b>	Farmoz Rodex B Rodenticide Pellets
<b>Active constituent/s:</b>	0.05 g/kg Brodifacoum
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use:</b>	To add an additional label name to the product 'AMGROW PATROL RODEX RODENT PELLETS'.
<b>Date of approval:</b>	13 January 2016
<b>Label approval no.:</b>	48793/104438

<b>Application no.:</b>	104439
<b>Product name:</b>	Farmoz Rodex B Rat Blocks
<b>Active constituent/s:</b>	0.05 g/kg brodifacoum
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use:</b>	To add an additional label name to the product under 'AMGROW PATROL RODEX RAT BLOCKS'.
<b>Date of approval:</b>	13 January 2016
<b>Label approval no.:</b>	50363/104439

## Veterinary Chemical Products and Approved Labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

### 1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

<b>Application no.:</b>	103889
<b>Product name:</b>	Beezed LV Anthelmintic for Sheep Cattle and Goats
<b>Active constituent/s:</b>	45.3 g/L oxfendazole
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the control of mature and immature roundworms, lungworms and tapeworms in sheep, cattle and goats.
<b>Date of registration/approval:</b>	22 December 2015
<b>Product registration no.:</b>	81725
<b>Label approval no.:</b>	81725/103889
<b>Application no.:</b>	103891
<b>Product name:</b>	Leviclear Oral Anthelmintic for Sheep And Cattle
<b>Active constituent/s:</b>	32 g/L Levamisole Hydrochloride
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the treatment of gastro-intestinal parasites and lungworm in sheep and cattle.
<b>Date of registration/approval:</b>	22 December 2015
<b>Product registration no.:</b>	81726
<b>Label approval no.:</b>	81726/103891
<b>Application no.:</b>	103897
<b>Product name:</b>	Combinator LV Plus Selenium Oral Anthelmintic For Sheep
<b>Active constituent/s:</b>	67.8 g/L levamisole (as levamisole hydrochloride), 50g/L fenbendazole, 1 g/L selenium (as sodium selenate)
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For control of levamisole and fenbendazole sensitive mature and immature roundworms in sheep and lambs and as an aid in controlling selenium deficiencies in sheep and lambs.
<b>Date of registration/approval:</b>	23 December 2015
<b>Product registration no.:</b>	81727
<b>Label approval no.:</b>	81727/103897



<b>Application no.:</b>	104087
<b>Product name:</b>	TIXFIX Pour-On Tick Development Inhibitor
<b>Active constituent/s:</b>	25 g/L fluazuron
<b>Applicant name:</b>	Merial Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of use</b>	For strategic control of the cattle tick, <i>hipicephalus microplus</i> , (including all known acaricide resistant strains) on beef cattle.
<b>Date of registration/approval:</b>	23 December 2015
<b>Product registration no.:</b>	81807
<b>Label approval no.:</b>	81807/104087
<b>Application no.:</b>	55750
<b>Product name:</b>	Troy Vangard Allwormer Tablets For Small Dogs
<b>Active constituent/s:</b>	Each tablet contains 75 mg febantel, 15 mg praziquantel, 14.9 mg pyrantel as the embonate
<b>Applicant name:</b>	Troy Laboratories Pty Ltd
<b>Applicant ACN:</b>	000 283 769
<b>Summary of use</b>	For use in the control of gastrointestinal worms, tapeworms and the shedding of giardia spp. oocysts in small dogs.
<b>Date of registration/approval:</b>	23 December 2015
<b>Product registration no.:</b>	67312
<b>Label approval no.:</b>	67312/55750
<b>Application no.:</b>	55751
<b>Product name:</b>	Troy Vangard Allwormer Tablets For Medium Dogs
<b>Active constituent/s:</b>	Each tablet contains 250 mg febantel, 50 mg praziquantel, 49.8 mg pyrantel (as the embonate)
<b>Applicant name:</b>	Troy Laboratories Pty Ltd
<b>Applicant ACN:</b>	000 283 769
<b>Summary of use</b>	For use in the control of gastrointestinal worms, tapeworms and the shedding of giardia spp. oocysts in medium dogs.
<b>Date of registration/approval:</b>	23 December 2015
<b>Product registration no.:</b>	67313
<b>Label approval no.:</b>	67313/55751
<b>Application no.:</b>	104084
<b>Product name:</b>	Combinator Plus Selenium Oral Anthelmintic for Sheep
<b>Active constituent/s:</b>	40 g/L levamisole (as hydrochloride), 25 g/L fenbendazole, 0.5 g/L selenium (as sodium selenate)
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For use in the control of levamisole and fenbendazole sensitive mature and immature roundworms in sheep and lambs, and as an aid in controlling selenium deficiencies in sheep and lambs.
<b>Date of registration/approval:</b>	23 December 2015
<b>Product registration no.:</b>	81804
<b>Label approval no.:</b>	81804/104084

<b>Application no.:</b>	103899
<b>Product name:</b>	Beezed Broad Spectrum Anthelmintic for Sheep, Lambs and Goats
<b>Active constituent/s:</b>	19 g/L albendazole
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the control of benzimidazole-sensitive mature and immature gastrointestinal roundworms, large lungworms, tapeworms and aids in control of adult liver fluke in sheep, lambs and goats.
<b>Date of registration/approval:</b>	13 January 2016
<b>Product registration no.:</b>	81728
<b>Label approval no.:</b>	81728/103899

<b>Application no.:</b>	104050
<b>Product name:</b>	Cattlemax Injection Antiparasitic for Cattle
<b>Active constituent/s:</b>	10 mg/mL ivermectin
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For treatment of ivermectin sensitive parasites of cattle.
<b>Date of registration/approval:</b>	15 January 2016
<b>Product registration no.:</b>	81783
<b>Label approval no.:</b>	81783/104050

## 2. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	105149
<b>Product name:</b>	Mecmax Antiparasitic Injection For Cattle
<b>Active constituent/s:</b>	10 mg/ml ivermectin
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of variation:</b>	To change the distinguishing product name from 'CATTLEMAX ANTIPARASITIC INJECTION FOR CATTLE' to 'MECMAX ANTIPARASITIC INJECTION FOR CATTLE'.
<b>Date of variation:</b>	10 December 2015
<b>Product registration no.:</b>	52528
<b>Label approval no.:</b>	52528/105149

<b>Application no.:</b>	103910
<b>Product name:</b>	Equivac HeV Hendra Virus Vaccine for Horses
<b>Active constituent/s:</b>	100 µg/mL g-potein (sG) of hendra virus
<b>Applicant name:</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN:</b>	156 476 425
<b>Summary of variation:</b>	To extend the use to include foals and pregnant mares.
<b>Date of variation:</b>	20 January 2016
<b>Product registration no.:</b>	68996
<b>Label approval no.:</b>	68996/103910

## Approved Active Constituents

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

### 1. ACTIVE CONSITUTENT

<b>Application no.:</b>	102574
<b>Active constituent/s:</b>	Diuron
<b>Applicant name:</b>	Sanonda (Australia) Pty Ltd
<b>Applicant ACN:</b>	059 813 973
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	16 December 2015
<b>Approval no.:</b>	81216

<b>Application no.:</b>	101745
<b>Active constituent/s:</b>	Florasulam
<b>Applicant name:</b>	<b>Error! Reference source not found.</b>
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	24 December 2015
<b>Approval no.:</b>	80830

<b>Application no.:</b>	102738
<b>Active constituent/s:</b>	Fludioxonil
<b>Applicant name:</b>	Agroserve Pty Ltd
<b>Applicant ACN:</b>	163 422 464
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	5 January 2016
<b>Approval no.:</b>	81283

<b>Application no.:</b>	102824
<b>Active constituent/s:</b>	Triclopyr Butoxyethyl Ester
<b>Applicant name:</b>	Jiangsu Pesticide Research Institute Company Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	15 January 2016
<b>Approval no.:</b>	81325

<b>Application no.:</b>	102726
<b>Active constituent/s:</b>	Transfluthrin
<b>Applicant name:</b>	Tagros Chemicals India, Ltd.
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in agricultural chemical products.
<b>Date of approval:</b>	19 January 2016
<b>Approval no.:</b>	81276

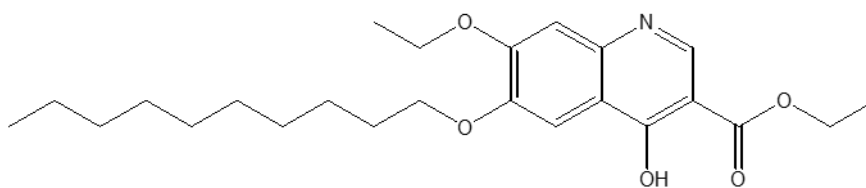
## New Active Constituent Decoquinolate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Zoetis Australia Pty Ltd for the approval of a new active constituent, decoquinolate, and an application for the registration of a new product containing the new active constituent. The product is DECCOX.

### PARTICULARS OF THE ACTIVE CONSTITUENT

<b>Common name:</b>	Decoquinolate
<b>IUPAC name:</b>	Ethyl 6- <i>n</i> -decyloxy-7-ethoxy-4-quinoline-3-carboxylate
<b>CAS name:</b>	3-quinolinecarboxylic acid, 6-(decyloxy)-7-ethoxy-4-hydroxy-, ethyl ester
<b>CAS registry number:</b>	18507-89-6
<b>Manufacturer's codes:</b>	E11280809
<b>Minimum purity:</b>	98%
<b>Molecular formula:</b>	C <sub>24</sub> H <sub>35</sub> NO <sub>5</sub>
<b>Molecular weight:</b>	417.54

**Structure:**



<b>Chemical family:</b>	Quinolone
<b>Mode of action:</b>	Coccidiostat that arrests the development of sporozoites of <i>Eimeria</i> spp.

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

Decoquinolate is a new active constituent for which there is no compendial specification available.

The APVMA has evaluated the chemistry aspects of decoquinolate active constituent. The assessment includes consideration of the manufacturing process and quality control procedures, the impurities, analysis of the chemical composition (batch analysis and analytical method inclusive), specifications, stability and packaging. The APVMA found these details of the active constituent acceptable.

The Office of Chemical Safety (OCS) within the Department of Health has completed a toxicology evaluation of decoquinolate. The OCS found that decoquinolate is a low acute oral toxicant and a low acute inhalational toxicant. Decoquinolate is expected to be of low acute dermal toxicity since the compound is poorly soluble, and is neither a skin irritant nor a skin sensitiser. Toxicity is low following repeat-dosing. The active constituent is not an eye irritant or a carcinogen. It does not cause effects on reproductive parameters. Although it does not cause maternal effects in developmental studies, it causes minor developmental variations, such as retarded skeletal ossification, in foetal animals. Decoquinolate is not teratogenic and was negative in a range of *in vitro* mutagenicity/genotoxicity studies. The weight of evidence indicates that decoquinolate is not genotoxic.

The current Acceptable Daily Intake (ADI) for decoquinate has been revised to 0.075 mg/kg bw/d. The revision is based on a NOEL of 15 mg/kg bw/d from a 12-week study in dogs. To this NOEL, a 200-fold safety factor has been applied. The safety factor consists of factors of 10 each for intra-species and inter-species variation, together with an additional factor of 2 for the database which consisted largely of studies that were conducted prior to Good Laboratory Practice.

An Acute Reference Dose (ARfD) for decoquinate has not been considered necessary since the acute toxicity studies and reproductive/developmental toxicity studies suggest that the acute effects associated with a single exposure to decoquinate are unlikely to present an acute hazard to people.

The Delegate to the Secretary of the Department of Health for scheduling has included decoquinate in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons.

The APVMA accepts the findings and recommendations of its advisors on the safety criteria. The APVMA is satisfied that the proposed use of decoquinate would not be an undue hazard to the safety of people exposed to it during its handling and use.

#### **PARTICULARS OF THE PRODUCT**

<b>Proposed product name:</b>	<b>DECCOX</b>
<b>Applicant company:</b>	Zoetis Australia Pty Limited
<b>Name of active constituent:</b>	Decoquinate
<b>Signal heading:</b>	Schedule 5
<b>Summary of proposed use:</b>	For the prevention and control of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. mivati</i> , <i>E. maxima</i> and <i>E. brunetti</i> in broiler chickens.
<b>Pack sizes:</b>	25 kg
<b>Withholding period:</b>	Meat: Zero (0) days. Eggs: DO NOT USE in chickens which are producing or may in the future produce eggs or egg products which may be used or processed for human consumption. Restraint: DO NOT USE in laying hens.

#### **SUMMARY OF THE APVMA'S EVALUATION OF DECCOX IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994**

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:
  - (i) The APVMA is satisfied that the proposed use of **DECCOX** would not be an undue hazard to the safety of people exposed to it during its handling and use.

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

The OCS has estimated the acute toxicity of **DECCOX** based on information that was provided for decoquinatate and information available on the excipients in the formulation. The OCS has concluded that **DECCOX** is expected to have low acute oral, dermal and inhalational toxicity. **DECCOX** is expected to be neither a skin irritant nor a skin sensitiser. The product is expected to be a slight eye irritant.

Human exposure on broiler farms to **DECCOX** is expected to be minimal since the feed distribution will be mostly automatic. Margin of Exposure estimates have indicated that the risk from repeated exposure is acceptable, such that personal protective equipment is not required.

To mitigate the acute and repeat-dose risks associated with **DECCOX**, the OCS has recommended first aid statement (a) – *If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26*. This first aid instruction will be included on the product label. The OCS has recommended the following safety directions – *May irritate the eyes. Avoid contact with eyes. Wash hands after use*. These safety directions will be included on the product labels. Precautionary re-entry or re-handling statements are not required, considering the toxicity profile of decoquinatate and **DECCOX**, and that the re-handling of treated feed is limited through automation of the feed distribution on farm.

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

- (ii) The APVMA is satisfied that the proposed use of **DECCOX** will not be an undue hazard to the safety of people using anything containing its residues.

The APVMA has conducted a residues assessment of **DECCOX**. Parent decoquinatate has been identified in a radio-labelled study as the marker residues in broiler tissues. Parent decoquinatate has been taken as the residue definition for decoquinatate.

In the radio-labelled study, decoquinatate residues in broiler chicken liver, kidney, muscle and skin/fat samples have been determined at 2, 6 and 12 hours after the last of two daily doses administered for seven consecutive days. Based on a regression analysis, parent decoquinatate was 0.61 mg/kg in liver, 0.32 mg/kg in kidney, 0.07 mg/kg in muscle and 0.30 mg/kg in fat at 2 hours after the last dose. The highest parent decoquinatate residues calculated 2, 6 and 12 hours after the last dose were 0.419, 0.268, 0.239 and 0.069 mg/kg in liver, skin/fat, kidney and muscle respectively. These results support the proposed MRLs of 1.0 for liver and skin/fat, 0.8 mg/kg for kidney and 0.5 mg/kg for meat, and the proposed withholding period of zero (0) days.

Residues data for eggs have not been provided. The following restraint statements have been supported: *DO NOT USE in laying hens. DO NOT USE in chickens which are producing or may in the future produce eggs or egg products which may be used or processed for human consumption*.

The Residues and Trade Team has determined that the chronic dietary exposure to decoquinatate is acceptable. The dietary exposure is <2 per cent of the ADI for decoquinatate when the JECFA daily food basket was used, and equivalent to <1 per cent of the ADI when the National Estimated Daily Intake was used. An acute dietary exposure estimation is not required as an ARfD for decoquinatate has not been established.

- (iii) The APVMA is satisfied that the proposed use of **DECCOX** containing the active constituent decoquinatate is not likely to be harmful to human beings if used according to the product label directions.

The Delegate to the Secretary of the Department of Health for scheduling has included decoquinatate in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons. The signal heading for Schedule 5 (CAUTION), and the recommended first aid instructions and safety directions will be included on the product label.

- (iv) The APVMA is satisfied that the proposed use of the new products **DECCOX** containing the active constituent decoquinatate, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The Department of the Environment has conducted an environmental risk assessment and has determined that the proposed use of **DECCOX** is unlikely to pose an unacceptable risk to birds, aquatic organisms, earthworms, soil micro-organisms and non-target vegetation. The Department of the Environment has recommended an environmental protection statement and disposal statements for the label.

The APVMA has considered these findings and accepts the recommendations of the Department of the Environment. The product label will contain an environmental protection statement, *DO NOT contaminate wetlands or watercourses with this product or used containers*, and the recommended disposal statement, *Shake and empty contents into medicated feed. Do not dispose of undiluted chemicals on-site. If not recycling, break, crush or puncture and deliver empty packaging to an approved waste management facility. Empty bag and left-over product should not be burnt.*

The APVMA has assessed the safety of **DECCOX** when administered in feed to male and female broiler chickens continuously at inclusions of 15, 30, 40, 90, 150 and 300 ppm for several weeks. Safety studies at 300 ppm (10X) have shown no pathological or clinical adverse effects.

Chickens in an acute oral toxicity study have not shown any effects over 7 days to one oral treatment of 11 g decoquinatate/kg bw. In contrast, depressed growth has been observed for 31 days in chickens within 7 days of an in-feed treatment of 3200 ppm decoquinatate in a sub-acute study. In chronic toxicity studies, inclusions up to 1600 ppm decoquinatate fed to chickens for up to 180 days have not caused macroscopic or histopathological drug effects. Day old chicks have tolerated decoquinatate fed at 100,000 ppm in rations for 28 days in another chronic toxicity study.

The APVMA is satisfied that **DECCOX** would not have an unintended effect that is harmful to broiler chickens. A precaution warning users against adding the product to feed containing bentonite will be included on the product label. Bentonite interferes with the assay method of decoquinatate, but does not interfere with the activity of decoquinatate. Samples of feed containing bentonite and **DECCOX** would not assay properly.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

- (i) 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.

**DECCOX** is intended for use in broiler chickens for preventing and controlling coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. mivati*, *E. maxima* and *E. brunetti* in broiler chickens. Data from dose determination studies, floor pen and battery trials, and confirmatory field studies have been provided. They support that **DECCOX** is efficacious when administered in-feed at 30 ppm and fed continuously to broiler chickens. Some sporozoites of *E. maxima* were able to progress to gametocytes before degenerating. Australian species of *Eimeria* is as susceptible to **DECCOX** as the overseas species.

Microbiological studies of *E. tenella* and *E. necatrix* in chickens have suggested the potential of *Eimeria* exists to develop resistance to decoquinatate under practical field usage in intensive animal production.

The APVMA has concluded that the data generated from the studies are consistent with the claim: For the prevention and control of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. mivati*, *E. maxima* and *E. brunetti* in broiler chickens.

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:

- (i) The APVMA is considering whether the proposed use of DECCOX would not adversely affect trade between Australia and places outside Australia.

Approximately 3.6 per cent of the total production of chicken meat in Australian is exported, primarily to South Africa, the Philippines, Hong Kong, Singapore and the South Pacific islands.

The proposed Australian decoquinatate MRLs of 0.5 mg/kg for meat, 0.8 mg/kg for kidney and 1.0 mg/kg for liver and skin/fat are the same as those established in the EU and is lower than the MRLs established by the USA, China and Taiwan. Codex has not established MRLs for decoquinatate and the established Japanese MRLs for chicken kidney, liver and meat (0.1 mg/kg) are lower than Australia's.

The APVMA has concluded that the trade risk associated with the proposed use of **DECCOX** is low.

#### FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, [www.apvma.gov.au/consultation/public](http://www.apvma.gov.au/consultation/public).

#### MAKING A SUBMISSION

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **decoquinatate** should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **DECCOX** should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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



Written submissions should be addressed in writing to:

Enquiries

Registration Management and Evaluation

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)

## Cancellation of Label Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the following label approval:

Product no.	Product name	Holder	Cancelled Label Approvals	Date of effect
64597	VETMEC LEV POUR-ON FOR CATTLE	CHEMVET AUSTRALIA PTY LTD	64597/48738	11 January 2016

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

### SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 11 January 2016 at wholesale and retail level, until 11 January 2017.

After 11 January 2017 it will be an offence against the Agvet Codes to have possession or custody of the product bearing a cancelled label with the intention to supply, or to supply the product bearing a cancelled label.

### USE

A person may continue to use the product bearing a cancelled label according to its label instructions until 11 January 2017.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing a cancelled label in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product bearing a cancelled label after the approval has been cancelled until 11 January 2017.

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

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

### APVMA CONTACT

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

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

**Phone:** +61 2 6210 4749

**Fax:** +61 2 6210 4776

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

## 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

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

**ACTIV PHARMACEUTICALS  
PTY LTD**

**ACN:** 081 432 411

2 Blackmore Road

SMEATON GRANGE NSW 2567

**LICENCE NO:** 2236

**Product Types:\***

- *Category 2:* Creams/lotions, ointments, gels, pastes, sprays and liquids
- *Category 4:* Premixes (liquids) and supplements (liquids)

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply.

**Licence Issued:** 7 December 2015

**AUSTRALIAN PHARMAVET  
CONTRACT MANUFACTURING  
PTY LTD**

**ACN:** 607 905 733

92 Antimony Street

CAROLE PARK QLD 4300

**LICENCE NO:** 2240

**Product Types:\***

- *Category 2:* Tablets, creams/lotions, ointments, pastes, powders, sprays and liquids
- *Category 3:* Liquids, sprays and powders
- *Category 4:* Powders

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, packaging, labelling, strip, blister and sachet packaging, tableting, analysis and testing (physical), storage and release for supply.

**Licence Issued:** 22 December 2015

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

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**VETAFARM  
MANUFACTURING PTY LTD**

**ACN:** 152 427 453

50 Webb Street  
BOMEN NSW 2650

**LICENCE NO:** 2239

**Product Types:\***

- *Category 2:* Tablets, bolus, gels, powders and liquids
- *Category 3:* Liquids and sprays

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, filling, granulation, dry milling, packaging, labelling, tableting, analysis and testing (chemical, physical and antibiotic assay), storage and release for supply.

**Licence Issued:** 23 December 2015

## 2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

**APEX LABORATORIES PTY  
LTD**

**ACN:** 000 397 240

61 Chivers Road  
SOMERSBY NSW 2250

**LICENCE NO:** 2119

**Product Types: \***

- *Category 2:* Tablets, creams/lotion, ointments, pastes, powders and liquids

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, dry milling, microencapsulation, granulation, tableting, tablet coating, analysis and testing (physical), storage and release for supply.

**Amended Licence Issued:** 2 December 2015

**DHL SUPPLY CHAIN  
(AUSTRALIA) PTY LIMITED**

**ACN:** 071 798 617

52 Huntingwood Drive  
HUNTINGWOOD NSW 2184

**LICENCE NO:** 6071

**Product Types: \***

- *Category 6:* Single step manufacture

**Step(s) of Manufacture:** Secondary packaging, secondary/supplementary labelling, storage and release for supply.

**Amended Licence Issued:** 24 December 2015

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

### 3. LICENCE CANCELLATIONS

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

**PROBIOTEC PHARMA PTY LIMITED**                      **LICENCE NO:** 2008  
**ACN:** 076 755 354                      **Date Cancelled:** 15 December 2015  
83 Cherry Lane  
LAVERTON NORTH VIC 3026

**ASTRA MANUFACTURING PTY. LTD.**                      **LICENCE NO:** 2225  
**ACN:** 164 506 147                      **Date Cancelled:** 23 December 2015  
894–906 Taylors Road  
DANDENONG SOUTH VIC 3175

### 4. LICENCE SUSPENSIONS

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

Nil

### 5. REVOCATION OF LICENCE CANCELLATION

The APVMA has revoked the cancellation of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

### 6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

**Modern Ark Pty Ltd**                      **LICENCE NO:** 2215  
**ACN:** 104 514 801                      **Date revoked:** 14 December 2015  
10 Activity Street  
WARWICK QLD 4370

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

## APVMA CONTACT

Manufacturing Quality and Licensing Section  
Legal and Compliance Program  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

**Phone:** +61 2 6210 4899

**Fax:** +61 2 6210 4813

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

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

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