



**Commonwealth  
of Australia**

**Gazette**

No. APVMA 10, Tuesday, 16 May 2017

Published by The Australian Pesticides and Veterinary Medicines Authority

**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.

© Commonwealth of Australia 2017

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority. Requests and inquiries concerning reproduction and rights should be addressed to:

Director, Public Affairs and Communications  
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 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/news-and-publications/publications/gazette](http://www.apvma.gov.au/news-and-publications/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 4812

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

## CONTENTS

Agricultural Chemical Products and Approved Labels.....	4
Veterinary Chemical Products and Approved Labels .....	12
Approved Active Constituents .....	17
Cancellation of Active Constituent Approval at the Request of the Holder .....	18
Cancellation of Active Constituent Approval at the Request of the Holder .....	19
New Agricultural Active Constituent <i>Streptomyces Lydicus</i> WYEC108.....	20
Actinovate Biofungicide Containing the New Active Constituent <i>Streptomyces Lydicus</i> .....	22
Amendments to the APVMA MRL Standard.....	24
Proposal to amend Schedule 20 in the Australia New Zealand Food Standards Code.....	25
Variations to Schedule 20 of the Australia New Zealand Food Standards Code.....	29
Licensing of Veterinary Chemical Manufacturers .....	34

## 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>	106918
<b>Product name:</b>	Rexade Herbicide
<b>Active constituent/s:</b>	150 g/kg pyroxsulam, 50 g/kg halauxifen as the methyl ester, 318.6 g/kg cloquintocet
<b>Applicant name:</b>	Dow Agrosciences Australia Limited
<b>Applicant ACN:</b>	003 771 659
<b>Summary of use:</b>	For the control of post-emergent grass and broadleaf weeds in triticale and wheat, excluding durum varieties
<b>Date of registration:</b>	28 April 2017
<b>Product registration no.:</b>	82842
<b>Label approval no.:</b>	82842/106918

<b>Application no.:</b>	106777
<b>Product name:</b>	Crusader GoDRI Herbicide
<b>Active constituent/s:</b>	215 g/kg pyroxsulam, 451.5 g/kg cloquintocet
<b>Applicant name:</b>	Dow Agrosciences Australia Limited
<b>Applicant ACN:</b>	003 771 659
<b>Summary of use:</b>	For the control or suppression of grass and broadleaf weeds in wheat and triticale, except durum varieties
<b>Date of registration:</b>	28 April 2017
<b>Product registration no.:</b>	82791
<b>Label approval no.:</b>	82791/106777

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

<b>Application no.:</b>	105389
<b>Product name:</b>	Brunnings Weed Kill for Lawns Spot Granules
<b>Active constituent/s:</b>	50 g/kg iron present as ferrous sulphate
<b>Applicant name:</b>	Brunnings Garden Products Pty Ltd
<b>Applicant ACN:</b>	050 655 760
<b>Summary of use:</b>	For the control of certain weeds in lawns
<b>Date of registration:</b>	26 April 2017
<b>Product registration no.:</b>	82299
<b>Label approval no.:</b>	82299/105389

<b>Application no.:</b>	106341
<b>Product name:</b>	Anthem Insecticide Granule
<b>Active constituent/s:</b>	0.5 g/kg fipronil
<b>Applicant name:</b>	Sherwood Chemicals Australasia Pty Ltd
<b>Applicant ACN:</b>	136 993 630
<b>Summary of use:</b>	For the control of argentine stem weevil, funnel ant and mole cricket in recreational, domestic and commercial turf
<b>Date of registration:</b>	26 April 2017
<b>Product registration no.:</b>	82644
<b>Label approval no.:</b>	82644/106341

<b>Application no.:</b>	108584
<b>Product name:</b>	Applonil 900 WG Fungicide
<b>Active constituent/s:</b>	900 g/kg chlorothalonil
<b>Applicant name:</b>	Grow Choice Pty Limited
<b>Applicant ACN:</b>	069 839 961
<b>Summary of use:</b>	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and vegetables
<b>Date of registration:</b>	26 April 2017
<b>Product registration no.:</b>	83540
<b>Label approval no.:</b>	83450/108584
<b>Application no.:</b>	107733
<b>Product name:</b>	Relyon Starlet 250EC Insecticide/Miticide
<b>Active constituent/s:</b>	250 g/L bifenthrin
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use:</b>	For the control of insect pests and mites of apricots, bananas, barley, canola, citrus, clover, cotton, cucurbits, faba beans, field peas, grapes, lucerne, lucerne seed crops, lupins, navy beans, nectarines, peaches pears, plums, poppies, subterranean clover, sugarcane, tomatoes and wheat
<b>Date of registration:</b>	28 April 2017
<b>Product registration no.:</b>	83211
<b>Label approval no.:</b>	83211/107733
<b>Application no.:</b>	108479
<b>Product name:</b>	Yates Garden and Path Weedkiller Spot Spray
<b>Active constituent/s:</b>	1.5 g/L MCPA present as the dimethylamine salt, 0.3 g/L dicamba present as the dimethylamine salt
<b>Applicant name:</b>	Duluxgroup (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 049 427
<b>Summary of use:</b>	For the control of bindii, clover and other broadleaf weeds in pathways, garden beds, rockeries, driveways and along fences in the home garden
<b>Date of registration:</b>	28 April 2017
<b>Product registration no.:</b>	83494
<b>Label approval no.:</b>	83494/108479
<b>Application no.:</b>	107868
<b>Product name:</b>	Mortein Home Expert High Performance Flea Bomb
<b>Active constituent/s:</b>	10 g/kg permethrin, 1.07 g/kg fenoxycarb
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of use:</b>	For the control of fleas with protection from fleas for up to 9 months
<b>Date of registration:</b>	1 May 2017
<b>Product registration no.:</b>	83269
<b>Label approval no.:</b>	83269/107868

<b>Application no.:</b>	108473
<b>Product name:</b>	Yates Garden and Path Weedkiller Concentrate
<b>Active constituent/s:</b>	150 g/L MCPA present as the dimethylamine salt, 25 g/L dicamba present as the dimethylamine salt
<b>Applicant name:</b>	Duluxgroup (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 049 427
<b>Summary of use:</b>	For the control of bindii, clover and other broadleaf weeds in pathways, garden beds, rockeries, driveways and along fences in the home garden
<b>Date of registration:</b>	1 May 2017
<b>Product registration no.:</b>	83493
<b>Label approval no.:</b>	83493/108473
<b>Application no.:</b>	110248
<b>Product name:</b>	Rid Australia Terminator High Performance Odourless Multi Insect Killer Fast Knockdown
<b>Active constituent/s:</b>	0.9 g/kg d-allethrin 20:80, 0.9 g/kg d-phenothrin, 4.05 g/kg tetramethrin 20:80
<b>Applicant name:</b>	Aaron Laboratories Proprietary Limited
<b>Applicant ACN:</b>	004 856 848
<b>Summary of use:</b>	For the control of ants, cockroaches, flies, mosquitoes, moths, silverfish, spiders and wasps
<b>Date of registration:</b>	2 May 2017
<b>Product registration no.:</b>	84371
<b>Label approval no.:</b>	84371/110248
<b>Application no.:</b>	106856
<b>Product name:</b>	Richgro Naturally Based Fruit Fly Spray
<b>Active constituent/s:</b>	7.5 g/L garlic, 0.3 g/L pyrethrins, 1.2 g/L piperonyl butoxide
<b>Applicant name:</b>	A. Richards Pty Ltd
<b>Applicant ACN:</b>	008 734 852
<b>Summary of use:</b>	For the control of fruit flies in the home garden
<b>Date of registration:</b>	3 May 2017
<b>Product registration no.:</b>	82819
<b>Label approval no.:</b>	82819/106856
<b>Application no.:</b>	108396
<b>Product name:</b>	Trio 2,4-D 680 EC Herbicide
<b>Active constituent/s:</b>	680 g/L 2,4-D present as the 2-ethylhexyl ester
<b>Applicant name:</b>	CTS Chemicals Pty Ltd
<b>Applicant ACN:</b>	605 759 644
<b>Summary of use:</b>	For the control of various weeds in crops, pastures and non-agricultural areas
<b>Date of registration:</b>	3 May 2017
<b>Product registration no.:</b>	83485
<b>Label approval no.:</b>	83485/108396
<b>Application no.:</b>	109263
<b>Product name:</b>	Baythroid Advanced Insect Killer Concentrate
<b>Active constituent/s:</b>	25 g/L beta-cyfluthrin
<b>Applicant name:</b>	Bayer Cropscience Pty Ltd
<b>Applicant ACN:</b>	000 226 022
<b>Summary of use:</b>	For the control of insects in indoor and outdoor situations in and around the home
<b>Date of registration:</b>	3 May 2017
<b>Product registration no.:</b>	83932
<b>Label approval no.:</b>	83932/109263

<b>Application no.:</b>	106375
<b>Product name:</b>	Agro-Gold 1-HR Action Weed Killer
<b>Active constituent/s:</b>	16 g/L glyphosate present as the ammonium salt, 20.5 g/L nonanoic acid
<b>Applicant name:</b>	Agro-Alliance (Australia) Pty Ltd
<b>Applicant ACN:</b>	130 864 603
<b>Summary of use:</b>	For the spot treatment of weeds in garden beds, rockeries and lawns. Also for driveways, along fences and lawn edges and prior to planting new lawns or garden beds
<b>Date of registration:</b>	5 May 2017
<b>Product registration no.:</b>	82654
<b>Label approval no.:</b>	82654/106375

<b>Application no.:</b>	110202
<b>Product name:</b>	Shot Down Fast Knockdown Flying Insect Spray Odourless
<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 the control of insects around the home and garden
<b>Date of registration:</b>	9 May 2017
<b>Product registration no.:</b>	84363
<b>Label approval no.:</b>	84363/110202

<b>Application no.:</b>	110207
<b>Product name:</b>	Rid Australia Terminator High Performance Crawling Insect Killer Dual Action Surface Spray Kills Fast Protects for up to 6 months
<b>Active constituent/s:</b>	0.7 g/kg imiprothrin, 2 g/kg cypermethrin
<b>Applicant name:</b>	Aaron Laboratories Proprietary Limited
<b>Applicant ACN:</b>	004 856 848
<b>Summary of use:</b>	For kill and protection against crawling insects
<b>Date of registration:</b>	9 May 2017
<b>Product registration no.:</b>	84366
<b>Label approval no.:</b>	84366/110207

### 3. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	109942
<b>Product name:</b>	Surefire Weedpro Bioaqua 360 Herbicide
<b>Active constituent/s:</b>	360 g/L glyphosate present as the isopropylamine salt
<b>Applicant name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'WEEDPRO BIOAQUA 360 HERBICIDE' to 'SUREFIRE WEEDPRO BIOAQUA 360 HERBICIDE'
<b>Date of variation:</b>	16 March 2017
<b>Product registration no.:</b>	82251
<b>Label approval no.:</b>	82251/109942

<b>Application no.:</b>	109943
<b>Product name:</b>	Tebuthiuron 200 Herbicide
<b>Active constituent/s:</b>	200 g/kg tebuthiuron
<b>Applicant name:</b>	Granular Products Pty Ltd
<b>Applicant ACN:</b>	110 555 952
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'REGAIN HERBICIDE' to 'TEBUTHIURON 200 HERBICIDE'
<b>Date of variation:</b>	16 March 2017
<b>Product registration no.:</b>	81434
<b>Label approval no.:</b>	81434/109943
<b>Application no.:</b>	108259
<b>Product name:</b>	Accensi Fipronil Residual Termiticide and Insecticide
<b>Active constituent/s:</b>	100 g/L fipronil
<b>Applicant name:</b>	Accensi Pty Ltd
<b>Applicant ACN:</b>	079 875 184
<b>Summary of variation:</b>	To extend the use to include ants and to change the distinguishing product name and the name that appears on the label from 'ACCENSI FIPRONIL RESIDUAL TERMITICIDE' to 'ACCENSI FIPRONIL RESIDUAL TERMITICIDE AND INSECTICIDE'
<b>Date of variation:</b>	6 April 2017
<b>Product registration no.:</b>	68569
<b>Label approval no.:</b>	68569/108259
<b>Application no.:</b>	108600
<b>Product name:</b>	Radiate Termiticide and Insecticide
<b>Active constituent/s:</b>	100 g/L fipronil
<b>Applicant name:</b>	FMC Australasia Pty Ltd
<b>Applicant ACN:</b>	095 326 891
<b>Summary of variation:</b>	To include claims for control of ants and to change the distinguishing product name and the name that appears on the label from 'RADIATE TERMITICIDE' to 'RADIATE TERMITICIDE AND INSECTICIDE'
<b>Date of variation:</b>	24 April 2017
<b>Product registration no.:</b>	68515
<b>Label approval no.:</b>	68515/108600
<b>Application no.:</b>	104049
<b>Product name:</b>	Terbyne Xtreme 875 WG Herbicide
<b>Active constituent/s:</b>	875 g/kg terbuthylazine
<b>Applicant name:</b>	Sipcam Pacific Australia Pty Ltd
<b>Applicant ACN:</b>	073 176 888
<b>Summary of Variation</b>	To extend uses for the control of flax-leaf fleabane amongst other labelled weeds in chickpeas in a mandatory tank mix
<b>Date of Variation :</b>	26 April 2017
<b>Product registration no.:</b>	68613
<b>Label approval no.:</b>	68613/104049



<b>Application no.:</b>	108829
<b>Product name:</b>	Oxysept Agri Peroxyacetic Acid Sanitiser
<b>Active constituent/s:</b>	299 g/L hydrogen peroxide, 50 g/L peroxyacetic acid
<b>Applicant name:</b>	Ecolab Pty Limited
<b>Applicant ACN:</b>	000 449 990
<b>Summary of Variation:</b>	To vary the directions for use and re-entry period
<b>Date of Variation :</b>	26 April 2017
<b>Product registration no.:</b>	70095
<b>Label approval no.:</b>	70095/108829
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Conquest Dimethoate 400 Systemic Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	Conquest Crop Protection Pty Ltd
<b>Holder ACN:</b>	098 814 932
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the restraint in the critical comments and withholding periods for lucerne, pasture, pasture seed, fodder crops and oilseeds from 'DO NOT use after crop emergence' to 'DO NOT use more than 7 days after crop emergence'. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	1 May 2017
<b>Product registration no.:</b>	55704
<b>Label approval no.:</b>	RV3017H
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Danadim Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	FMC Australasia Pty Ltd
<b>Holder ACN:</b>	095 326 891
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the restraint in the critical comments and withholding periods for lucerne, pasture, pasture seed, fodder crops and oilseeds from 'DO NOT use after crop emergence' to 'DO NOT use more than 7 days after crop emergence'. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	1 May 2017
<b>Product registration no.:</b>	56454
<b>Label approval no.:</b>	RV0317I
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Titan Dimethoate 400 Systemic Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	Titan Ag Pty Ltd
<b>Holder ACN:</b>	122 081 574
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the restraint in the critical comments and withholding periods for lucerne, pasture, pasture seed, fodder crops and oilseeds from 'DO NOT use after crop emergence' to 'DO NOT use more than 7 days after crop emergence'. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	1 May 2017
<b>Product registration no.:</b>	62511
<b>Label approval no.:</b>	RV0317M

<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Accensi Dimethoate 400 Systemic Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	Accensi Pty Ltd
<b>Holder ACN:</b>	122 081 574
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the restraint in the critical comments and withholding periods for lucerne, pasture, pasture seed, fodder crops and oilseeds from 'DO NOT use after crop emergence' to 'DO NOT use more than 7 days after crop emergence'. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	1 May 2017
<b>Product registration no.:</b>	63470
<b>Label approval no.:</b>	RV0317N
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Rogor Upgrade Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	FMC Australasia Pty Ltd
<b>Holder ACN:</b>	110 199 169
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the restraint in the critical comments and withholding periods for lucerne, pasture, pasture seed, fodder crops and oilseeds from 'DO NOT use after crop emergence' to 'DO NOT use more than 7 days after crop emergence'. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	1 May 2017
<b>Product registration no.:</b>	65260
<b>Label approval no.:</b>	RV0317Q
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	ACP Dimethoate 400 Systemic insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	Australis Crop Protection Pty Ltd
<b>Holder ACN:</b>	150 711 185
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the restraint in the critical comments and withholding periods for lucerne, pasture, pasture seed, fodder crops and oilseeds from 'DO NOT use after crop emergence' to 'DO NOT use more than 7 days after crop emergence'. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	1 May 2017
<b>Product registration no.:</b>	66538
<b>Label approval no.:</b>	RV0317R
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Apparent Decimator 400 Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	Apparent Pty. Ltd.
<b>Holder ACN:</b>	143 724 136
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the restraint in the critical comments and withholding periods for lucerne, pasture, pasture seed, fodder crops and oilseeds from 'DO NOT use after crop emergence' to 'DO NOT use more than 7 days after crop emergence'. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	1 May 2017
<b>Product registration no.:</b>	70165
<b>Label approval no.:</b>	RV0317T, RV0317U

<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Nufarm Dimethoate Systemic Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	Nufarm Australia Limited
<b>Holder ACN:</b>	004 377 780
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, amended the critical comments for tobacco and ornamental plants to restore the explanatory words '* refer to mixing application section' that had been omitted from the critical comments for tobacco, ornamentals and tree crops during the review process. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	9 May 2017
<b>Product registration no.:</b>	32962
<b>Label approval no.:</b>	RV0317A
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Relyon Dimex 400EC Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	RuralCo Holdings Limited
<b>Holder ACN:</b>	009 660 879
<b>Summary of variation:</b>	This product was registered shortly before the finalisation of the reconsideration of all dimethoate products on 6 March 2017. The APVMA has, with the holder's consent, amended the label instructions of this product to comply with the dimethoate reconsideration outcomes of 6 March 2017 so that these instructions are consistent with those of other products containing dimethoate. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	9 May 2017
<b>Product registration no.:</b>	83009
<b>Label approval no.:</b>	RV0317X
<b>Period of supply earlier version of label</b>	As the earlier label was approved in January 2017, there may be existing product bearing this earlier label version that is now no longer approved. The APVMA has determined that subsection 81(3) of the Agvet Code is to apply in respect of the earlier approved version of the label (107303) that has been varied as a result of this decision and that supply of product bearing this label may take place no later than 6 March 2019. After 6 March 2019, all product that is supplied should bear the varied approved label RV0317X.
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	AW Omethoate 290 SL Insecticide
<b>Active constituent/s:</b>	290 g/kg Omethoate
<b>Holder name:</b>	AgriWest Pty Ltd
<b>Holder ACN:</b>	108 899 181
<b>Summary of variation:</b>	This product was not registered at the time of the finalisation of the reconsideration of all omethoate products on 1 December 2016. The product registration has since been reinstated. The APVMA has, with the holder's consent, amended the label instructions of this product to comply with the omethoate reconsideration outcomes of 1 December 2016 so that these instructions are consistent with those of other products containing omethoate. This product is an insecticide and miticide for a range of agricultural crops.
<b>Date of variation:</b>	9 May 2017
<b>Product registration no.:</b>	61681
<b>Label approval no.:</b>	RV1216
<b>Period of supply earlier version of label</b>	As the earlier label was approved in 2007, there may be existing product bearing this earlier label version that is now no longer approved. The APVMA has determined that subsection 81(3) of the Agvet Code is to apply in respect of the earlier approved version of the label (0107) that has been varied as a result of this decision and that supply may take place no later than 1 December 2017. After 1 December 2017, all product that is supplied should bear the varied approved label RV1216.

## 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>	107320
<b>Product name:</b>	Frontline Pet Care Home and Environment Flea Spray
<b>Active constituent/s:</b>	5 g/L permethrin 40:60 cis trans, 10 g/L piperonyl butoxide, 50 mg/L pyriproxyfen
<b>Applicant name:</b>	Merial Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of use:</b>	For use in treating fleas in the environment of dogs and cats
<b>Date of registration:</b>	28 April 2017
<b>Product registration no.:</b>	83014
<b>Label approval no.:</b>	83014/107320

<b>Application no.:</b>	109193
<b>Product name:</b>	Starmec LV Pour-On For Cattle
<b>Active constituent/s:</b>	10 g/L ivermectin
<b>Applicant name:</b>	The Hunter River Company Pty Limited
<b>Applicant ACN:</b>	133 798 615
<b>Summary of use:</b>	For the treatment and control of ivermectin sensitive internal and external parasites of beef and dairy cattle
<b>Date of registration:</b>	5 May 2017
<b>Product registration no.:</b>	83891
<b>Label approval no.:</b>	83891/109193

### 2. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	110199
<b>Product name:</b>	Monthly Spot-On Flea Treatment For Very Large Dogs
<b>Active constituent/s:</b>	195 g/L indoxacarb (s-isomer)
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'MONTHLY SPOT-ON FLEA TREATMENT FOR VERY LARGE DOGS—VET SERIES' to 'MONTHLY SPOT-ON FLEA TREATMENT FOR VERY LARGE DOGS'
<b>Date of variation:</b>	3 April 2017
<b>Product registration no.:</b>	83290
<b>Label approval no.:</b>	83290/110199

<b>Application no.:</b>	110216
<b>Product name:</b>	Monthly Spot-On Flea Treatment For Kittens & Cats Up To 4 kg
<b>Active constituent/s:</b>	195 g/L indoxacarb (s-isomer)
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'MONTHLY SPOT-ON FLEA TREATMENT FOR KITTENS & CATS UP TO 4KG—VET SERIES' to 'MONTHLY SPOT-ON FLEA TREATMENT FOR KITTENS & CATS UP TO 4KG'
<b>Date of variation:</b>	3 April 2017
<b>Product registration no.:</b>	83293
<b>Label approval no.:</b>	83293/110216
<b>Application no.:</b>	110200
<b>Product name:</b>	Monthly Spot-On Flea Treatment For Large Dogs
<b>Active constituent/s:</b>	195 g/L indoxacarb (s-isomer)
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'MONTHLY SPOT-ON FLEA TREATMENT FOR LARGE DOGS—VET SERIES' to 'MONTHLY SPOT-ON FLEA TREATMENT FOR LARGE DOGS'
<b>Date of variation:</b>	3 April 2017
<b>Product registration no.:</b>	83294
<b>Label approval no.:</b>	83294/110200
<b>Application no.:</b>	110203
<b>Product name:</b>	Monthly Spot-On Flea Treatment For Medium Dogs
<b>Active constituent/s:</b>	195 g/L indoxacarb (s-isomer)
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'MONTHLY SPOT-ON FLEA TREATMENT FOR MEDIUM DOGS—VET SERIES' to 'MONTHLY SPOT-ON FLEA TREATMENT FOR MEDIUM DOGS'
<b>Date of variation:</b>	3 April 2017
<b>Product registration no.:</b>	83295
<b>Label approval no.:</b>	83295/110203
<b>Application no.:</b>	110204
<b>Product name:</b>	Monthly Spot-On Flea Treatment For Small Dogs
<b>Active constituent/s:</b>	195 g/L indoxacarb (s-isomer)
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'MONTHLY SPOT-ON FLEA TREATMENT FOR SMALL DOGS—VET SERIES' to 'MONTHLY SPOT-ON FLEA TREATMENT FOR SMALL DOGS'
<b>Date of variation:</b>	3 April 2017
<b>Product registration no.:</b>	83296
<b>Label approval no.:</b>	83296/110204

<b>Application no.:</b>	110211
<b>Product name:</b>	Monthly Spot-On Flea Treatment For Very Small Dogs
<b>Active constituent/s:</b>	195 g/L indoxacarb (s-isomer)
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'MONTHLY SPOT-ON FLEA TREATMENT FOR VERY SMALL DOGS—VET SERIES' to 'MONTHLY SPOT-ON FLEA TREATMENT FOR VERY SMALL DOGS'
<b>Date of variation:</b>	3 April 2017
<b>Product registration no.:</b>	83289
<b>Label approval no.:</b>	83289/110211

<b>Application no.:</b>	110215
<b>Product name:</b>	Monthly Spot-On Flea Treatment For Cats Over 4 kg
<b>Active constituent/s:</b>	195 g/L indoxacarb (s-isomer)
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'MONTHLY SPOT-ON FLEA TREATMENT FOR CATS OVER 4KG—VET SERIES' to 'MONTHLY SPOT-ON FLEA TREATMENT FOR CATS OVER 4KG'
<b>Date of variation:</b>	3 April 2017
<b>Product registration no.:</b>	83291
<b>Label approval no.:</b>	83291/110215

<b>Application no.:</b>	107150
<b>Product name:</b>	Bravecto 1400 mg Fluralaner Chewable Tablets For Very Large Dogs
<b>Active constituent/s:</b>	136.4 g/kg fluralaner
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of Variation</b>	To extend the claim for treatment and control of demodex spp. mite infestations, sarcoptic mange (sarcoptes scabiei) infestations, and ear mite (otodectes cynotis) infestations
<b>Date of variation:</b>	28 April 2017
<b>Product registration no.:</b>	68873
<b>Label approval no.:</b>	68873/107150

<b>Application no.:</b>	107152
<b>Product name:</b>	Bravecto 1000 mg Fluralaner Chewable Tablets For Large Dogs
<b>Active constituent/s:</b>	136.4 g/kg fluralaner
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation</b>	To extend the claim for treatment and control of demodex spp. mite infestations, sarcoptic mange (sarcoptes scabiei) infestations, and ear mite (otodectes cynotis) infestations
<b>Date of Variation :</b>	28 April 2017
<b>Product registration no.:</b>	68870
<b>Label approval no.:</b>	68870/10715

<b>Application no.:</b>	107153
<b>Product name:</b>	Bravecto 500 mg Fluralaner Chewable Tablets For Medium Dogs
<b>Active constituent/s:</b>	136.4 g/kg fluralaner
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To extend the claim for treatment and control of demodex spp. mite infestations, sarcoptic mange (sarcoptes scabiei) infestations, and ear mite (otodectes cynotis) infestations
<b>Date of Variation:</b>	28 April 2017
<b>Product registration no.:</b>	68871
<b>Label approval no.:</b>	68871/107153

<b>Application no.:</b>	107154
<b>Product name:</b>	Bravecto 250 mg Fluralaner Chewable Tablets For Small Dogs
<b>Active constituent/s:</b>	136.4 g/kg fluralaner
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To extend the claim for treatment and control of demodex spp. mite infestations, sarcoptic mange (sarcoptes scabiei) infestations, and ear mite (otodectes cynotis) infestations
<b>Date of Variation:</b>	28 April 2017
<b>Product registration no.:</b>	68872
<b>Label approval no.:</b>	68872/107154

<b>Application no.:</b>	107155
<b>Product name:</b>	Bravecto 112.5 mg Fluralaner Chewable Tablets For Very Small Dogs
<b>Active constituent/s:</b>	136.4 g/kg fluralaner
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To extend the claim for treatment and control of demodex spp. mite infestations, sarcoptic mange (sarcoptes scabiei) infestations, and ear mite (otodectes cynotis) infestations
<b>Date of variation:</b>	28 April 2017
<b>Product registration no.:</b>	68867
<b>Label approval no.:</b>	68867/107155

<b>Application no.:</b>	105120
<b>Product name:</b>	Vetergesic Injection for Cats, Dogs and Horses
<b>Active constituent/s:</b>	0.3 mg/mL buprenorphine as buprenorphine hydrochloride
<b>Applicant name:</b>	Ceva Animal Health Pty Ltd
<b>Applicant ACN:</b>	002 692 426
<b>Summary of use:</b>	For the relief of post-operative pain in the dog and cat. For the relief of post-operative pain in the horse only in conjunction with a sedative agent. For the potentiation of sedation in the dog and horse
<b>Date of registration/approval:</b>	5 May 2017
<b>Product registration no.:</b>	82164
<b>Label approval no.:</b>	82164/105120

<b>Application no.:</b>	109184
<b>Product name:</b>	Covine Clipshield Liquid Blowfly Treatment for Sheep
<b>Active constituent/s:</b>	500 g/L cyromazine
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use:</b>	For the protection of long wool sheep from strike by blowfly, including organophosphate resistant strains when applied by jetting or dipping
<b>Date of registration/approval:</b>	5 May 2017
<b>Product registration no.:</b>	83885
<b>Label approval no.:</b>	83885/109184



## 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 CONSTITUENT

<b>Application no.:</b>	107966
<b>Active constituent/s:</b>	1-methylcyclopropene
<b>Applicant name:</b>	Floritech International Pty Ltd
<b>Applicant ACN:</b>	607 170 294
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	28 April 2017
<b>Approval no.:</b>	83317

## Cancellation of Active Constituent Approval at the Request of the Holder

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

Approval number	Active constituent name	Approval holder	Date of effect
55604	Chlorthal-Dimethyl	Crop Care Australasia Pty Ltd	29 March 2017

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

### SUPPLY

A person may supply or cause to be supplied active constituent 55604 manufactured prior to 29 March 2017 at wholesale, until 29 March 2018.

After 29 March 2018 it will be an offence against the Agvet Codes to have possession or custody of the active constituent with the intention to supply, or to supply the active constituent.

### USE

A person may continue to use the active constituent until 29 March 2018.

The supply and use of the active constituent must be in accordance with its conditions of approval.

Any person who possesses, has custody of, uses, or otherwise deals with the listed active constituent 55604 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 active constituent after the approval has been cancelled until 29 March 2018.

It is an offence to possess, have custody of, use, or deal with the active constituent 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 4773

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

## Cancellation of Active Constituent Approval at the Request of the Holder

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

Approval number	Active constituent name	Approval holder	Date of effect
52641	Chlorthal-Dimethyl	Nufarm Australia Limited	29 March 2017

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

### SUPPLY

A person may supply or cause to be supplied active constituent 52641 manufactured prior to 29 March 2017 at wholesale, until 29 March 2018.

After 29 March 2018 it will be an offence against the Agvet Codes to have possession or custody of the active constituent with the intention to supply, or to supply the active constituent.

### USE

A person may continue to use the active constituent until 29 March 2018.

The supply and use of the active constituent must be in accordance with its conditions of approval,

Any person who possesses, has custody of, uses, or otherwise deals with the listed active constituent 52641 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 active constituent after the approval has been cancelled until 29 March 2018.

It is an offence to possess, have custody of, use, or deal with the active constituent 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 4773

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

## New Agricultural Active Constituent *Streptomyces Lydicus* WYEC108

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, *streptomyces lydicus* WYEC108, a gram-positive soil-dwelling bacterium, for use as a biological fungicidal active constituent in agricultural chemical products.

<b>Common name:</b>	<i>Streptomyces lydicus</i> WYEC108
<b>Description:</b>	A gram-positive, aerobic, filamentous soil bacteria producing grey spiralled chains of spores in an aerial mycelium
<b>Order:</b>	Actinomycetales
<b>Family:</b>	Streptomycetacea
<b>Genus and species:</b>	<i>Streptomyces lydicus</i>
<b>Strain:</b>	WYEC108
<b>Mode of action:</b>	Acts as a mycoparasite of fungal pathogens and excretes antifungal metabolites into the rhizosphere after colonisation of plant root tips

### SUMMARY OF THE APVMA'S EVALUATION OF *STREPTOMYCES LYDICUS* WYEC108 ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry and manufacturing aspects of the *streptomyces lydicus* WYEC108 for use as an active constituent (methods of identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

Impurities of toxicological significance are not expected to occur in *streptomyces lydicus* WYEC108 as a result of the raw materials and the manufacturing process used.

The APVMA has considered the toxicological aspects of *streptomyces lydicus* WYEC108, and concluded that there are no toxicological concerns regarding the approval of this active constituent. An Acceptable Daily Intake and an Acute Reference Dose have not been established for *streptomyces lydicus* WYEC108 as a result of its low toxicity profile and lack of any apparent pathogenicity or infectivity to mammals.

*Streptomyces lydicus* WYEC108 has been considered by the Advisory Committee on Chemicals Scheduling (ACCS). Based on the data provided and the advice of the ACCS, the Scheduling Delegate concluded that *streptomyces lydicus* WYEC108 was of low toxicity and has included *streptomyces lydicus* WYEC108 in Appendix B (substances considered not to require control by scheduling) of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).

The APVMA is satisfied that the proposed manufacture and use of *streptomyces lydicus* WYEC108 would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

## MAKING A SUBMISSION

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of streptomyces lydicus WYEC108 should be granted. 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.

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 the following information:

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

All personal and confidential commercial information (CCI)<sup>1</sup> material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Director of Chemistry and Manufacture  
Scientific Assessment and Chemical Review Program  
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)

---

<sup>1</sup> A full definition of 'confidential commercial information' is contained in the [Agricultural and Veterinary Chemicals Code Act 1994](#)

## Actinovate Biofungicide Containing the New Active Constituent *Streptomyces Lydicus*

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is actinovate biofungicide.

### PARTICULARS OF THE APPLICATION

<b>Proposed product name(s):</b>	Actinovate Biofungicide
<b>Applicant company:</b>	Novozymes BioAg Limited
<b>Name of active constituent:</b>	<i>Streptomyces lydicus</i> WYEC108
<b>Signal heading:</b>	Not required
<b>Summary of proposed use:</b>	For use as a preventative fungicide that will be applied as a foliar or soil drench, or seed treatment in agriculture, horticulture, greenhouse, nursery and turf.
<b>Pack sizes:</b>	56 g; 500 g; 7.72 kg
<b>Withholding period:</b>	Harvest: NOT REQUIRED WHEN USED AS DIRECTED

### SUMMARY OF THE APVMA'S EVALUATION OF ACTINOVATE BIOFUNGICIDE 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 actinovate biofungicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
  - (ii) The APVMA is satisfied that the proposed use of actinovate biofungicide will not be an undue hazard to the safety of people using anything containing its residues.
  - (iii) The APVMA is satisfied that the proposed use of actinovate biofungicide containing the active constituent *streptomyces lydicus* WYEC108, is not likely to be harmful to human beings if used according to the product label directions.
  - (iv) The APVMA is satisfied that the proposed use of the new products actinovate biofungicide containing the active constituent *streptomyces lydicus* WYEC108, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.
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.

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:
- (ii) The APVMA is satisfied that the proposed use of actinovate biofungicide would not adversely affect trade between Australia and places outside Australia.

#### **FURTHER INFORMATION**

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

#### **MAKING A SUBMISSION**

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether actinovate biofungicide 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.

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

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

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

**Phone:** +61 2 6210 4701

**Fax:** +61 2 6210 4721

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

## Amendments to the APVMA MRL Standard

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

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* and the changes will have effect the day after the instrument is registered.

Details of the amendment can be found in the [Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) Amendment Instrument 2017 \(No. 5\)](#).

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

The *MRL Standard* is accessible via the Federal Register of Legislation website [www.legislation.gov.au](http://www.legislation.gov.au) or the links above.

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



## **Proposal to amend Schedule 20 in the Australia New Zealand Food Standards Code**

In the previous notice on page 20, the APVMA gazetted amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*, have been made.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2017 (No. 5)*) to MRLs into Schedule 20—Maximum residue limits in the *Australia New Zealand Food Standards Code*.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

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

FSANZ will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization.

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

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.

**PROPOSED VARIATION TO SCHEDULE 20 IN THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE  
(16 May 2017)**

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

**To commence: on gazettal of variation**

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] omitting from each of the following chemicals, the foods and associated MRLs

---

**Agvet chemical: Bixafen**

*Permitted residue—commodities of plant origin:*  
Bixafen

*Permitted residue—commodities of animal origin:*  
Sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen

---

Rape seed	*0.01
-----------	-------

---

[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

---

**Agvet chemical: Bixafen**

*Permitted residue—commodities of plant origin:*  
Bixafen

*Permitted residue—commodities of animal origin:*  
Sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen

---

All other foods	0.03
Cereal grains [except barley; wheat]	*0.01
Milk fats	0.5
Oilseed	*0.01

---

---

**Agvet chemical: Clopyralid**

*Permitted residue: Clopyralid*

---

All other foods except animal food commodities	0.1
--	-----

---

---

**Agvet chemical: Clothianidin**

*Permitted residue: Clothianidin*

---

All other foods except animal food commodities	0.02
Mango	T0.05

---

---

**Agvet chemical: Flumioxazin**

*Permitted residue: Flumioxazin*

Avocado	*0.02
Blueberries	*0.02
Citrus fruits	*0.05
Olives	*0.02
Pome fruits	*0.02
Pomegranate	*0.02
Stone fruits	*0.02
Tree nuts	*0.02

---

**Agvet chemical: Imazamox**

*Permitted residue: Imazamox*

Sorghum	*0.02
---------	-------

---

**Agvet chemical: Imazapyr**

*Permitted residue: Imazapyr*

Sorghum	0.02
---------	------

[1.3] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

---

**Agvet chemical: Bixafen**

*Permitted residue—commodities of plant origin:  
 Bixafen*

*Permitted residue—commodities of animal origin:  
 Sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide  
 (bixafen-desmethyl), expressed as bixafen*

Barley	T0.02
Edible offal (mammalian)	0.7
Meat (mammalian) (in the fat)	0.2
Milks	0.05
Pulses	*0.01
Wheat	T0.02

---

**Agvet chemical: Buprofezin**

*Permitted residue: Buprofezin*

Tomato	T1
--------	----

---

**Agvet chemical: Clopyralid**

*Permitted residue: Clopyralid*

Poppy Seed	T1
------------	----

## INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20—Maximum residue limits in the *Australia New Zealand Food Standards Code*.

Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

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

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

**DEADLINE FOR PUBLIC SUBMISSIONS: 6 pm (AEST) 13 June 2017**

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

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

For further information please contact:

MRL Contact Officer

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

**Phone:** +61 2 6210 4897

**Fax:** +61 2 6210 4840

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

## Variations to Schedule 20 of the Australia New Zealand Food Standards Code

The Australian Pesticides and Veterinary Medicines Authority (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 Schedule 20—Maximum residue limits of the *Australia New Zealand Food Standards Code*. This notice pertains to proposals (No. 2) gazetted on 7 February 2017 (No. APVMA 3).

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 Schedule 20. A copy of the Amendment Instrument (No. APVMA 5, 2017) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislation available on the Legislation website at [www.legislation.gov.au](http://www.legislation.gov.au).

Based on dietary exposure assessments and current health standards, the APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied that these MRLs are not harmful to public health. MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 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.

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

A copy of these variations have been given to FSANZ.

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

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

For further information please contact:

MRL Contact Officer

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

**Phone:** +61 2 6210 4897

**Fax:** +61 2 6210 4840

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



**Australian Government**

---

**Australian Pesticides and  
Veterinary Medicines Authority**

***Australia New Zealand Food Standards Code—  
Schedule 20—Maximum residue limits Variation  
Instrument No. APVMA 5, 2017***

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

Jason Lutze  
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this Eleventh day of May 2017

## Part 1 Preliminary

### 1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code—Schedule 20—Maximum residue limits Variation Instrument No. APVMA 5, 2017*.

### 2 Commencement

In accordance with subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this instrument commences on the day 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 10 of 16 May 2017.

### 3 Object

The object of this instrument is for the APVMA to make variations to Schedule 20—Maximum residue limits in 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 Schedule 20—Maximum residue limits in 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. Schedule 20 was published in the *Food Standards Gazette* FSC 96 on Thursday 10 April 2015 and was registered as a legislative instrument on 1 April 2015 (F2015L00468).

## Part 2 Variations to Schedule 20—Maximum Residue Limits

### 5 Variations to Schedule 20

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

# Schedule

## Variations to Schedule 20—Maximum residue limits

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] omitting from each of the following chemicals, the foods and associated MRLs

---

**Agvet chemical: Pirimicarb**

*Permitted residue: Sum of pirimicarb, demethyl-pirimicarb and the N-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb*

---

Fruit [except strawberry]	0.5
---------------------------	-----

---

[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

---

**Agvet chemical: Flonicamid**

*Permitted residue: Flonicamid [N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [N-(4-trifluoromethylnicotinoyl)glycine]*

---

All other foods except animal food commodities	0.2
--	-----

---



---

**Agvet chemical: Imazamox**

*Permitted residue: Imazamox*

---

All other foods except animal food commodities'	0.05
---	------

---



---

**Agvet chemical: Monepantel**

*Permitted residue: Monepantel*

---

Cattle fat	7
Cattle kidney	1
Cattle liver	2
Cattle meat	0.3
Milks	*0.05

---



---

**Agvet chemical: Pirimicarb**

*Permitted residue: Sum of pirimicarb, demethyl-pirimicarb and the N-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb*

---

All other foods except animal food commodities	0.05
Blackberries	T2
Fruit [except blackberries; strawberry]	0.5

---



---

**Agvet chemical: Propiconazole**

*Permitted residue: Propiconazole*

---

All other foods except animal food commodities	0.05
--	------

---



---

**Agvet chemical: Pyriproxyfen**

*Permitted residue: Pyriproxyfen*

---

All other foods except animal food commodities	0.1
Chervil	T5
Coriander (leaves, roots, stems)	T5
Galangal, Greater	T*0.05
Galangal, Lesser	T*0.05
Mizuna	T5
Rose and dianthus (edible flowers)	T5
Rucola (rocket)	T5
Turmeric, root	T*0.05

---

**Agvet chemical: Spirotetramat**

*Permitted residue: 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*

---

All other foods except animal food commodities	0.1
--	-----

---

## Licensing of Veterinary Chemical Manufacturers

---

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).

---

### 1. NEW 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: 614 716 700

2 Cal Close

SOMERSBY NSW 2250

**LICENCE NO:** 2245

**Product Types:** \*

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

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

**Licence Issued:** 28 April 2017

### 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]

**DELTA LABORATORIES PTY  
LIMITED**

ACN: 050 324 742

8 Warringah Close

SOMERSBY NSW 2250

**LICENCE NO:** 1056

**Product Types:** \*

- *Category 1:* Sterile products.
- *Category 2:* Creams/lotions, ointments, pastes, sprays and liquids.

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat and filtration), analysis and testing (physical and chemical), storage and release for supply.

**Amended Licence Issued:** 13 April 2017

---

\* 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*

**SPHERE HEALTHCARE PTY.  
LIMITED**

**ACN:** 054 309 705

10–12 Church Street

MOOREBANK NSW 2170

**LICENCE NO:** 2187

**Product Types:** \*

- *Category 2:* Tablets, pellets, capsules, capsules (soft gelatine), creams/lotions, ointments, pastes, powders, liquids and suspensions
- *Category 4:* Premixes, supplements and probiotics

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, dry milling of powders, wet milling of powders, granulation, filling, packaging, labelling, strip, blister or sachet packaging, soft gelatine capsule manufacture, tableting, tablet coating, capsule filling from bulk, analysis and testing (physical, chemical and microbiological), storage and release for supply.

**Amended Licence Issued:** 19 April 2017

**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:** 27 April 2017

**PADULA SERUMS PTY. LTD.**

**ACN:** 167 348 610

26 Howitt Ave

BAIRNSDALE VIC 3875

**LICENCE NO:** 1105

**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 and endotoxin), storage and release for supply.

**Amended Licence Issued:** 28 April 2017

---

\* 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].

<b>HESLOP CONTRACT CASTERS PTY LTD</b>	<b>LICENCE NO:</b> 6125
<b>ACN:</b> 116 308 233	<b>Date Cancelled:</b> 3 April 2017
8 Pitt Street	
RESERVOIR VIC 3073	

### 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].

Nil

### 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)

---

\* 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*