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of Australia**

**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,

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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 EXISTING ACTIVE CONSTITUENTS

<b>Application no.:</b>	104559
<b>Product name:</b>	International VC Offshore Racing Finish
<b>Active constituent/s:</b>	A 546 g/L xylene B 1000 g/kg cuprous oxide
<b>Applicant name:</b>	Akzo Nobel Pty Limited
<b>Applicant ACN:</b>	000 119 424
<b>Summary of use:</b>	For use as an antifouling and racing finish on the below waterline areas of boats to help prevent fouling growth
<b>Date of registration:</b>	7 April 2017
<b>Product registration no.:</b>	81981
<b>Label approval no.:</b>	81981/104559
<b>Application no.:</b>	109720
<b>Product name:</b>	Superway Buffalo Soldier Selective Herbicide
<b>Active constituent/s:</b>	200 g/L bromoxynil present as the n-octanoyl ester, 200 g/L MCPA present as the ethyl hexyl ester
<b>Applicant name:</b>	Superway Garden Ag & Pest Products Pty Ltd
<b>Applicant ACN:</b>	056 553 274
<b>Summary of use:</b>	For the control of broadleaf weeds in wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf
<b>Date of registration:</b>	22 May 2017
<b>Product registration no.:</b>	84106
<b>Label approval no.:</b>	84106/109720
<b>Application no.:</b>	106632
<b>Product name:</b>	Kelpie Gly 540 Herbicide
<b>Active constituent/s:</b>	540 g/L glyphosate present as the potassium salt
<b>Applicant name:</b>	Sinochem International Australia Pty Ltd
<b>Applicant ACN:</b>	160 164 616
<b>Summary of use:</b>	For the non-selective control of many annual and perennial weeds in a range of agricultural and non-agricultural situations
<b>Date of registration:</b>	25 May 2017
<b>Product registration no.:</b>	82743
<b>Label approval no.:</b>	82743/106632
<b>Application no.:</b>	108278
<b>Product name:</b>	eChem GrazMore 400 Herbicide
<b>Active constituent/s:</b>	300 g/L triclopyr present as the butoxyethyl ester, 100 g/L picloram present as hexyloxypropylamine salt
<b>Applicant name:</b>	Echem (Aust) Pty Limited
<b>Applicant ACN:</b>	089 133 095
<b>Summary of use:</b>	For the control of a range of environmental and noxious woody and herbaceous weeds.
<b>Date of registration:</b>	25 May 2017
<b>Product registration no.:</b>	83435
<b>Label approval no.:</b>	83435/108278

<b>Application no.:</b>	108520
<b>Product name:</b>	Agsure Chlorpyrifos 500 Insecticide
<b>Active constituent/s:</b>	500 g/L chlorpyrifos (an anti-cholinesterase compound)
<b>Applicant name:</b>	Elders Rural Services Australia Limited
<b>Applicant ACN:</b>	004 045 121
<b>Summary of use:</b>	For the control of certain insect pests in fruit, vegetables, field crops, pastures, other situations and for the post-construction management of subterranean termites
<b>Date of registration:</b>	26 May 2017
<b>Product registration no.:</b>	83508
<b>Label approval no.:</b>	83508/108520
<b>Application no.:</b>	108711
<b>Product name:</b>	Apparent Gunpowder Insecticide
<b>Active constituent/s:</b>	900 g/kg amorphous silica
<b>Applicant name:</b>	Apparent Pty. Ltd
<b>Applicant ACN:</b>	143 724 136
<b>Summary of use:</b>	For the control of various stored product insect pests in farm-stored feed grain
<b>Date of registration:</b>	26 May 2017
<b>Product registration no.:</b>	83611
<b>Label approval no.:</b>	83611/108711
<b>Application no.:</b>	108597
<b>Product name:</b>	Qualipro I-pro 365 Fungicide
<b>Active constituent/s:</b>	365 g/L iprodione
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use:</b>	For control of various fungal diseases in recreational turf
<b>Date of registration:</b>	26 May 2017
<b>Product registration no.:</b>	83549
<b>Label approval no.:</b>	83549/108597
<b>Application no.:</b>	108554
<b>Product name:</b>	Chemforce Propyzamide 500 WG Herbicide
<b>Active constituent/s:</b>	500 g/kg propyzamide
<b>Applicant name:</b>	Chemforce 2010 Pty Ltd
<b>Applicant ACN:</b>	146 807 356
<b>Summary of use:</b>	For selective control of certain grasses and broadleaf weeds in lettuce, sports turf, home lawns, legumes seed crops and pastures
<b>Date of registration:</b>	26 May 2017
<b>Product registration no.:</b>	83528
<b>Label approval no.:</b>	83528/108554
<b>Application no.:</b>	108812
<b>Product name:</b>	Accensi Glyphosate 360 Biaquatic Weed Killer
<b>Active constituent/s:</b>	360 g/L glyphosate present as the isopropylamine salt
<b>Applicant name:</b>	Accensi Pty Ltd
<b>Applicant ACN:</b>	079 875 184
<b>Summary of use:</b>	For use in the garden and around aquatic areas for the control of broadleaf and grass weeds
<b>Date of registration:</b>	26 May 2017
<b>Product registration no.:</b>	83663
<b>Label approval no.:</b>	83663/108812

<b>Application no.:</b>	107560
<b>Product name:</b>	Accensi Paraquat Total 250 Herbicide
<b>Active constituent/s:</b>	250 g/L paraquat present as paraquat dichloride
<b>Applicant name:</b>	Accensi Pty Ltd
<b>Applicant ACN:</b>	079 875 184
<b>Summary of use:</b>	For the control of a wide range of grasses and broadleaf weeds in a range of agricultural and non-agricultural situations
<b>Date of registration:</b>	29 May 2017
<b>Product registration no.:</b>	83115
<b>Label approval no.:</b>	83115/107560
<b>Application no.:</b>	104441
<b>Product name:</b>	Palmero TX Herbicide
<b>Active constituent/s:</b>	75 g/kg isoxaflutole, 750 g/kg terbuthylazine
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use:</b>	For control of various broadleaf weeds and grasses in chickpeas and fallow
<b>Date of registration:</b>	30 May 2017
<b>Product registration no.:</b>	81927
<b>Label approval no.:</b>	81927/104441
<b>Application no.:</b>	108541
<b>Product name:</b>	Sierraron 4G Herbicide
<b>Active constituent/s:</b>	40 g/kg dichlobenil
<b>Applicant name:</b>	Everris Australia Pty Ltd
<b>Applicant ACN:</b>	148 200 962
<b>Summary of use:</b>	For pre-emergent weed control in orchards and vineyards; established shrubs and trees in flower beds, lawns in gardens and nursery stock in pots or field; blackcurrants, raspberries and gooseberries and for weed control around commercial, industrial and aquatic areas
<b>Date of registration:</b>	31 May 2017
<b>Product registration no.:</b>	83522
<b>Label approval no.:</b>	83522/108541
<b>Application no.:</b>	108121
<b>Product name:</b>	Macspred Glufosinate 200 SL Herbicide
<b>Active constituent/s:</b>	200 g/L glufosinate-ammonium
<b>Applicant name:</b>	Macspred Pty Ltd
<b>Applicant ACN:</b>	011 029 495
<b>Summary of use:</b>	For the non-residual control of broadleaf and grass weeds in various situations
<b>Date of registration:</b>	1 June 2017
<b>Product registration no.:</b>	83359
<b>Label approval no.:</b>	83359/108121
<b>Application no.:</b>	108926
<b>Product name:</b>	Rely Herbicide 10 GR
<b>Active constituent/s:</b>	10 g/kg oxadiazon
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use:</b>	For use in various turfs for the control of weeds
<b>Date of registration:</b>	1 June 2017
<b>Product registration no.:</b>	83750
<b>Label approval no.:</b>	83750/108926

<b>Application no.:</b>	108967
<b>Product name:</b>	Raystar Imidacloprid 350 SC Insecticide
<b>Active constituent/s:</b>	350 g/L imidacloprid
<b>Applicant name:</b>	Raystar Cropprotection Pty Ltd
<b>Applicant ACN:</b>	610 946 784
<b>Summary of use:</b>	For the control of greyback, childers canegrub in sugarcane and silverleaf whitefly in various vegetable crops in a soil applied treatment
<b>Date of registration:</b>	1 June 2017
<b>Product registration no.:</b>	83783
<b>Label approval no.:</b>	83783/108967
<b>Application no.:</b>	108968
<b>Product name:</b>	Raystar 2,4-D 625 Dimethylamine Salt SL Herbicide
<b>Active constituent/s:</b>	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
<b>Applicant name:</b>	Raystar Cropprotection Pty Ltd
<b>Applicant ACN:</b>	610 946 784
<b>Summary of use:</b>	For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugarcane, peanuts, and non-agricultural areas
<b>Date of registration:</b>	1 June 2017
<b>Product registration no.:</b>	83784
<b>Label approval no.:</b>	83784/108968
<b>Application no.:</b>	105729
<b>Product name:</b>	ACP Commissioner 150 EC Insecticide
<b>Active constituent/s:</b>	150 g/L indoxacarb
<b>Applicant name:</b>	TGAC Australia Pty. Ltd
<b>Applicant ACN:</b>	134 570 700
<b>Summary of use:</b>	For the control of various species of insect pests in azuki beans, chickpeas, faba beans, mungbeans and soybeans
<b>Date of registration:</b>	1 June 2017
<b>Product registration no.:</b>	82435
<b>Label approval no.:</b>	82435/105729
<b>Application no.:</b>	108933
<b>Product name:</b>	Patriot Fungicide
<b>Active constituent/s:</b>	200 g/L tebuconazole, 100 g/L trifloxystrobin
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use:</b>	For control of fungal diseases in recreational turf
<b>Date of registration:</b>	1 June 2017
<b>Product registration no.:</b>	83757
<b>Label approval no.:</b>	83757/108933
<b>Application no.:</b>	108931
<b>Product name:</b>	Raystar Chlorothalonil 720 SC Fungicide
<b>Active constituent/s:</b>	720 g/L chlorothalonil
<b>Applicant name:</b>	Raystar Cropprotection Pty Ltd
<b>Applicant ACN:</b>	610 946 784
<b>Summary of use:</b>	For the control of fungal diseases on almonds, bananas, cucurbits, grapes, ornamentals, peanuts, stone fruit, tobacco and vegetables
<b>Date of registration:</b>	1 June 2017
<b>Product registration no.:</b>	83755
<b>Label approval no.:</b>	83755/108931

<b>Application no.:</b>	108793
<b>Product name:</b>	Sprawl Organosilicone Surfactant
<b>Active constituent/s:</b>	1020 g/L polyether modified polysiloxane
<b>Applicant name:</b>	Agspec Australia Pty Ltd
<b>Applicant ACN:</b>	109 573 953
<b>Summary of use:</b>	For use with glyphosate and certain brushweed herbicides to improve coverage, penetration and uptake on brush and woody weeds and ryegrass. Also for use with fungicides, insecticides, miticides and foliar micronutrients
<b>Date of registration:</b>	5 June 2017
<b>Product registration no.:</b>	83656
<b>Label approval no.:</b>	83656/108793

## 2. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	106575
<b>Product name:</b>	Fipforce Dust Termiticide & Insecticide
<b>Active constituent/s:</b>	5 g/kg fipronil
<b>Applicant name:</b>	Sherwood Chemicals Public Company Limited
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	To change the product name from 'ULTRAFORCE DUST TERMITICIDE & INSECTICIDE' to 'FIPFORCE DUST TERMITICIDE & INSECTICIDE' and to extend use to include control of nuisance ants
<b>Date of variation:</b>	22 May 2017
<b>Product registration no.:</b>	69588
<b>Label approval no.:</b>	69588/106575

<b>Application no.:</b>	106004
<b>Product name:</b>	Genfarm LV MCPA 570 Herbicide
<b>Active constituent/s:</b>	570 g/L MCPA present as the 2-ethyl hexyl ester
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of variation:</b>	To extend use to control an additional weed
<b>Date of variation:</b>	25 May 2017
<b>Product registration no.:</b>	66979
<b>Label approval no.:</b>	66979/106004

<b>Application no.:</b>	108582
<b>Product name:</b>	Stamina Systemic Fungicide
<b>Active constituent/s:</b>	400 g/kg myclobutanil
<b>Applicant name:</b>	Agrinova New Zealand Limited
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	To extend the claims for use to include the control of powdery mildew on strawberries
<b>Date of variation:</b>	30 May 2017
<b>Product registration no.:</b>	80302
<b>Label approval no.:</b>	80302/108582

<b>Application no.:</b>	104078
<b>Product name:</b>	Mortein Outdoor Fly & Mosquito Automatic Spray Citronella
<b>Active constituent/s:</b>	8 g/kg permethrin, 6 g/kg transfluthrin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To amend the directions for use by extending time before automatic shut off to 5 hours
<b>Date of variation:</b>	30 May 2017
<b>Product registration no.:</b>	68099
<b>Label approval no.:</b>	68099/104078



<b>Application no.:</b>	104079
<b>Product name:</b>	Mortein Outdoor Fly & Mosquito Automatic Spray Odourless
<b>Active constituent/s:</b>	8 g/kg permethrin, 6 g/kg transfluthrin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To amend the directions for use by extending time before automatic shut off to 5 hours
<b>Date of variation:</b>	30 May 2017
<b>Product registration no.:</b>	68097
<b>Label approval no.:</b>	68097/104079
<b>Application no.:</b>	106011
<b>Product name:</b>	Gallery 750 Dry Flowable Herbicide
<b>Active constituent/s:</b>	750 g/kg isoxaben
<b>Applicant name:</b>	Dow Agrosiences Australia Limited
<b>Applicant ACN:</b>	003 771 659
<b>Summary of variation:</b>	To extend use to cereals and industrial situations
<b>Date of variation:</b>	31 May 2017
<b>Product registration no.:</b>	47333
<b>Label approval no.:</b>	47333/106011
<b>Application no.:</b>	108128
<b>Product name:</b>	Termidor HE Residual Termiticide
<b>Active constituent/s:</b>	96 g/L fipronil
<b>Applicant name:</b>	BASF Australia Ltd
<b>Applicant ACN:</b>	008 437 867
<b>Summary of variation:</b>	To amend spacing for rod application for termite control
<b>Date of variation:</b>	31 May 2017
<b>Product registration no.:</b>	80820
<b>Label approval no.:</b>	80820/108128
<b>Application no.:</b>	108324
<b>Product name:</b>	Fumaphos Fumigation Tablets
<b>Active constituent/s:</b>	330 g/kg phosphine (PH <sub>3</sub> ) present as aluminium phosphide
<b>Applicant name:</b>	National Fumigants Pty Ltd
<b>Applicant ACN:</b>	090 505 785
<b>Summary of variation:</b>	To extend the use to include the control of rabbits in burrows and make minor variations to label instructions
<b>Date of variation:</b>	2 June 2017
<b>Product registration no.:</b>	52020
<b>Label approval no.:</b>	52020/108324
<b>Application no.:</b>	109642
<b>Product name:</b>	Surefire Spectrum 350 SC Soil Insecticide
<b>Active constituent/s:</b>	350 g/L imidacloprid
<b>Applicant name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of variation:</b>	To extend use to include injection treatment for control of certain pests in bananas
<b>Date of variation:</b>	2 June 2017
<b>Product registration no.:</b>	66265
<b>Label approval no.:</b>	62265/109642

<b>Application no.:</b>	107589
<b>Product name:</b>	Nufarm Digger Fungicide
<b>Active constituent/s:</b>	250 g/L difenoconazole
<b>Applicant name:</b>	Nufarm Australia Limited
<b>Applicant ACN:</b>	004 377 780
<b>Summary of variation:</b>	To extend use to control of powdery mildew in wine grapes
<b>Date of variation:</b>	2 June 2017
<b>Product registration no.:</b>	65130
<b>Label approval no.:</b>	65130/107589
<b>Application no.:</b>	Not applicable—variation by the APVMA under s29A of the Agvet Code
<b>Product name:</b>	Imtrade Dimethoate 400 EC Insecticide
<b>Active constituent/s:</b>	400 g/kg Dimethoate
<b>Holder name:</b>	Imtrade Australia Pty Ltd
<b>Holder ACN:</b>	090 151 134
<b>Summary of variation:</b>	The APVMA has, with the holder's consent, varied this label to remove an incorrect withholding period reference from the critical comments for lucerne, pasture, pasture seed, fodder crops and oilseeds
<b>Date of variation:</b>	29 May 2017
<b>Product registration no.:</b>	69555
<b>Label approval no.:</b>	RV0317S

### 3. LABEL APPROVAL

<b>Application no.:</b>	108721
<b>Product name:</b>	Oxafert Herbicide And Fertiliser
<b>Active constituent/s:</b>	10 g/kg oxadiazon
<b>Applicant name:</b>	Farmalinx Pty Ltd
<b>Applicant ACN:</b>	134 353 245
<b>Summary of variation:</b>	To approve a new label for the product 'OXAFERT HERBICIDE AND FERTILISER' with the label name 'OXAFERT PK HERBICIDE AND FERTILISER'
<b>Date of variation:</b>	24 May 2017
<b>Product registration no.:</b>	70376
<b>Label approval no.:</b>	70376/108721
<b>Application no.:</b>	108807
<b>Product name:</b>	Dupont Avatar Insecticide
<b>Active constituent/s:</b>	300 g/kg indoxacarb
<b>Applicant name:</b>	Du Pont (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 716 469
<b>Summary of variation:</b>	To approve a new label for the product 'DUPONT AVATAR INSECTICIDE' with the label name 'DUPONT AVATAR EVO INSECTICIDE'
<b>Date of variation:</b>	29 May 2017
<b>Product registration no.:</b>	52546
<b>Label approval no.:</b>	52546/108807
<b>Application no.:</b>	109498
<b>Product name:</b>	Wither 700 Spray Adjuvant
<b>Active constituent/s:</b>	350 g/L soyal phospholipids, 350 g/L propionic acid
<b>Applicant name:</b>	Victorian Chemical Company Proprietary Limited
<b>Applicant ACN:</b>	004 188 863
<b>Summary of variation:</b>	To approve a new label for the product 'WITHER 700 SPRAY ADJUVANT' with the label name 'COOLA-700 SPRAY ADJUVANT'
<b>Date of variation:</b>	29 May 2017
<b>Product registration no.:</b>	64342
<b>Label approval no.:</b>	64342/109498

## 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>	109185
<b>Product name:</b>	Covine Clipshield Spray-On Blowfly Treatment For Sheep
<b>Active constituent/s:</b>	60 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 against fly strike for eleven weeks when used as directed
<b>Date of registration:</b>	24 May 2017
<b>Product registration no.:</b>	83886
<b>Label approval no.:</b>	83886/109185
<b>Application no.:</b>	103322
<b>Product name:</b>	Eradicator Pour-On Lousicide For Sheep
<b>Active constituent/s:</b>	35 g/L imidacloprid
<b>Applicant name:</b>	Jurox Pty Limited
<b>Applicant ACN:</b>	000 932 230
<b>Summary of use:</b>	For the control of body lice ( <i>bovicola ovis</i> ) on sheep
<b>Date of registration:</b>	26 May 2017
<b>Product registration no.:</b>	81540
<b>Label approval no.:</b>	81540/103322
<b>Application no.:</b>	109742
<b>Product name:</b>	Paramec Pour On for Cattle
<b>Active constituent/s:</b>	10 g/L ivermectin
<b>Applicant name:</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN:</b>	156 000 430
<b>Summary of use:</b>	For external treatment of cattle for control of internal and external parasites of beef and dairy cattle
<b>Date of registration:</b>	29 May 2017
<b>Product registration no.:</b>	84128
<b>Label approval no.:</b>	84128/109742
<b>Application no.:</b>	109958
<b>Product name:</b>	Purina Total Care Heartwormer, Allwormer & Flea Control Tasty Chew for Large Dogs
<b>Active constituent/s:</b>	460 mg lufenuron, 228 mg praziquantel, 23 mg milbemycin oxime
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of use:</b>	For the control of fleas, heartworm, worms and flea allergy dermatitis on large dogs
<b>Date of registration:</b>	29 May 2017
<b>Product registration no.:</b>	84238
<b>Label approval no.:</b>	84238/109958

<b>Application no.:</b>	109961
<b>Product name:</b>	Purina Total Care Heartwormer, Allwormer & Flea Control Tasty Chew for Medium Dogs
<b>Active constituent/s:</b>	230 mg lufenuron, 114 mg praziquantel, 11.5 mg milbemycin oxime
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of use:</b>	For the control of fleas, heartworm, worms and flea allergy dermatitis on medium dogs
<b>Date of registration:</b>	29 May 2017
<b>Product registration no.:</b>	84239
<b>Label approval no.:</b>	84239/109961

<b>Application no.:</b>	109962
<b>Product name:</b>	Purina Total Care Heartwormer, Allwormer & Flea Control Tasty Chew for Small Dogs
<b>Active constituent/s:</b>	115 mg lufenuron, 57 mg praziquantel, 5.75 mg milbemycin oxime
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of use:</b>	For the control of fleas, heartworm, worms and flea allergy dermatitis on small dogs
<b>Date of registration:</b>	29 May 2017
<b>Product registration no.:</b>	84240
<b>Label approval no.:</b>	84240/109962

<b>Application no.:</b>	109177
<b>Product name:</b>	Covine Toromec Pour-On For Cattle
<b>Active constituent/s:</b>	5 g/L ivermectin
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use:</b>	For the treatment and control of ivermectin sensitive internal and external parasites of cattle
<b>Date of registration:</b>	31 May 2017
<b>Product registration no.:</b>	83883
<b>Label approval no.:</b>	83883/109177

## 2. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	110286
<b>Product name:</b>	CCD CTC Chlortetracycline Hydrochloride Water Soluble Powder
<b>Active constituent/s:</b>	950 g/kg chlortetracycline hydrochloride
<b>Applicant name:</b>	CCD Animal Health Pty Ltd
<b>Applicant ACN:</b>	151 737 950
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'PHARMACHLOR CTC CHLORTETRACYCLINE SOLUBLE POWDER' to 'CCD CTC CHLORTETRACYCLINE HYDROCHLORIDE WATER SOLUBLE POWDER'
<b>Date of variation:</b>	5 April 2017
<b>Product registration no.:</b>	54719
<b>Label approval no.:</b>	54719/110286

<b>Application no.:</b>	110336
<b>Product name:</b>	Fortekor Flavour 5 Mg Tablets For Dogs and Cats
<b>Active constituent/s:</b>	5 mg/Tb benazepril hydrochloride
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of variation:</b>	To remove the use for the treatment of hypertrophic cardiomyopathy in cats
<b>Date of variation:</b>	10 April 2017
<b>Product registration no.:</b>	61193
<b>Label approval no.:</b>	61193/110336

<b>Application no.:</b>	110367
<b>Product name:</b>	Fortekor Flavour 2.5 Mg Tablets For Dogs and Cats
<b>Active constituent/s:</b>	2.5 mg/Tb benazepril hydrochloride
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of variation:</b>	To remove the use for the treatment of hypertrophic cardiomyopathy in cats
<b>Date of variation:</b>	17 April 2017
<b>Product registration no.:</b>	56829
<b>Label approval no.:</b>	56829/110367
<b>Application no.:</b>	110368
<b>Product name:</b>	Fortekor Flavour 20 Mg Tablets For Dogs and Cats
<b>Active constituent/s:</b>	20 mg/Tb benazepril hydrochloride
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of variation:</b>	To remove the use for the treatment of hypertrophic cardiomyopathy in cats
<b>Date of variation:</b>	17 April 2017
<b>Product registration no.:</b>	61192
<b>Label approval no.:</b>	61192/110368
<b>Application no.:</b>	104913
<b>Product name:</b>	Avenge Pour-On Blowfly Strike Prevention and Lousicide for Sheep
<b>Active constituent/s:</b>	35 g/L imidacloprid
<b>Applicant name:</b>	Bayer Australia Ltd (Animal Health)
<b>Applicant ACN:</b>	000 138 714
<b>Summary of variation:</b>	To extend use for prevention of blowfly strike for up to 14 weeks when applied to sheep with long wool
<b>Date of variation:</b>	11 May 2017
<b>Product registration no.:</b>	62598
<b>Label approval no.:</b>	62598/104913
<b>Application no.:</b>	50618
<b>Product name:</b>	Elanco AF0602 Paylean 20 Ractopamine Hydrochloride Premix
<b>Active constituent/s:</b>	20 g/kg ractopamine hydrochloride (equivalent to 17.8 g/kg ractopamine)
<b>Applicant name:</b>	Elanco Animal Health a Div of Eli Lilly Aust Pty Ltd
<b>Applicant ACN:</b>	000 233 992
<b>Summary of variation:</b>	For increased rate of weight gain and improved feed efficiency in finisher turkeys
<b>Date of variation:</b>	24 May 2017
<b>Product registration no.:</b>	54172
<b>Label approval no.:</b>	54172/50618

## 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>	110041
<b>Active constituent/s:</b>	Clethodim Manufacturing Concentrate
<b>Applicant name:</b>	Sumitomo Chemical Australia Pty Limited
<b>Applicant ACN:</b>	081 096 255
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	23 May 2017
<b>Approval no.:</b>	84282

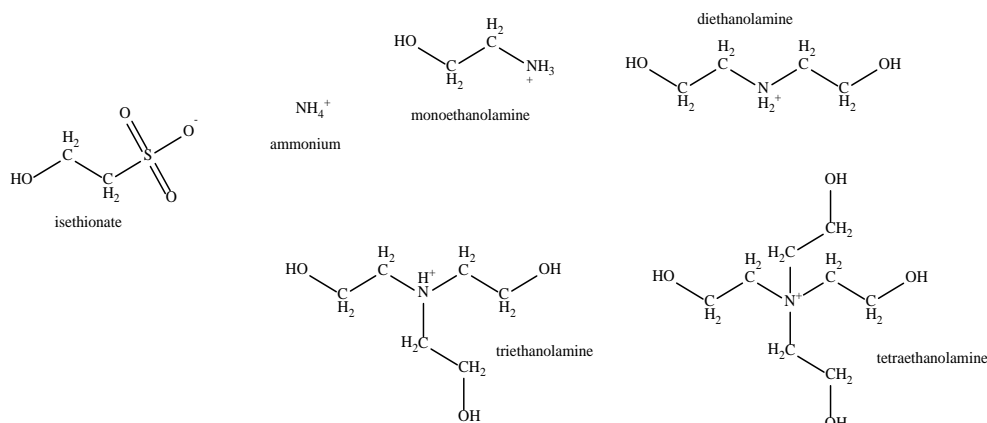
<b>Application no.:</b>	107613
<b>Active constituent/s:</b>	Propineb
<b>Applicant name:</b>	Sabero Australia Pty Limited
<b>Applicant ACN:</b>	087 313 059
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	23 May 2017
<b>Approval no.:</b>	83138

## New Agricultural Active Constituent Mixed Amine Salts of Isethionate Manufacturing Concentrate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, mixed amine salts of isethionate manufacturing concentrate, for use as a spray adjuvant in agricultural products.

<b>Common Name</b>	Mixed amine salts of isethionate manufacturing concentrate
<b>IUPAC Name:</b>	Ammonium 2-hydroxyethanesulfonate, 2-hydroxyethylammonium 2-hydroxyethanesulfonate, bis(2-hydroxyethyl)ammonium 2-hydroxyethanesulfonate, tris(2-hydroxyethyl)ammonium 2-hydroxyethanesulfonate, tetrakis(2-hydroxyethyl)ammonium 2-hydroxyethanesulfonate
<b>CAS Number:</b>	57267-78-4 (ammonium isethionate). CAS numbers not available for the other salts
<b>Molecular Formula:</b>	C <sub>2</sub> H <sub>9</sub> NO <sub>4</sub> S (ammonium salt); C <sub>4</sub> H <sub>13</sub> NO <sub>5</sub> S (monoethanolamine salt); C <sub>6</sub> H <sub>17</sub> NO <sub>6</sub> S (diethanolamine salt); C <sub>8</sub> H <sub>21</sub> NO <sub>7</sub> S (triethanolamine salt); C <sub>10</sub> H <sub>25</sub> NO <sub>8</sub> S (tetraethanolamine salt)
<b>Molecular Weight:</b>	143.2 g mol <sup>-1</sup> (ammonium salt); 187.2 g mol <sup>-1</sup> (monoethanolamine salt); 231.3 g mol <sup>-1</sup> (diethanolamine salt); 275.3 g mol <sup>-1</sup> (triethanolamine salt); 319.4 g mol <sup>-1</sup> (tetraethanolamine salt)

**Structure:**



**Chemical Family:** Alkyl sulfonate

### SUMMARY OF THE APVMA'S EVALUATION OF MIXED AMINE SALTS OF ISETHIONATE ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of the manufacturing concentrate of mixed amine salts of isethionate for use as an active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for mixed amine salts of isethionate manufacturing concentrate:

Constituent	Specification	Level
Mixed amine salts of isethionate	Active content	Minimum 660 g/kg
	Ethylene oxide	Maximum 0.1 mg/kg
	1,4-dioxane	Maximum 1.5 mg/kg

Other impurities of toxicological significance are not expected to occur in mixed amine salts of isethionate manufacturing concentrate as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of mixed amine salts of isethionate, and concluded that there are no toxicological concerns regarding the approval of this active constituent. An Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) have not been established, considering the low acute toxicity of the salts of isethionate.

Mixed amine salts of isethionate have 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 isethionate, as mixed ammonium and ethanolamine salts of 2-hydroxyethanesulfonic acid, were of low toxicity and has included isethionate, as mixed ammonium and ethanolamine salts of 2-hydroxyethanesulfonic acid, 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 mixed amine salts of isethionate 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 mixed amine salts of isethionate manufacturing concentrate 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.

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)

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



## Farmalinx Fix-It Tank Mix Enhancing Agent Containing Mixed Amine Salts of Isethionate (Ammonium Isethionate, Monoethanolamine Isethionate, Diethanolamine Isethionate, Triethanolamine Isethionate and Tetraethanolamine Isethionate)

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 69736/61533—Farmalinx Fix-It Tank Mix Enhancing Agent.

### PARTICULARS OF THE APPLICATION

<b>Proposed product name(s):</b>	69736/61533—Farmalinx Fix-It Tank Mix Enhancing Agent
<b>Applicant company:</b>	Farmalinx Pty Ltd
<b>Name of active constituent:</b>	Mixed amine salts of isethionate (ammonium isethionate, monoethanolamine isethionate, diethanolamine isethionate, triethanolamine isethionate and tetraethanolamine isethionate)
<b>Signal heading:</b>	Not applicable (Appendix B)
<b>Summary of proposed use:</b>	For improvement of physical compatibility and performance of pesticide formulations under adverse environmental conditions
<b>Pack sizes:</b>	1–1000 L
<b>Withholding period:</b>	Not applicable

### SUMMARY OF THE APVMA'S EVALUATION OF FARMALINX FIX-IT TANK MIX ENHANCING AGENT 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 Farmalinx Fix-It Tank Mix Enhancing Agent 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 toxicological aspects of the active constituent have been assessed and considering the low acute toxicity of the salts of isethionate an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) have not been established and the active has been placed into Appendix B (substances considered not to require control by scheduling) of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).

Six acute toxicology studies conducted on the product in accordance with contemporary test guidelines were submitted and considered to be adequate for the assessment of the toxicological profile of the product. Based on findings from the studies, the product has low acute oral, low acute dermal and low acute inhalational toxicity. It is a slight eye irritant but is not a skin irritant or a skin sensitiser.

An exposure assessment was conducted using estimates from the Pesticide Handler Exposure Database Surrogate Exposure Guide (1998), and used in conjunction with the hazard profile to determine that the proposed use of the product would not be an undue health hazard to humans. Based on the outcomes of the risk assessment, appropriate First Aid Instructions and Safety Directions have been established.

After consideration of the hazards associated with the proposed product, along with the exposure and risks expected with use of the proposed product, it was considered that Farmalinx Fix-It Tank Mix Enhancing Agent will not be an undue health hazard to humans.

- (ii) The APVMA is satisfied that the proposed use of Farmalinx Fix-It Tank Mix Enhancing Agent will not be an undue hazard to the safety of people using anything containing its residues. Products from metabolism of the active constituent are present as naturally occurring metabolites. Hence residues from the active constituent are not distinguishable from the naturally-occurring background levels.
- (iii) The APVMA is satisfied that the proposed use of Farmalinx Fix-It Tank Mix Enhancing Agent containing the active constituent mixed amine salts of isethionate (ammonium isethionate, monoethanolamine isethionate, diethanolamine isethionate, triethanolamine isethionate and tetraethanolamine isethionate) 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 Farmalinx Fix-It Tank Mix Enhancing Agent is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

One biodegradability and three ecotoxicity studies were submitted to address environmental fate and effects on non-target species. The biodegradability of the test substance was assessed using Organisation for Economic Co-operation and Development (OECD) test method 301D which found that the substance was biodegradable. The ecotoxicity tests on the adjuvant and results from the United States Environmental Protection Agency (USEPA) ECOTOX database allowed the hazard of the product to be classified as low since the LC (EC) 50s are less than 0.1 g/L. However, there was insufficient data to determine aquatic safety of the product, and therefore a restriction 'Do not apply in aquatic situations' will be added to the label.

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.

Two field trials were submitted to demonstrate reduction in effect of hard water on performance of glyphosate and reduction in antagonism between glyphosate and atrazine and compared to an industry standard. Both product and the standard were applied at 0.5%, 1%, 1.5% and 2% with glyphosate formulations either alone or in tank-mix with atrazine. The trials were conducted using tap water and hard water and targeted annual ryegrass and wild radish weeds. Fresh weight analysis was undertaken 14 days after application with results analysed using factorial analysis of variance. The assessment of the treatments indicated that the effect of hard water on efficacy as well as the antagonism between atrazine and glyphosate were reduced (in a similar manner as the standard) by use of Farmalinx Fix-It Tank Mix Enhancing Agent. Bioequivalence in efficacy to reduce the effect of hard water on the performance of glyphosate formulations and to reduce antagonism between glyphosate and atrazine was demonstrated between the proposed product and an industry standard.

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 Farmalinx Fix-It Tank Mix Enhancing Agent would not adversely affect trade between Australia and places outside Australia. As noted in 1 (i) above, residues are not expected to be measurable from the use of the product, considering that the active constituent metabolites are naturally-occurring and thus not distinguishable from the background environmental levels. Since residues are not distinguishable, the use of the product is not expected to impact trade.

### 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 Farmalinx Fix-It Tank Mix Enhancing Agent 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)<sup>1</sup> 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)

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

## 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 affect 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. 6)*.

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

The *MRL Standard* is accessible via the 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 of the Australia New Zealand Food Standards Code

In the previous notice, on page 20 of APVMA Gazette 12, 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. 6)*) 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 (WTO).

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

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to 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  
(13 June 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] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

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**Agvet chemical: Fluazinam**

*Permitted residue: Fluazinam*

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Strawberry	T*0.05
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**Agvet chemical: Pyraflufen-ethyl**

*Permitted residue: Sum of pyraflufen-ethyl and its acid metabolite (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid)*

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Broad bean (dry) (fava bean)	*0.02
Field pea (dry)	*0.02

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**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*

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Maize	T*0.02
Sorghum	T*0.02

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**INVITATION FOR SUBMISSIONS**

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary 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) 11 July 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. 3) gazetted on 21 March 2017 (No. APVMA 6).

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 6, 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 minimizing 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  
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**Australian Government**  

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**Australian Pesticides and  
Veterinary Medicines Authority**

***Australia New Zealand Food Standards Code —  
Schedule 20 — Maximum residue limits  
variation Instrument No. APVMA 6, 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 Fifth day of June 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 6, 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 12 of 13 June 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] inserting in alphabetical order

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**Agvet chemical: Cloquintocet acid**

see *Cloquintocet mexyl*

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*Residues arising from the use of cloquintocet acid are covered by the MRLs for cloquintocet mexyl*

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

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**Agvet chemical: Metolachlor**

*Permitted residue: Metolachlor*

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All other foods except animal food commodities	0.02
Beetroot	T0.7
Beetroot leaves	T15

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**Agvet chemical: Propyzamide**

*Permitted residue: Propyzamide*

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All other foods except animal food commodities	0.02
Quinoa	T0.02

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

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**Agvet chemical: Fluopicolide**

*Permitted residue: Fluopicolide*

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All other foods	0.01
Bulb vegetables [except onion, bulb]	3
Edible offal (mammalian)	*0.01
Eggs	*0.01
Fruiting vegetables, cucurbits	0.5
Lettuce, head	30
Lettuce, leaf	30
Meat (mammalian) (in the fat)	*0.01
Milks	*0.01
Onion, bulb	0.1
Poppy seed	0.5
Potato	0.05
Poultry, edible offal of	*0.01
Poultry meat (in the fat)	*0.01

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**Agvet chemical: Propamocarb**

*Permitted residue: Propamocarb (base)*

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Bulb vegetables [except onion, bulb]	30
Edible offal (mammalian)	*0.01
Eggs	*0.01
Fruiting vegetables, cucurbits	5
Lettuce, head	70
Lettuce, leaf	70
Meat (mammalian)	*0.01
Milks	*0.01
Onion, bulb	0.5
Poppy seed	5
Potato	0.05
Poultry, edible offal of	*0.01
Poultry meat	*0.01

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## 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]

<b>SYMBIO LABORATORIES PTY LTD</b>	<b>LICENCE NO:</b> 6210
<b>ACN:</b> 079 645 015	<b>Product Types:*</b>
2 Sirius Road	<ul style="list-style-type: none"><li>• <i>Category 6:</i> Single step manufacture</li></ul>
LANE COVE (WEST)	<b>Step(s) of Manufacture:</b> Analysis and testing (physical, chemical and microbiological)
NSW 2066	<b>Licence Issued:</b> 18 May 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]

<b>BIOPROPERTIES PTY. LTD.</b>	<b>LICENCE NO:</b> 1061
<b>ACN:</b> 007 303 728	<b>Product Types:*</b>
11–15 Moores Road	<ul style="list-style-type: none"><li>• <i>Category 1:</i> Immunobiologicals, sterile diluents</li></ul>
GLENORIE NSW 2157	<b>Step(s) of Manufacture:</b> Quality assurance (QA) of raw materials, management of donor animals, virus cultivation, mycoplasma cultivation, bacterial fermentation, oocyst antigen production, oocyst processing, formulation including blending, aseptic filling, filling, packaging, labelling, microbiological reduction treatment (heat, chemical, filtration), sterilisation (heat, chemical, filtration), freeze-drying, analysis and testing (physical, immunobiological, microbiological, oocyst counts), storage and release for supply.
	<b>Amended Licence Issued:</b> 25 May 2017

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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*

**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:** 25 May 2017

### 3. LICENCE CANCELLATIONS

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

**APEX LABORATORIES PTY.  
LTD.**

**ACN:** 000 397 240

2 Cal Close

SOMERSBY NSW 2250

**LICENCE NO:** 2241

**Date Cancelled:** 11 May 2017

**PHIBRO ANIMAL HEALTH PTY  
LIMITED**

**ACN:** 093 869 991

Unit 4; 129 Magowar Road

GIRRAWEE NSW 2145

**LICENCE NO:** 6121

**Date Cancelled:** 22 May 2017

### 4. LICENCE SUSPENSIONS

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

**UNIVERSITY OF NEW  
ENGLAND**

**ABN:** 75 792 454 315

Reproductive & Metabolic

Endocrinology Laboratory

School of Science & Technology

McClymont Building

University of New England

ARMIDALE NSW 2351

**LICENCE NO:** 6142

**Date Suspended:** 25 May 2017 to 25 September 2017

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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*

## 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  
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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*

## Cancellation of Product Registrations and Associated Label Approvals at the Request of the Holder

At the request of the holder, the APVMA has cancelled the suspended product registrations and the associated label approvals of the following products:

Product no	Product name	Label approval number	Registrant/approval holder	Date of effect
50787	UNIROYAL CHEMICAL COTTON PLANTER BOX PROTECTANT	50787/0498 50787/0603	AMGROW PTY LTD	1 June 2017
50789	UNIROYAL CHEMICAL TERRACLOR COTTON SEED PROTECTANT	50789/0498 50789/0300	AMGROW PTY LTD	1 June 2017
55743	TERRACLOR SEED TREATMENT	55743/1106 55743/0105	AMGROW PTY LTD	1 June 2017
45883	UNIROYAL CHEMICAL TERRACLOR SUPER-X E.C SOIL FUNGICIDE	45883/0903	AMGROW PTY LTD	1 June 2017

The following instructions set out how a person can deal with the cancelled product registrations and associated label approvals.

### SUPPLY

A person may supply or cause to be supplied product manufactured prior to 1 June 2017 at wholesale and retail level, until 1 June 2018.

After 1 June 2018 it will be an offence against the Agvet Codes to have possession or custody of the product registrations with the intention to supply, or to supply the product registrations and associated label approvals listed in the table above.

### USE

A person may continue to use the products according to its label instructions until 1 June 2018.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product registrations and associated label approvals listed above 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 products after the registration has been cancelled until 1 June 2018.

The supply and use of the product registrations and associated label approvals 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 registrations and associated label approvals listed in the table in a manner that contravenes the above instructions.



## APVMA CONTACT

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