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# Gazette

**Agricultural and  
Veterinary Chemicals**

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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](http://apvma.gov.au).

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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>	121381
<b>Product name:</b>	Biflex Wood Treatment
<b>Active constituent/s:</b>	100 g/L bifenthrin
<b>Applicant name:</b>	FMC Australasia Pty Ltd
<b>Applicant ACN:</b>	095 326 891
<b>Summary of use:</b>	For the protection of timber and timber based products from damage by borers and termites as specified in the directions for use table
<b>Date of registration:</b>	29 October 2019
<b>Product registration no.:</b>	88463
<b>Label approval no.:</b>	88463/121381

<b>Application no.:</b>	119224
<b>Product name:</b>	Surefire Strike 240EC Herbicide
<b>Active constituent/s:</b>	240 g/L oxyfluorfen
<b>Applicant name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of use:</b>	For the selective control of certain broadleaf and grass weeds
<b>Date of registration:</b>	29 October 2019
<b>Product registration no.:</b>	87772
<b>Label approval no.:</b>	87772/119224

<b>Application no.:</b>	121013
<b>Product name:</b>	Vitalyse Spa Sanitiser
<b>Active constituent/s:</b>	504 g/kg available chlorine (Cl) present as sodium dichloroisocyanurate
<b>Applicant name:</b>	Focus Products Pty Ltd
<b>Applicant ACN:</b>	073 540 520
<b>Summary of use:</b>	For the control of algae and bacteria in outdoor spas and hot tub water
<b>Date of registration:</b>	4 November 2019
<b>Product registration no.:</b>	88355
<b>Label approval no.:</b>	88355/121013

<b>Application no.:</b>	118089
<b>Product name:</b>	Off! Tropical Strength Plus Smooth & Dry Insect Repellent Spray
<b>Active constituent/s:</b>	250 g/kg diethyltoluamide
<b>Applicant name:</b>	SC Johnson & Son Pty Ltd
<b>Applicant ACN:</b>	000 021 009
<b>Summary of use:</b>	For use as a personal insect repellent to repel mosquitoes and other biting insects
<b>Date of registration:</b>	4 November 2019
<b>Product registration no.:</b>	87318
<b>Label approval no.:</b>	87318/118089

<b>Application no.:</b>	121786
<b>Product name:</b>	Barmac 2,4-D Amine 625 Selective Herbicide
<b>Active constituent/s:</b>	625 g/L 2,4 D present as the dimethylamine salt
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of use:</b>	For the control of broadleafed weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas as per the directions for use
<b>Date of registration:</b>	4 November 2019
<b>Product registration no.:</b>	88602
<b>Label approval no.:</b>	88602/121786

<b>Application no.:</b>	121592
<b>Product name:</b>	Barmac 2,4-D 475 Dual Selective Herbicide
<b>Active constituent/s:</b>	475 g/L 2,4-D present as the dimethylamine + diethanolamine salts
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of use:</b>	For the control of emerged broadleaf weeds prior to sowing crops and pastures in conservation tillage situations and for selective weed control in crops and situations detailed in the directions for use
<b>Date of registration:</b>	4 November 2019
<b>Product registration no.:</b>	88524
<b>Label approval no.:</b>	88524/121592

<b>Application no.:</b>	121456
<b>Product name:</b>	Farmalinx MSMA 800 Herbicide
<b>Active constituent/s:</b>	800 g/L MSMA
<b>Applicant name:</b>	Farmalinx Pty Ltd
<b>Applicant ACN:</b>	134 353 245
<b>Summary of use:</b>	For control of annual and perennial grasses and burrs in cotton, annual and perennial grasses in sugarcane, grass weeds in couch turf, prickly pear and grasses and burrs in non-crop areas
<b>Date of registration:</b>	5 November 2019
<b>Product registration no.:</b>	88479
<b>Label approval no.:</b>	88479/121456

<b>Application no.:</b>	121460
<b>Product name:</b>	Farmalinx Tree and Blackberry Killer
<b>Active constituent/s:</b>	50 g/L triclopyr present as the butoxyethyl ester
<b>Applicant name:</b>	Farmalinx Pty Ltd
<b>Applicant ACN:</b>	134 353 245
<b>Summary of use:</b>	For control of blackberry, lantana, groundsel, privet, wattles and other woody weeds in the home garden
<b>Date of registration:</b>	5 November 2019
<b>Product registration no.:</b>	88480
<b>Label approval no.:</b>	88480/121460

<b>Application no.:</b>	118188
<b>Product name:</b>	Anhui Guangxin Azoxystrobin 250SC Fungicide
<b>Active constituent/s:</b>	250 g/L azoxystrobin
<b>Applicant name:</b>	Anhui Guangxin Agrochemical Co Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For control of various diseases of grapes, potatoes, tomatoes, cucurbits, avocados, mangoes, passionfruit and poppies
<b>Date of registration:</b>	7 November 2019
<b>Product registration no.:</b>	87365
<b>Label approval no.:</b>	87365/118188

<b>Application no.:</b>	119232
<b>Product name:</b>	Nasi 800 Herbicide
<b>Active constituent/s:</b>	800 g/L thiobencarb
<b>Applicant name:</b>	Grochem Australia Pty Ltd
<b>Applicant ACN:</b>	169 400 033
<b>Summary of use:</b>	For the control of barnyard grass and certain annual sedges, including dirty dora in rice
<b>Date of registration:</b>	7 November 2019
<b>Product registration no.:</b>	87774
<b>Label approval no.:</b>	87774/119232

<b>Application no.:</b>	121498
<b>Product name:</b>	Redox Sodium Hypochlorite 10% Solution
<b>Active constituent/s:</b>	100 g/L available chlorine (Cl) present as sodium hypochlorite
<b>Applicant name:</b>	Redox Pty Ltd
<b>Applicant ACN:</b>	000 762 345
<b>Summary of use:</b>	For the control of algae and bacteria in swimming pools
<b>Date of registration:</b>	8 November 2019
<b>Product registration no.:</b>	88494
<b>Label approval no.:</b>	88494/121498

<b>Application no.:</b>	118707
<b>Product name:</b>	Tekko Pro Insect Growth Regulator
<b>Active constituent/s:</b>	12 g/L pyriproxyfen, 12 g/L novaluron
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use:</b>	For the control of flea larvae and immature Brown-banded and German cockroaches in and around commercial, domestic, industrial and public buildings
<b>Date of registration:</b>	8 November 2019
<b>Product registration no.:</b>	87581
<b>Label approval no.:</b>	87581/118707

<b>Application no.:</b>	117991
<b>Product name:</b>	Avow Insecticide
<b>Active constituent/s:</b>	44 g/kg emamectin present as emamectin benzoate
<b>Applicant name:</b>	Agritrading Pty Limited
<b>Applicant ACN:</b>	134 291 295
<b>Summary of use:</b>	For the control of Diamondback Moth (Cabbage Moth) and Cabbage White Butterfly in brassica vegetables, and Heliothis in capsicum, lettuce and tomatoes
<b>Date of registration:</b>	8 November 2019
<b>Product registration no.:</b>	87263
<b>Label approval no.:</b>	87263/117991

## 2. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	122289
<b>Product name:</b>	Sharpen Herbicide
<b>Active constituent/s:</b>	700 g/kg saflufenacil
<b>Applicant name:</b>	BASF Australia Ltd
<b>Applicant ACN:</b>	008 437 867
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'SHARPEN WG HERBICIDE' to 'SHARPEN HERBICIDE'
<b>Date of variation:</b>	25 October 2019
<b>Product registration no.:</b>	62853
<b>Label approval no.:</b>	62853/122289

<b>Application no.:</b>	120802
<b>Product name:</b>	Contact Organics FarmSafe Weed Terminator Concentrate Herbicide
<b>Active constituent/s:</b>	900 g/L acetic acid, 10 g/L hydrochloric acid
<b>Applicant name:</b>	Contact Organics Pty Ltd
<b>Applicant ACN:</b>	607 848 091
<b>Summary of variation:</b>	To add additional pack sizes
<b>Date of variation:</b>	29 October 2019
<b>Product registration no.:</b>	86050
<b>Label approval no.:</b>	86050/120802

<b>Application no.:</b>	121689
<b>Product name:</b>	Farmalinx Iprine 250 Fungicide
<b>Active constituent/s:</b>	250 g/L iprodione
<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 'FARMALINX IPRINE 250 FUNGICIDE' with the label name 'PROFORCE VOLTAR GT 250 SC FUNGICIDE'
<b>Date of variation:</b>	29 October 2019
<b>Product registration no.:</b>	64295
<b>Label approval no.:</b>	64295/121689

<b>Application no.:</b>	122312
<b>Product name:</b>	Conquest Bayonet Flexi 500 Fungicide
<b>Active constituent/s:</b>	500 g/L flutriafol
<b>Applicant name:</b>	Conquest Crop Protection Pty Ltd
<b>Applicant ACN:</b>	098 814 932
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'Conquest Pro 500 In-Furrow Fungicide' to 'Conquest Bayonet Flexi 500 Fungicide'
<b>Date of variation:</b>	30 October 2019
<b>Product registration no.:</b>	80012
<b>Label approval no.:</b>	80012/122312

<b>Application no.:</b>	121623
<b>Product name:</b>	Nufarm CRUCIAL Advanced Technology Herbicide
<b>Active constituent/s:</b>	600 g/L glyphosate as potassium, monomethylamine & mono-ammonium salt
<b>Applicant name:</b>	Nufarm Australia Limited
<b>Applicant ACN:</b>	004 377 780
<b>Summary of variation:</b>	To add use patterns from reference products and to reformat the label
<b>Date of variation:</b>	4 November 2019
<b>Product registration no.:</b>	86761
<b>Label approval no.:</b>	86761/121623

<b>Application no.:</b>	121766
<b>Product name:</b>	Farmalinx Propicon 550 EC Fungicide
<b>Active constituent/s:</b>	550 g/L propiconazole, 371 g/L hydrocarbon liquid
<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 'FARMALINX PROPICON 550 EC FUNGICIDE' with the label name 'PROFORCE SPARTAN 550 FUNGICIDE'
<b>Date of variation:</b>	5 November 2019
<b>Product registration no.:</b>	68606
<b>Label approval no.:</b>	68606/121766

<b>Application no.:</b>	121768
<b>Product name:</b>	Farmalinx Bifentin 100 SC Termiticide And Insecticide
<b>Active constituent/s:</b>	100 g/L bifenthrin
<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 'FARMALINX BIFENTIN 100 SC TERMITICIDE AND INSECTICIDE' with the label name 'PROFORCE RUMBLER 100 SC INSECTICIDE'
<b>Date of variation:</b>	5 November 2019
<b>Product registration no.:</b>	67815
<b>Label approval no.:</b>	67815/121768

<b>Application no.:</b>	121769
<b>Product name:</b>	Farmalinx Brawler Herbicide
<b>Active constituent/s:</b>	750 g/kg halosulfuron-methyl
<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 'FARMALINX BRAWLER HERBICIDE' with the label name 'PROFORCE PROSEGE 750 DF HERBICIDE'
<b>Date of variation:</b>	5 November 2019
<b>Product registration no.:</b>	87820
<b>Label approval no.:</b>	87820/121769

<b>Application no.:</b>	121472
<b>Product name:</b>	Titan Simazine 900 WG Herbicide
<b>Active constituent/s:</b>	900 g/kg simazine
<b>Applicant name:</b>	Titan Ag Pty Ltd
<b>Applicant ACN:</b>	122 081 574
<b>Summary of variation:</b>	To add use patterns to the label
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	62193
<b>Label approval no.:</b>	62193/121472



<b>Application no.:</b>	121484
<b>Product name:</b>	Titan Atrazine 900 WG Herbicide
<b>Active constituent/s:</b>	900 g/kg atrazine
<b>Applicant name:</b>	Titan Ag Pty Ltd
<b>Applicant ACN:</b>	122 081 574
<b>Summary of variation:</b>	To update the directions for use to add use patterns
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	62191
<b>Label approval no.:</b>	62191/121484

<b>Application no.:</b>	121495
<b>Product name:</b>	4farmers Triclopyr 755 Herbicide
<b>Active constituent/s:</b>	755 g/L triclopyr present as the butoxyethyl ester
<b>Applicant name:</b>	4 Farmers Australia Pty Ltd
<b>Applicant ACN:</b>	160 092 428
<b>Summary of variation:</b>	To include additional restraints on the label
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	83396
<b>Label approval no.:</b>	83396/121495

<b>Application no.:</b>	121844
<b>Product name:</b>	Farmalinx Abacin 18 EC Insecticide/Miticide
<b>Active constituent/s:</b>	265 g/L N-methyl-2-pyrrolidone, 18 g/L abamectin
<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 'Farmalinx Abacin 18 EC Insecticide/Miticide' with the label name 'ProForce Malice 18 Miticide'
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	65471
<b>Label approval no.:</b>	65471/121844

<b>Application no.:</b>	121825
<b>Product name:</b>	Farmalinx Bazooka Dry 800 SG Herbicide
<b>Active constituent/s:</b>	800 g/kg glyphosate present as the acid and ammonium salt
<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 'Farmalinx Bazooka Dry 800 SG Herbicide' with the label name 'ProForce Rapid Fire 800 SG Herbicide'
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	68210
<b>Label approval no.:</b>	68210/121825

<b>Application no.:</b>	121843
<b>Product name:</b>	Farmalinx Firestorm Herbicide
<b>Active constituent/s:</b>	350 g/L terbuthylazine, 100 g/L glyphosate present as the isopropylamine salt, 60 g/L amitrole, 15 g/L oxyfluorfen
<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 'Farmalinx Firestorm Herbicide' with the label name 'ProForce Numchuk Quad Herbicide'
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	81009
<b>Label approval no.:</b>	81009/121843

<b>Application no.:</b>	120439
<b>Product name:</b>	Campbell Fludy 230SC Fungicide
<b>Active constituent/s:</b>	230 g/L fludioxonil
<b>Applicant name:</b>	Colin Campbell (Chemicals) Pty Ltd
<b>Applicant ACN:</b>	000 045 590
<b>Summary of variation:</b>	To include the control of postharvest diseases of mangoes and pomegranates
<b>Date of variation:</b>	7 November 2019
<b>Product registration no.:</b>	83843
<b>Label approval no.:</b>	83843/120439

<b>Application no.:</b>	121539
<b>Product name:</b>	Smart Pass 450 Herbicide
<b>Active constituent/s:</b>	450 g/L 2,4-D present as the isopropylamine salt
<b>Applicant name:</b>	Crop Smart Pty Ltd
<b>Applicant ACN:</b>	093 927 961
<b>Summary of variation:</b>	To update the label as per the review of 2,4-D
<b>Date of variation:</b>	7 November 2019
<b>Product registration no.:</b>	66069
<b>Label approval no.:</b>	66069/121539

<b>Application no.:</b>	121551
<b>Product name:</b>	Smart Ester 680 Herbicide
<b>Active constituent/s:</b>	680 g/L 2,4-D present as the 2-ethylhexyl ester
<b>Applicant name:</b>	Crop Smart Pty Ltd
<b>Applicant ACN:</b>	093 927 961
<b>Summary of variation:</b>	To add the restraints required as per the review of 2,4 -D
<b>Date of variation:</b>	7 November 2019
<b>Product registration no.:</b>	65116
<b>Label approval no.:</b>	65116/121551

<b>Application no.:</b>	119110
<b>Product name:</b>	4Farmers Prosulfocarb Herbicide
<b>Active constituent/s:</b>	800 g/L prosulfocarb
<b>Applicant name:</b>	4 Farmers Australia Pty Ltd
<b>Applicant ACN:</b>	160 092 428
<b>Summary of variation:</b>	To extend the use to barley and to vary the application timing
<b>Date of variation:</b>	8 November 2019
<b>Product registration no.:</b>	82536
<b>Label approval no.:</b>	82536/119110

<b>Application no.:</b>	121576
<b>Product name:</b>	Imtrade Triclopyr 750 EC Herbicide
<b>Active constituent/s:</b>	750 g/L triclopyr present as the butoxyethyl ester
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of variation:</b>	To remove any knapsack or handheld uses, update of Safety Directions and First Aid instructions
<b>Date of variation:</b>	8 November 2019
<b>Product registration no.:</b>	82974
<b>Label approval no.:</b>	82974/121576

<b>Application no.:</b>	121578
<b>Product name:</b>	Imtrade Hurricane Ultimate 750 Herbicide
<b>Active constituent/s:</b>	750 g/L triclopyr present as the butoxyethyl ester
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of variation:</b>	To remove any knapsack or handheld uses
<b>Date of variation:</b>	8 November 2019
<b>Product registration no.:</b>	65917
<b>Label approval no.:</b>	65917/121578

<b>Application no.:</b>	121606
<b>Product name:</b>	Abrade Abrasive Barrier Insecticide
<b>Active constituent/s:</b>	450 g/L amorphous silica
<b>Applicant name:</b>	Grow Choice Pty Limited
<b>Applicant ACN:</b>	161 264 884
<b>Summary of variation:</b>	To add pest control in mustard and tomatoes under the APVMA permit to label project
<b>Date of variation:</b>	8 November 2019
<b>Product registration no.:</b>	58149
<b>Label approval no.:</b>	58149/121606

## 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>	108435
<b>Product name:</b>	Cormedin 5 Mg Tablets For Dogs
<b>Active constituent/s:</b>	5 mg/Tb pimobendan
<b>Applicant name:</b>	Jurox Pty Limited
<b>Applicant ACN:</b>	000 932 230
<b>Summary of use:</b>	For the treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation) and the treatment of preclinical DCM in large breed dogs
<b>Date of registration:</b>	31 October 2019
<b>Product registration no.:</b>	83486
<b>Label approval no.:</b>	83486/108435

<b>Application no.:</b>	108442
<b>Product name:</b>	Cormedin 1.25 mg Tablets For Dogs
<b>Active constituent/s:</b>	1.25 mg/Tb pimobendan.
<b>Applicant name:</b>	Jurox Pty Limited
<b>Applicant ACN:</b>	000 932 230
<b>Summary of use:</b>	For the treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation) and the treatment of preclinical DCM in large breed dogs
<b>Date of registration:</b>	31 October 2019
<b>Product registration no.:</b>	83487
<b>Label approval no.:</b>	83487/108442

<b>Application no.:</b>	108451
<b>Product name:</b>	Cormedin 2.5 mg Tablets For Dogs
<b>Active constituent/s:</b>	2.5 mg/Tb pimobendan.
<b>Applicant name:</b>	Jurox Pty Limited
<b>Applicant ACN:</b>	000 932 230
<b>Summary of use:</b>	For the treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation) and the treatment of preclinical DCM in large breed dogs
<b>Date of registration:</b>	31 October 2019
<b>Product registration no.:</b>	83489
<b>Label approval no.:</b>	83489/108451

<b>Application no.:</b>	121206
<b>Product name:</b>	Sowmate Oral Progestagen For Horses
<b>Active constituent/s:</b>	2.2 mg/mL altrenogest
<b>Applicant name:</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN:</b>	156 000 430
<b>Summary of use:</b>	For use in horses for regulation and control of the breeding cycle of mares and the maintenance of pregnancy in habitually aborting mares, or mares at risk of early abortion
<b>Date of registration:</b>	5 November 2019
<b>Product registration no.:</b>	88398
<b>Label approval no.:</b>	88398/121206

<b>Application no.:</b>	118180
<b>Product name:</b>	Zycan Single Dose Injection
<b>Active constituent/s:</b>	100 mg/mL polysulphated glycosaminoglycan
<b>Applicant name:</b>	Randlab Australia Pty Ltd
<b>Applicant ACN:</b>	114 948 837
<b>Summary of use:</b>	An aid in the treatment of traumatic and degenerative aseptic joint disease in horses
<b>Date of registration:</b>	7 November 2019
<b>Product registration no.:</b>	87359
<b>Label approval no.:</b>	87359/118180

<b>Application no.:</b>	118063
<b>Product name:</b>	Sowmate Oral Progestagen For Pigs
<b>Active constituent/s:</b>	4 mg/mL altrenogest
<b>Applicant name:</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN:</b>	156 000 430
<b>Summary of use:</b>	Registration of an oral solution for the programming of oestrus in sexually mature gilts and primiparous sows intended for breeding
<b>Date of registration:</b>	7 November 2019
<b>Product registration no.:</b>	87302
<b>Label approval no.:</b>	87302/118063

<b>Application no.:</b>	121481
<b>Product name:</b>	Monemix 100 Premix
<b>Active constituent/s:</b>	100 g/kg monensin (as monensin sodium)
<b>Applicant name:</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN:</b>	156 000 430
<b>Summary of use:</b>	For improving feed efficiency in feedlot cattle; as an aid in the control of bloat in feedlot cattle and dairy cows; to increase milk production in dairy cows under many conditions; as an aid in reducing the severity of non-clinical ketosis in lactating dairy cows; to improve weight gain, feed efficiency and reproductive performance in heifers; to improve weight gain and feed efficiency in pasture cattle and sheep; and as an aid in the prevention of coccidiosis in chickens, cattle and goats
<b>Date of registration:</b>	7 November 2019
<b>Product registration no.:</b>	88487
<b>Label approval no.:</b>	88487/121481

## 2. VARIATIONS OF REGISTRATION

<b>Application no.:</b>	122204
<b>Product name:</b>	Marks-Min Injectable Trace Mineral With Vitamin B12 For Cattle
<b>Active constituent/s:</b>	26.7 g/L zinc as zinc disodium EDTA, 10g/L copper as disodium copper EDTA, 6.7 g/L manganese as disodium manganese EDTA, 3.3 g/L selenium as sodium selenate, 1.4 g/L cyanocobalamin
<b>Applicant name:</b>	Boehringer Ingelheim Animal Health Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'Element Injectable Trace Mineral With Vitamin B12 For Cattle' to 'Marks-Min Injectable Trace Mineral With Vitamin B12 For Cattle'
<b>Date of variation:</b>	22 October 2019
<b>Product registration no.:</b>	87283
<b>Label approval no.:</b>	87283/122204

<b>Application no.:</b>	122205
<b>Product name:</b>	Marks-Min Copper Free Injectable Trace Mineral With Vitamin B12 For Cattle & Sheep
<b>Active constituent/s:</b>	26.7 g/L zinc as zinc disodium EDTA, 6.7 g/L manganese as disodium manganese EDTA, 3.3 g/L selenium as sodium selenite, 1.4 g/L cyanocobalamin
<b>Applicant name:</b>	Boehringer Ingelheim Animal Health Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'Element Injectable Trace Mineral, Copper Free For Cattle & Sheep' to 'Marks-Min Copper Free Injectable Trace Mineral With Vitamin B12 For Cattle & Sheep'
<b>Date of variation:</b>	22 October 2019
<b>Product registration no.:</b>	87286
<b>Label approval no.:</b>	87286/122205

<b>Application no.:</b>	122207
<b>Product name:</b>	Marks-Min Selenium Free Injectable Trace Mineral With Vitamin B12 For Cattle
<b>Active constituent/s:</b>	26.7 g/L zinc as disodium zinc EDTA, 10 g/L copper as disodium copper EDTA, 6.7 g/L manganese as disodium manganese EDTA, 1.4 g/L cyanocobalamin
<b>Applicant name:</b>	Boehringer Ingelheim Animal Health Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'Element Injectable Trace Mineral With Vitamin B12, Selenium Free For Cattle' to 'Marks-Min Selenium Free Injectable Trace Mineral With Vitamin B12 For Cattle'
<b>Date of variation:</b>	22 October 2019
<b>Product registration no.:</b>	87287
<b>Label approval no.:</b>	87287/122207

<b>Application no.:</b>	122213
<b>Product name:</b>	Marks-Min Se B12 Injectable For Cattle & Sheep
<b>Active constituent/s:</b>	3.3 g/L selenium as sodium selenite, 1.4 g/L cyanocobalamin
<b>Applicant name:</b>	Boehringer Ingelheim Animal Health Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'Element Injectable Selenium And Vitamin B12 For Cattle & Sheep' to 'Marks-Min Se B12 Injectable For Cattle & Sheep'
<b>Date of variation:</b>	22 October 2019
<b>Product registration no.:</b>	87288
<b>Label approval no.:</b>	87288/122213

<b>Application no.:</b>	118335
<b>Product name:</b>	Equivac WNV
<b>Active constituent/s:</b>	Each 1 mL dose contains inactivated West Nile Virus strain VM-2 RP $\geq$ 1.0
<b>Applicant name:</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN:</b>	156 476 425
<b>Summary of variation:</b>	To vary the approved label to amend the pack sizes and align with the Vet Labelling Code
<b>Date of variation:</b>	29 October 2019
<b>Product registration no.:</b>	67146
<b>Label approval no.:</b>	67146/118335

### 3. VARIATION OF LABEL APPROVAL

<b>Application no.:</b>	121511
<b>Product name:</b>	Arrest Easy-dose Pour-on Cattle Lice And Fly Treatment
<b>Active constituent/s:</b>	15 g/L deltamethrin
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To update trade advice (ESI) of 21 days
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	55098
<b>Label approval no.:</b>	55098/121511

<b>Application no.:</b>	121510
<b>Product name:</b>	Multimin Injection For Cattle
<b>Active constituent/s:</b>	40 g/L zinc as disodium zinc EDTA, 15 g/L copper as disodium copper EDTA, 10 g/L manganese as disodium manganese EDTA, 5 g/L selenium as sodium selenite
<b>Applicant name:</b>	Virbac (Australia) Pty Ltd
<b>Applicant ACN:</b>	77 003 268 871
<b>Summary of variation:</b>	To vary the product claims and label approval
<b>Date of variation:</b>	6 November 2019
<b>Product registration no.:</b>	59628
<b>Label approval no.:</b>	59628/121510

## 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>	118339
<b>Active constituent/s:</b>	MCPA-2-ethylhexyl ester
<b>Applicant name:</b>	Titan Ag Pty Ltd
<b>Applicant ACN:</b>	122 081 574
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	29 October 2019
<b>Approval no.:</b>	87428

<b>Application no.:</b>	119818
<b>Active constituent/s:</b>	tebuthiuron
<b>Applicant name:</b>	Agro-alliance (Australia) Pty Ltd
<b>Applicant ACN:</b>	130 864 603
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	29 October 2019
<b>Approval no.:</b>	87924

<b>Application no.:</b>	118172
<b>Active constituent/s:</b>	glycosaminoglycan polysulfate
<b>Applicant name:</b>	Randlab Australia Pty Ltd
<b>Applicant ACN:</b>	114 948 837
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	29 October 2019
<b>Approval no.:</b>	87351

<b>Application no.:</b>	119478
<b>Active constituent/s:</b>	2,4-D
<b>Applicant name:</b>	Shandong Binnong Technology Co Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	30 October 2019
<b>Approval no.:</b>	87817

<b>Application no.:</b>	118022
<b>Active constituent/s:</b>	diuron
<b>Applicant name:</b>	Gharda Australia Pty Ltd
<b>Applicant ACN:</b>	087 753 151
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	30 October 2019
<b>Approval no.:</b>	87279



<b>Application no.:</b>	118059
<b>Active constituent/s:</b>	altrenogest
<b>Applicant name:</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN:</b>	156 000 430
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	30 October 2019
<b>Approval no.:</b>	87299

<b>Application no.:</b>	119829
<b>Active constituent/s:</b>	praziquantel
<b>Applicant name:</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN:</b>	076 745 198
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	5 November 2019
<b>Approval no.:</b>	84391

<b>Application no.:</b>	118275
<b>Active constituent/s:</b>	butaphosphan
<b>Applicant name:</b>	Randlab Australia Pty Ltd
<b>Applicant ACN:</b>	114 948 837
<b>Summary of use:</b>	For use in veterinary chemical products
<b>Date of approval:</b>	6 November 2019
<b>Approval no.:</b>	87402

<b>Application no.:</b>	118433
<b>Active constituent/s:</b>	pyraclostrobin
<b>Applicant name:</b>	Fufarm Co Pty Ltd
<b>Applicant ACN:</b>	614 090 336
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	7 November 2019
<b>Approval no.:</b>	87477

<b>Application no.:</b>	119779
<b>Active constituent/s:</b>	chlortetracycline hydrochloride
<b>Applicant name:</b>	South Yarra Pharma Pty Ltd
<b>Applicant ACN:</b>	629 173 351
<b>Summary of variation:</b>	For use in veterinary chemical products
<b>Date of variation:</b>	5 November 2019
<b>Approval no.:</b>	87911

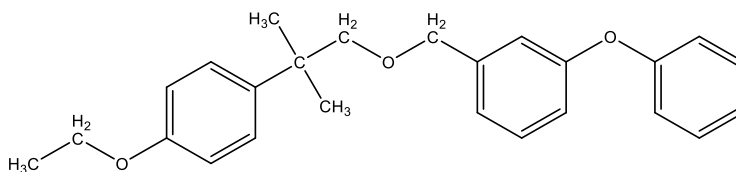
## New Active Constituent: Etofenprox

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, etofenprox. Etofenprox is an insecticide proposed initially for use in stone fruit for control of Queensland fruit fly and Mediterranean fruit fly.

### PARTICULARS OF THE ACTIVE CONSTITUENT

<b>Common name:</b>	Etofenprox
<b>IUPAC name:</b>	1-[[2-(4-Ethoxyphenyl)-2-methylpropoxy]methyl]-3-phenoxybenzene
<b>CAS name:</b>	1-[[2-(4-Ethoxyphenyl)-2-methylpropoxy]methyl]-3-phenoxybenzene
<b>CAS registry number:</b>	80844-07-1
<b>Manufacturer's codes:</b>	MTI-500
<b>Minimum purity:</b>	980 g/kg
<b>Molecular formula:</b>	C <sub>25</sub> H <sub>28</sub> O <sub>3</sub>
<b>Molecular weight:</b>	376.5 g mol <sup>-1</sup>

**Structure:**



**Chemical family:** Pyrethroid ether

**Mode of action:** Acts on the nervous system of insects by disturbing the function of neurons through interaction with the sodium channel. Etofenprox has a contact and stomach activity against a wide variety of insect pests, with fast knockdown.

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

The APVMA has evaluated the chemistry aspects of etofenprox active constituent (physico-chemical properties, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has completed a toxicological evaluation of etofenprox.

An Acceptable Daily Intake (ADI) of 0.03 mg/kg bw/d has been established, based on a No-Observed Adverse Effect Level (NOAEL) of 3.1 mg/kg bw/d in a 2-year dietary rat study, and applying an uncertainty factor of 100.

An Acute Reference Dose of 1 mg/kg bw has been established, based on a NOAEL of 100 mg/kg bw in two oral gavage developmental toxicity studies in rabbits, after applying a safety factor of 100.

Etofenprox has been entered in Appendix B, Part 3 of the Poison Standard (substances not requiring control by scheduling), with an implementation date of 1 June 2018.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for etofenprox:

Specification	Level
Etofenprox content	Minimum 980 g/kg

Other compounds of toxicological significance are not expected to occur in etofenprox technical active constituent.

The APVMA is satisfied that the proposed importation and use of etofenprox would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

#### **FURTHER INFORMATION**

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's ['Public Consultation'](#) page.

#### **MAKING A SUBMISSION**

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

Submissions must be received by the APVMA within **28 days** of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

When making a submission please include a:

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

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  
GPO Box 3262  
SYDNEY NSW 2001

**Phone:** +61 2 6770 2300

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

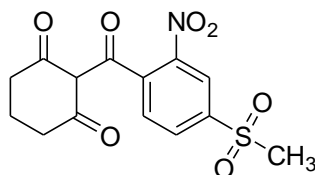
## New Agricultural Active Constituent: Mesotrione

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, mesotrione, for use in the control of broadleaf weeds in wheat, barley and durum wheat.

### PARTICULARS OF THE ACTIVE CONSTITUENT

<b>Common Name:</b>	Mesotrione
<b>IUPAC Name:</b>	2-[4-(methanesulfonyl)-2-nitrobenzoyl]cyclohexane-1,3-dione
<b>CAS Name:</b>	2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione
<b>CAS Registry Number:</b>	104206-82-8
<b>Manufacturer's Code:</b>	ZA 1296
<b>Minimum Purity:</b>	940 g/kg (dry weight basis)
<b>Molecular Formula:</b>	C <sub>14</sub> H <sub>13</sub> NO <sub>7</sub> S
<b>Molecular Weight:</b>	339.3 g mol <sup>-1</sup>

**Structure:**



**Chemical Family:** Benzoylcyclohexanedione

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

The APVMA has evaluated the chemistry aspects of active constituent mesotrione (physico-chemical properties, identification, stability, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has considered the toxicological aspects of mesotrione. The ADI for mesotrione was established at 0.01 mg/kg bw/day. The ARfD for mesotrione was established at 0.1 mg/kg bw/day.

Mesotrione has been included in Schedule 5 of the Poison Standard, with no cut-off.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following active constituent standard be established for mesotrione:

Constituent	Level
Mesotrione	Minimum 940 g/kg (dry weight basis)

Impurities of toxicological significance are not expected to occur in mesotrione as a result of the raw materials and the synthetic route used.

The APVMA is satisfied that the proposed importation and use of mesotrione would not be an undue 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 mesotrione 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 a:

- 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:

Director of Chemistry and Manufacture  
Scientific Assessment and Chemical Review Program  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
SYDNEY NSW 2001

Phone: +61 2 6770 2300

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

## **New Chemical Products: Callisto Herbicide containing mesotrione**

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 **Callisto Herbicide**.

### **PARTICULARS OF THE APPLICATION**

<b>Proposed product name(s):</b>	Callisto Herbicide
<b>Applicant company:</b>	SYNGENTA AUSTRALIA PTY LTD
<b>Name of active constituent:</b>	Mesotrione
<b>Signal heading:</b>	Schedule 6
<b>Summary of proposed use:</b>	For the pre-emergent control of a range of broadleaf weeds in wheat and barley.
<b>Pack sizes:</b>	5 L to 100 L
<b>Withholding period:</b>	HARVEST: NOT REQUIRED WHEN USED AS DIRECTED GRAZING: DO NOT HARVEST, GRAZE OR CUT FOR STOCK FOOD FOR 10 WEEKS AFTER APPLICATION.

### **SUMMARY OF THE APVMA'S EVALUATION OF CALLISTO HERBICIDE 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 Callisto Herbicide 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 Callisto Herbicide 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 Callisto Herbicide containing the active constituent mesotrione 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 Callisto Herbicide 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.
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:

- (i) The proposed use of Callisto Herbicide 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 the APVMA website's '[Public Consultation](#)' page, or by contacting the APVMA as 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 Callisto Herbicide 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  
GPO Box 3262  
SYDNEY NSW 2001

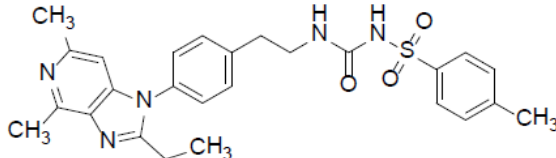
**Phone:** +61 2 6770 2300

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

## **New Active Constituent and New Chemical Products: Galliprant flavoured tablets for dogs containing the active grapiprant**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, **grapiprant** and an application for registration of a suite of new products containing the new active constituent. The products are **galliprant 100 mg**, **galliprant 60 mg** and **galliprant 20 mg flavoured tablets for dogs** for use in the treatment of pain and inflammation associated with osteoarthritis, in dogs.

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

<b>Common name:</b>	Grapiprant
<b>IUPAC Name:</b>	1-[2-[4-(2-ethyl-4,6-dimethylimidazo[4,5-c]pyridin-1-yl)phenyl]ethyl]-3-(4-methylphenyl)sulfonylurea
<b>Chemical Abstracts Name:</b>	<i>N</i> -({2-[4-(2-Ethyl-4,6-dimethyl-1 <i>H</i> -imidazo[4,5- <i>c</i> ]pyridin-1-yl)phenyl]ethyl}carbamoyl)-4-methylbenzenesulfonamide
<b>CAS Number:</b>	415903-37-6
<b>Molecular Formula:</b>	C <sub>26</sub> H <sub>29</sub> N <sub>5</sub> O <sub>3</sub> S
<b>Molecular Weight:</b>	491.6 g mol <sup>-1</sup>
<b>Structure:</b>	
<b>Chemical Family:</b>	Piprant class
<b>Mode of Action:</b>	Prostaglandin E2 EP4 receptor antagonist

### **SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT GRAPIPRANT IN ACCORDANCE WITH SECTION 5A OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994***

The APVMA has evaluated the chemistry aspects of **grapiprant** active constituent (identification, manufacturing process, quality controls, specifications, batch analysis results and analytical methods) and found them to be acceptable.

The active constituent, grapiprant is manufactured to the standard of the manufacturer's specifications.

Impurities of toxicological significance are not expected to occur in **grapiprant** as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of grapiprant, and concluded that there are no toxicological concerns to the approval of this active constituent. An ADI and ARfD were not established due to the currently proposed use only being in companion animals.

The Scheduling Delegate for the Poisons Standard (*Standard for the Uniform Scheduling of Medicines and Poisons – SUSMP*) made a decision to amend the current Poisons Standard to include a new entry for grapiprant in Schedule 4.



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

## PARTICULARS OF THE PRODUCT

<b>Proposed product name(s):</b>	GALLIPRANT 100 mg FLAVOURED TABLETS FOR DOGS GALLIPRANT 60 mg FLAVOURED TABLETS FOR DOGS GALLIPRANT 20 mg FLAVOURED TABLETS FOR DOGS
<b>Applicant company:</b>	Elanco Australasia Pty Ltd
<b>Name of active constituent:</b>	Grapiprant
<b>Signal heading:</b>	Schedule 4
<b>Summary of proposed use:</b>	For use in the treatment of pain and inflammation associated with osteoarthritis, in dogs.
<b>Pack sizes:</b>	7, 30, 90 tablets

### SUMMARY OF THE APVMA'S EVALUATION OF GALLIPRANT FLAVOURED TABLETS FOR DOGS 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*

The suite of products will be referred to in this summary collectively as **galliprant flavoured tablets for dogs**.

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 **galliprant flavoured tablets for dogs** would not be an undue hazard to the safety of people exposed to them during their handling or use.

The APVMA has conducted a risk assessment for the products and in conjunction with the estimated hazard profile, determined whether the proposed use of the products would not be an undue health hazard to humans, including exposures which may arise from handling the excreta or vomitus of treated dogs, or from the accidental ingestion of the tablets.

The APVMA estimated the acute toxicity of **galliprant flavoured tablets for dogs** from toxicological studies in laboratory animals using the active constituent and the product formulation. Based on the findings of the acute toxicological studies and the active constituent (grapiprant) and non-actives estimation, the products present a low acute oral, dermal and inhalation toxicity, non-irritating to the skin, eyes and skin. **Galliprant flavoured tablets for dogs** is presented as a formulated tablet and thus is unlikely to present a dermal or inhalation hazard.

It is expected that administration of **galliprant flavoured tablets for dogs** (sold under prescription) will primarily be conducted by pet owners rather than by a Veterinarian. Pet owners may be exposed to the product when administering the tablet into the mouth of a dog(s). There will be an opportunity for dermal, oral and accidental ocular exposure. However, it is anticipated that the use pattern, (administration of a pharmaceutical-grade tablet formulation to non-food-producing companion animals once per day) will result in negligible exposure. The greatest likely exposure will occur if a pet owner's child accidentally ingests a single tablet. Grapiprant has an oral LD<sub>50</sub> > 2000 mg/kg bw in the rat and >1000 mg/kg in dogs with no deaths observed at a single dose of 1000 mg/kg bw. Therefore, an acceptable margin of exposure (ie >100) exists for the reasonable worst case scenario of an acute

exposure following a child accidentally ingesting a misplaced tablet. Furthermore, it is noted that grapiprant was well tolerated in adults in a clinical trial following a single oral dose of between 1 and 1000 mg.

Based on the acute and repeat-dose risks associated with grapiprant, the following First Aid Instructions are considered appropriate: – *If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.*

The proposed safety direction “*Wash hands after use*” will mitigate the oral, dermal and ocular exposure.

- (ii) The APVMA is satisfied that the proposed use of **galliprant flavoured tablets for dogs** will not be an undue hazard to the safety of people using anything containing their residues. The product is for use in companion animals (dogs) which are non-food producing species and residues are unlikely to enter the food-chain.
- (iii) The APVMA is satisfied that the proposed use of **galliprant flavoured tablets for dogs** is not likely to be harmful to human beings if used according to the product label directions.

The active grapiprant is listed in Schedule 4 of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) with no cut-off or exemptions. The Schedule 4 signal heading is PRESCRIPTION ANIMAL REMEDY.

- (iv) The APVMA is satisfied that the proposed use of **galliprant flavoured tablets for dogs**, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.

The APVMA has conducted a VICH Phase I Preliminary assessment to determine the potential for entry of grapiprant into the environment. **Grapiprant** will only be used in dogs, which are non-food producing animals. As dogs are not intensively reared and treatments are on an individual basis, environmental exposure is expected to be negligible. The VICH phase I assessment concluded that the proposed use of grapiprant will not present a significant risk to the environment.

Disposal instructions are consistent with the Vet Labelling Code for the appropriate package size(s) and material will also be included on the label—*Disposal of container by wrapping with paper and putting in garbage.*

- (v) The APVMA has assessed the target animal safety of **galliprant flavoured tablets for dogs** in target animal safety studies which administered **Grapiprant** at 0.5X, 3X and 15X the recommended dose rate for 28 days and 1X, 3X and more than 5X the recommended dose rate once daily, for 9 consecutive months in dogs. Data from 2 clinical field studies with a total number of 551 dogs was also evaluated for safety. The most frequent adverse events observed linked to treatment were related to the digestive tract: vomiting, soft/loose/mucus stool, diarrhoea and inappetence. **Galliprant** did not produce any signs of kidney or liver toxicity in these studies. All observed adverse events were mild and transient. In the vast majority of cases, these signs were of limited duration and resolved without intervention, and were in no case severe. No deaths were reported.

To mitigate the safety issues for the target animals and advise about adverse effects, the following statements will be included on the labels:

- Precaution statements relating to young animals, breeding, pregnant or lactating animals, animals suffering from impaired cardiac function and monitoring animals with pre-existing gastro intestinal problems.

- Precaution statement regarding the concurrent use with other anti-inflammatories and protein bound drugs.
  - Side effects relating to mild and generally transient adverse reactions (vomiting, soft-formed, loose or mucous stool, diarrhoea, lethargy and inappetence) that have been observed in dogs treated with grapiprant.
2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria has been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of **galliprant flavoured tablets for dogs**, would be effective when used as directed.

The suite of products, **galliprant flavoured tablets for dogs** is intended for the treatment of pain and inflammation associated with osteoarthritis in dogs. The product is a tablet to be administered orally at the recommended dose of 2 mg/kg/day grapiprant.

The supporting information included a number of scientific publications, research or clinical efficacy studies in dogs (including pharmacokinetics and pharmacodynamics studies).

Two clinical field studies were performed to demonstrate the efficacy of the product. Study 1 was a dose range study conducted in 331 dogs with naturally occurring osteoarthritis. The dogs were treated with **galliprant flavoured tablets for dogs** at 2 mg/kg daily, 5 mg/kg daily, 4 mg/kg twice daily or placebo twice daily for 28 days to assess the control of pain and inflammation. Efficacy was shown at 2mg/kg/day. Study 2 was a blinded, randomized, multi-centre field study to determine if the proposed product was effective in treating dogs with osteoarthritis. A total of 262 dogs were enrolled in the study and **galliprant flavoured tablets for dogs** at 2 mg/kg daily was administered to the treatment groups. Efficacy was again shown at 2mg/kg/day.

A comparative study with a currently registered anti-inflammatory product was also conducted. The results of the study suggested that **galliprant flavoured tablets for dogs** would have a similar efficacy to the registered product.

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria has been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
- (i) The APVMA is satisfied that the proposed use of **galliprant flavoured tablets for dogs** would not adversely affect trade between Australia and places outside of Australia. The product is for use in dogs, which are not food-producing animals and which do not produce any major Australian export commodities.

## MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the new active **grapiprant** should be approved and whether the application for registration of the products **galliprant 100 mg, galliprant 60 mg and galliprant 20 mg flavoured tablets for dogs** should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to approve the active or grant the registration application for the products. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for the products; the safety, efficacy and trade criteria. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within **28 days** of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

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

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

Enquiries

Registration Management and Evaluation

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

SYDNEY NSW 2001

Phone: +61 2 6770 2300

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

## Licensing of Veterinary Chemical Manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code), 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](#).

### 1. NEW LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agvet Code:

**BARON RUBBER  
PROPRIETARY LIMITED**

**ACN:** 005 178 549

11 Northcorp Bvd

BROADMEADOWS VIC 3047

**Licence number:** 6222

**Product types:\***

- *Category 6:* (Single step manufacture)

**Steps of manufacture:** Quality assurance (QA) of raw materials, formulation including blending (rubber compounding), rubber insert moulding, analysis and testing (physical), storage, packaging, labelling

**Licence issued:** 17 April 2019

**DHL SUPPLY CHAIN  
AUSTRALIA) PTY LIMITED**

**ACN:** 071-798 617

227 Walters Road

ARNDELL PARK NSW 2148

**Licence number:** 6221

**Product types:**

- *Category 6* (Single-step manufacture)

**Steps of manufacture:** Storage only

**Licence issued:** 27 August 2019

### 2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agvet Code:

**FELTON GRIMWADE &  
BOSISTO'S PTY LTD**

**ACN:** 004 809 161

61-81 Clarinda Road

OAKLEIGH SOUTH VIC 3167

**Licence number:** 2053

**Product types: \***

- *Category 2:* (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) - Liquids

**Steps of manufacture:** Formulation including blending, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply.

**Amended licence issued:** 1 April 2019

**BALHAN INDUSTRIAL CO.  
PROPRIETARY LIMITED**

**ACN:** 004 705 435

81-89 Buckley Grove  
MOOLAP VIC 3220

**Licence number:** 2111

**Product types:** \*

- *Category 2:* (non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) – powders and liquids

**Steps of manufacture:** Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply.

**Amended licence issued:** 4 April 2019

**DELTA LABORATORIES PTY  
LIMITED**

**ACN:** 050 324 742

8 Warringah Close  
SOMERSBY NSW 2250

**Licence number:** 1056

**Product types:** \*

- *Category 1:* (Immunobiologicals and sterile veterinary preparations) – Sterile products.
- *Category 2:* (Non-sterile veterinary preparations except ectoparasiticides, premixes and supplements) – Creams/lotions, ointments, pastes, sprays and liquids.

**Steps 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:** 17 April 2019

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

**ACN:** 071 798 617

16 Picrite Close  
GREYSTANES NSW 2145

**Licence number:** 6071

**Product types:** \*

- *Category 6:* (Single step manufacture)

**Steps of manufacture:** Secondary packaging, secondary/supplementary labelling, storage and release for supply

**Amended licence issued:** 2 May 2019

**ACCESS INDUSTRIES FOR  
THE DISABLED LTD**

**ACN:** 001 797 511

131 Station Road  
SEVEN HILLS NSW 2147

**Licence number:** 6174

**Product types:** \*

- *Category 6:* (Single step manufacture) - Products in sealed containers or packages.

**Steps of manufacture:** Secondary packaging, secondary labelling, storage and release for supply

**Amended licence issued:** 18 June 2019

**VETLAB PTY LIMITED**

**Licence number:** 2206

**ACN:** 003 962 196

39 Harris Street

ST MARYS NSW 2760

**Product types:** \*

- *Category 2:* (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) - Pastes, powders, liquids, granules, and capsules — hard shell.
- *Category 3:* (Ectoparasiticides) - Liquids and powders
- *Category 4:* (Premixes and supplements) - Premixes and supplements

**Steps of manufacture:** Quality assurance (QA) of raw materials, formulation including blending, wet milling, dry milling, granulation, filling, capsule filling from bulk, packaging, labelling, sachet packaging, analysis and testing (physical and chemical), storage and release for supply.

**Amended licence issued:** 4 July 2019

**TROY LABORATORIES PTY LTD**

**Licence number:** 1092

**ACN:** 000 283 769

31 - 35 Glendenning Road

GLENDENNING NSW 2761

**Product types:** \*

- *Category 1:* (Immunobiologicals and sterile veterinary preparations) - Sterile products and terminally sterilised ointment
- *Category 2:* (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) - Tablets, creams/lotions, ointments, gels, pastes, powders, sprays, granules, suspensions and liquids
- *Category 3:* (Ectoparasiticides) - Liquids and sprays
- *Category 4:* (Premixes and supplements) - supplements

**Steps of manufacture:** Quality assurance (QA) of raw materials, formulation including blending, granulation, dry milling, aseptic filling, filling, packaging, labelling, strip, blister or sachet packaging, tableting, sterilisation (heat and filtration), microbiological reduction treatment (heat, filtration and chemical), analysis and testing (physical, chemical and endotoxin), storage and release for supply.

**Amended licence issued:** 12 July 2019

**AGRICURE PTY LIMITED**

**Licence number:** 2161

**ACN:** 000 178 790

19 Gantry Place

BRAEMAR NSW 2575

**Product types:** \*

- *Category 2:* (Non-sterile veterinary preparations except ectoparasiticides, premixes and supplements) - creams / lotions, ointments, pastes, powders, sprays and liquids.
- *Category 4:* (Premixes / supplements) - premixes and supplements

**Steps of manufacture:** Quality assurance (QA) of raw materials, formulation including blending, pelleting, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply.

**Amended licence issued:** 12 August 2019

**ALLTECH LIENERT  
AUSTRALIA PTY LTD.**

**ACN:** 008 293 007  
28 Durham Street  
FORBES NSW 2871

**Licence number:** 4085

**Product types:** \*

- *Category 4:* (Premixes and supplements) – Premixes, supplements

**Steps of manufacture:** Quality assurance (QA) of raw materials, formulation including blending, granulation (pellets), pellet extrusion, packaging, labelling, analysis and testing (physical), storage, and release for supply.

**Amended licence issued:** 06 September 2019

**EUROFINS CHEMICAL  
ANALYSIS PTY LTD**

**ACN:** 114 804 572  
110 Merrindale Drive  
CROYDON VIC 3136

**Licence number:** 6177

**Product types:**\*

- *Category 6:* (Single-step)

**Steps of manufacture:** Analysis and testing (physical, chemical, microbiological, sterility and Limulus Amoebocyte Lysate [LAL] test)

**Licence issued:** 1 October 2019

### 3. LICENCE CANCELLATIONS

The APVMA has cancelled the following licences under subsection 127(1) of the Agvet Code:

**ENDEAVOUR FOUNDATION**

**ACN:** 009 670 704  
59 – 65 Kurrajong Avenue  
MOUNT DRUITT NSW 2770

**Licence number:** 4088

**Date cancelled:** 15 March 2019

**HY GAIN FEEDS PTY LIMITED**

**ACN:** 006 198 821  
10 Hickson Road  
OFFICER VIC 3809

**Licence number:** 6088

**Date cancelled:** 15 March 2019

**INTERVET AUSTRALIA PTY  
LIMITED**

**ACN:** 008 467 034  
Unit B, 18 Lucca Road  
WYONG NSW 2259

**Licence number:** 6154

**Date cancelled:** 15 April 2019



**AFG QUALITY &  
REGULATORY CONSULTING  
PTY LTD.**

**Licence number:** 6214

**ACN:** 617 124 044

**Date cancelled:** 30 July 2019

Suite 1A, Level 2

802 Pacific Highway

GORDON NSW 2072

**4. LICENCE SUSPENSIONS**

The APVMA has suspended the following licences under subsection 127(1) of 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 Agvet Code:

Nil

**6. REVOCATION OF LICENCE SUSPENSION**

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agvet Code:

Nil

**APVMA CONTACT**

Manufacturing Quality and Licensing

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

SYDNEY NSW 2001

**Phone:** +61 2 6770 2300

**Email:** [mls@apvma.gov.au](mailto:mls@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 (MRL Standard) Instrument 2019*. 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 (MRL Standard) Amendment Instrument (No. 3) 2019*.

The amendments will be incorporated into the compilation of the *Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019*.

The *MRL Standard* is accessible via the [Federal Register of Legislation website](#).

For further information please contact:

MRL Contact Officer  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
SYDNEY NSW 2001

**Phone:** +61 2 6770 2401

**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 34 of APVMA Gazette No. 23, the APVMA gazetted amendments which it has approved to vary maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 3) 2019) 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 Australian Government and the New Zealand Government 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.

A Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) will be made.

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**

(14 November 2019)

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 sunset.

**To commence: on gazettal of variation**

[1] 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: 2,4-D**

*Permitted residue: 2,4-D*

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Walnuts	*0.05
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**Agvet chemical: Bifenthrin**

*Permitted residue: Bifenthrin*

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Truffle	T*0.01
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**Agvet chemical: Glufosinate and Glufosinate ammonium**

*Permitted residue: Sum of glufosinate-ammonium, N-acetyl glufosinate and 3-[hydroxy(methyl)-phosphinoyl] propionic acid, expressed as glufosinate (free acid)*

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All other foods except animal food commodities	0.1
Truffle	T*0.2

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**Agvet chemical: Glyphosate**

*Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate*

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Truffle	T*0.05
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**Agvet chemical: Mesotrione**

*Permitted residue: Mesotrione*

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Barley	*0.01
Edible offal (mammalian)	*0.01
Eggs	*0.01
Meat (mammalian)	*0.01
Milks	*0.01
Poultry, edible offal of	*0.01
Poultry meat	*0.01
Wheat	*0.01

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**Agvet chemical: Methiocarb**

*Permitted residue: Sum of methiocarb, its sulfoxide and sulfone, expressed as methiocarb*

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Truffle	T0.05
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**Agvet chemical: Sethoxydim**

*Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim*

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Stone fruits [except cherries]	T*0.03
Wine grapes	T*0.03

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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) 12 DECEMBER 2019**

## **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  
GPO Box 3262  
SYDNEY NSW 2001

**Phone:** +61 2 6770 2401

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

## Reconsideration of Neonicotinoid Approvals and Registrations

This *Gazette* notice is to inform the public that the APVMA, in accordance with Part 2, Division 4, of the Agvet Code, has commenced a reconsideration of certain neonicotinoid active constituent approvals, product registrations, and associated label approvals on the basis of potential risks to the environment and to ensure safety instructions on products meet contemporary standards.

The matters the APVMA is reconsidering and the work plan developed for the purposes of the reconsideration are outlined in detail below. The active constituents, product registrations, and label approvals that are being reconsidered are listed in Appendix A, at the end of this notice.

The APVMA invites written submissions from any person about the matters it is reconsidering. More details about how a person may make a submission are outlined below.

### BACKGROUND

The neonicotinoids are systemic nicotinic acetylcholine receptor competitive modulators (Class 4A). The following active constituents are currently approved for use in chemical products in Australia: Acetamiprid, Clothianidin, Dinotefuran, Imidacloprid, Nitenpyram, Thiacloprid, and Thiamethoxam. All current registered products containing nitenpyram as the active constituent are tablets used to control fleas in companion animals. As a result of the limited use pattern (in cats and dogs), and formulation (as oral tablets), the six registered products and one approved active constituent containing nitenpyram are considered to be outside the scope of this review. More information on active constituents, registered products, and associated use patterns is available on the APVMA [PubCRIS database](#).

Labels describe a wide variety of uses, including for horticulture, agriculture, and as veterinary medicines for livestock and companion animals. In agriculture, neonicotinoids provide control of both soil and selected foliar insect pests in sugarcane, cotton, and citrus. Neonicotinoids are also used:

- as an insecticidal seed dressing in legumes, canola, barley and cotton for the control of mites, aphids, and thrips;
- as pour-on lousicides and dips for sheep;
- in ultra-low volume sprays to control locusts in pasture and sorghum;
- in recreational and domestic settings and for commercial turf treatment; and,
- to protect structures from subterranean termite damage and to control subterranean termites around domestic and commercial structures.

### WHY THE APVMA IS RECONSIDERING APPROVALS AND REGISTRATIONS IN RELATION TO NEONICOTINOIDS

The current uses of neonicotinoids in Australia, as described above, are diverse. Neonicotinoids were nominated for review in 2019 and prioritised following the evaluation of new scientific information about risks to the environment (including to non-target invertebrates, birds, and small mammals in respect of their use), and to ensure safety instructions on products meet contemporary standards. There is also a need to ensure products meet contemporary standards, including those outlined in the APVMA [Pollinator risk assessment](#) and [Spray drift management](#) frameworks.

The new scientific information raised concerns for some uses, including where the potential exists for contamination of aquatic areas via runoff, and in applications where spray drift and adverse impacts on non-target species were considered to be likely.

The instructions for use on product labels are designed to reduce the risk of non-target exposure. However, non-target impacts from neonicotinoids have been reported domestically and internationally to occur in a number of ways, including:

- contact with neonicotinoid dusts in the air when treated seeds are planted;

- consumption of treated seeds after planting;
- consuming parts of plants grown from treated seed, or in treated soil;
- direct contact with sprays; and,
- runoff into waterways.

On this basis, the APVMA determined that consideration of these environmental concerns was required to ensure products on the Australian market meet contemporary safety standards.

The reconsideration will consider whether or not the continued use of the active constituents and/or products in accordance with the recommendations for its use that the APVMA has approved would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment. The reconsideration will also review labels for products containing neonicotinoids, to ensure they contain adequate instructions and warning statements in relation to environmental protection.

### **MATTERS THE APVMA IS PROPOSING TO RECONSIDER IN RELATION TO NEONICOTINOIDS**

For these reasons, the matters being reconsidered focus on the potential for unacceptable environmental risk in areas including:

- non-target invertebrates, including pollinators;
- birds; and,
- small animals.

To manage the potential risks, the APVMA is reviewing the following environmental aspects of product registrations for neonicotinoids including, but not limited to:

- aquatic degradation;
- persistence in environmental media (soil, water and sediment);
- translocation in plants;
- the partitioning in the environment (eg, deposition, adsorption); and
- toxicity to fish, non-target invertebrates, and sediment organisms.

The APVMA is also considering whether product labels carry adequate instructions and warning statements to protect community and worker health. The requirements for product labels are that the label contains adequate instructions. Such instructions include:

- the circumstances in which the product should be used;
- how the product should be used;
- the times when the product should be used;
- the frequency of the use of the product;
- the re-entry period after the use of the product;
- the withholding period after the use of the product;
- the disposal of the product and its container;
- the safe handling of the product and first aid in the event of an accident caused by handling the product; and,
- any other matter prescribed by the regulations.

### **REASONS FOR THOSE MATTERS BEING DEALT WITH IN THE RECONSIDERATION**

The matters that are dealt with in the reconsideration include component occupational health and safety and environment assessments. The [review scope document](#) is available on the APVMA website.



The APVMA is reconsidering neonicotinoid active constituent approvals, product registrations, and associated label approvals because of concerns relating to the environment and the adequacy of label instructions to protect human health. The basis for the reconsideration is whether the APVMA is satisfied that:

- a) the active constituent continues to meet the safety criteria as set out in Section 5A of the Agvet Code; and
- b) the product continues to meet the safety criteria as set out in Section 5A of the Agvet Code; and
- c) the label continues to meet the labelling criteria as set out in Section 5D of the Agvet Code; and
- d) the active constituent, product or label complies with any requirement prescribed by the regulations.

## **WORK PLAN**

The [Work Plan](#) has been prepared in accordance with subsection 31(2) of the Agvet Code. It outlines the scope of the reconsideration, matters still remaining to be assessed, the relevant data being assessed and expected timeframes as stipulated by regulation 78B of the *Agricultural and Veterinary Chemicals Code Regulations 1995*. The APVMA will update the Work Plan at least yearly or as necessary.

## **MAKING A SUBMISSION**

You may make a written submission about the matters being reconsidered and the reasons for the reconsideration. Submissions specifically addressing the areas of concern noted in the review scope document must be in writing.

## **PREPARING YOUR SUBMISSION**

When preparing your submission, the APVMA prefers you to:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, supporting them with relevant scientific information and indicating the source of the information you have used.

Electronic submissions are preferred; electronic submissions to the APVMA will be acknowledged via email. When making a submission please include:

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

Note that all submissions received are subject to legislation, including the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code. In providing your submission to the APVMA, you agree to the APVMA publicly disclosing your submission in whole or summary form. The contents of any submission will not be treated as confidential commercial information.

The closing date for submissions is 3 February 2020.

Submissions can be sent to:

Chemical Review  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
SYDNEY NSW 2001  
Phone: +61 2 6770 2400  
Email: [chemicalreview@apvma.gov.au](mailto:chemicalreview@apvma.gov.au)

**APPENDIX A. APPROVED ACTIVE CONSTITUENTS, REGISTERED PRODUCTS, AND APPROVED LABELS FOR PRODUCTS CONTAINING NEONICOTINOIDS INCLUDED IN THE REVIEW.**

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
ACTIVE	66604	ACETAMIPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	67797	ACETAMIPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	66895	ACETAMIPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	84541	ACETAMIPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	54234	ACETAMIPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	69006	ACETAMIPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	69666	ACETAMIPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	68154	CLOTHIANIDIN	ACTIVE CONSTITUENT	N/A
ACTIVE	70306	CLOTHIANIDIN	ACTIVE CONSTITUENT	N/A
ACTIVE	54438	CLOTHIANIDIN	ACTIVE CONSTITUENT	N/A
ACTIVE	55002	CLOTHIANIDIN	ACTIVE CONSTITUENT	N/A
ACTIVE	66933	CLOTHIANIDIN	ACTIVE CONSTITUENT	N/A
ACTIVE	69280	CLOTHIANIDIN	ACTIVE CONSTITUENT	N/A
ACTIVE	86719	CLOTHIANIDIN	ACTIVE CONSTITUENT	N/A
ACTIVE	69396	DINOTEFURAN	ACTIVE CONSTITUENT	N/A
ACTIVE	84993	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	55951	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	56140	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	63996	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	49016	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	68721	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	65850	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	82084	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	59475	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	65648	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	60615	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
ACTIVE	85081	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	59828	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	54193	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	85789	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	59231	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	59477	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	83018	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	66743	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	82384	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	85720	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	64994	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	83395	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	85588	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	60371	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	61456	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	62654	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	68755	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	69114	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	64766	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	65342	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	61289	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	85495	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	86024	IMIDACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	53207	THIACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	70331	THIACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	70332	THIACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	69309	THIACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	69665	THIACLOPRID	ACTIVE CONSTITUENT	N/A

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
ACTIVE	70432	THIACLOPRID	ACTIVE CONSTITUENT	N/A
ACTIVE	69270	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	68420	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	67773	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	82332	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	68437	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	81824	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	69350	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	51873	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	56676	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	56849	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	57983	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	63279	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	65385	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	86366	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	80645	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
ACTIVE	67243	THIAMETHOXAM	ACTIVE CONSTITUENT	N/A
PRODUCT	69722	ACETAMIPRID	AAKO COBRA 200 SL INSECTICIDE	61503
PRODUCT	81616	ACETAMIPRID	ACCENSI ACETAMIPRID RTU INSECTICIDE	103465
PRODUCT	70152	ACETAMIPRID	CORMORAN INSECTICIDE	111103, 62630
PRODUCT	58558	ACETAMIPRID	CROWN 225SL SYSTEMIC INSECTICIDE	0205, 1006, 56475
PRODUCT	65588	ACETAMIPRID	DEFENDER CONCENTRATE MAXGUARD SYSTEMIC, CONTACT & RESIDUAL INSECTICIDE	51368

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	60409	ACETAMIPRID	DEFENDER MAXGUARD SYSTEMIC, CONTACT & RESIDUAL INSECTICIDE KILLS & CONTROLS	1106, 53901, 59055
PRODUCT	67783	ACETAMIPRID	ECHEM ACETAM 225 INSECTICIDE	118882, 56868, 62701
PRODUCT	86725	ACETAMIPRID	IMTRADE VADER 225 SL INSECTICIDE	116456
PRODUCT	58300	ACETAMIPRID	INTRUDER INSECTICIDE	0207, 1004, 1103, 1205, 54640, 56671
PRODUCT	85510	ACETAMIPRID	JOKER 310 DC INSECTICIDE	113468
PRODUCT	67071	ACETAMIPRID	PRIMAL INSECTICIDE	55129
PRODUCT	81486	ACETAMIPRID	SKOPE INSECTICIDE	103202, 111498
PRODUCT	54233	ACETAMIPRID	SUPREME 225 SL INSECTICIDE	0903
PRODUCT	80807	ACETAMIPRID	TRIVOR INSECTICIDE	101694, 114012
PRODUCT	86898	CLOTHIANIDIN	FARMALINX SUCKER G INSECTICIDE	116932
PRODUCT	84811	CLOTHIANIDIN	FARMALINX SUCKER INSECTICIDE	111478, 116039
PRODUCT	81040	CLOTHIANIDIN	MAXFORCE ACTIV COCKROACH GEL	102203
PRODUCT	60687	CLOTHIANIDIN	SUMITOMO SAMURAI SYSTEMIC INSECTICIDE	0809, 100161, 103567, 111062, 1207, 60863
PRODUCT	60689	CLOTHIANIDIN	SUMITOMO SHIELD SYSTEMIC INSECTICIDE	0710, 0909, 1207, 51118
PRODUCT	60688	CLOTHIANIDIN	SUMITOMO STEALTH SYSTEMIC INSECTICIDE	0608, 0708

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	67779	CLOTHIANIDIN, IMIDACLOPRID	PONCHO PLUS INSECTICIDAL SEED TREATMENT	120311, 56861
PRODUCT	83015	DINOTEFURAN	SECLIRA DUST INSECTICIDE	107322
PRODUCT	83034	DINOTEFURAN	SECLIRA GEL COCKROACH BAIT	107360
PRODUCT	83016	DINOTEFURAN	SECLIRA PRESSURISED FLY BAIT	107323
PRODUCT	83032	DINOTEFURAN	SECLIRA PRESSURISED INSECTICIDE	107357
PRODUCT	83011	DINOTEFURAN	SECLIRA WSG INSECTICIDE	107309, 118582
PRODUCT	69398	DINOTEFURAN	STARKLE 200 SG INSECTICIDE	106114, 111741, 113017, 115512, 60731
PRODUCT	64648	IMIDACLOPRID	4FARMERS IMIDACLOPRID 200SC INSECTICIDE	48857
PRODUCT	65418	IMIDACLOPRID	4FARMERS IMIDACLOPRID 600 FLOWABLE SEED DRESSING INSECTICIDE	50881
PRODUCT	62350	IMIDACLOPRID	4FARMERS IMID-TRIADIMENOL SEED DRESSING	42909
PRODUCT	65585	IMIDACLOPRID	AC IMPRESSOR 350 SOIL INSECTICIDE	51360, 61087
PRODUCT	65197	IMIDACLOPRID	AC IMPRESSOR 600 SEED DRESSING	105083, 50382
PRODUCT	68572	IMIDACLOPRID	ACCENSI IMIDACLOPRID 200 SC TERMITICIDE	58612, 62030
PRODUCT	84785	IMIDACLOPRID	ACCENSI IMIDACLOPRID 600 FS FLOWABLE SEED DRESSING	111429
PRODUCT	63289	IMIDACLOPRID	ACCENSI IMIDACLOPRID HOSE-ON LAWN INSECTICIDE	0209, 59862

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	63906	IMIDACLOPRID	ACCENSI IMIDACLOPRID LAWN & GARDEN INSECTICIDE	0809, 59842
PRODUCT	60898	IMIDACLOPRID	ACCENSI IMIDACLOPRID READY TO USE INSECTICIDE	0107, 59888
PRODUCT	62884	IMIDACLOPRID	ACCENSI IMIDACLOPRID TURF AND ORNAMENTAL INSECTICIDE	0309, 59922
PRODUCT	65559	IMIDACLOPRID	ACCENSI ROSE SPRAY ADVANCED INSECT, MITE & DISEASE CONTROL RTU	51288, 59827
PRODUCT	82558	IMIDACLOPRID	ACP IMIDACLOPRID 600 SEED TREATMENT INSECTICIDE	106063
PRODUCT	69036	IMIDACLOPRID	ADVANTAGE ADVANTIX FOR DOGS 4-10 KG FLEAS & TICKS	59687
PRODUCT	69030	IMIDACLOPRID	ADVANTAGE ADVOCATE FOR CATS OVER 4 KG FLEAS, HEARTWORM & WORMS	59676
PRODUCT	69027	IMIDACLOPRID	ADVANTAGE ADVOCATE FOR DOGS 4-10 KG FLEAS, HEARTWORM & WORMS	59671
PRODUCT	50396	IMIDACLOPRID	ADVANTAGE FOR CATS OVER 4 KG	0103, 0308, 0406, 0500, 1097, 54914, 57508
PRODUCT	50399	IMIDACLOPRID	ADVANTAGE FOR DOGS 10 - 25 KG	0103, 0299, 0308, 0406, 0500, 1097, 54917, 57513
PRODUCT	50398	IMIDACLOPRID	ADVANTAGE FOR DOGS 4 - 10 KG	0103, 0308, 0406, 0500, 1097, 54916, 57511
PRODUCT	50400	IMIDACLOPRID	ADVANTAGE FOR DOGS OVER 25 KG	0103, 0309, 0406, 0500, 1097, 54912, 57503

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	50395	IMIDACLOPRID	ADVANTAGE FOR KITTENS & SMALL CATS UP TO 4 KG	0103, 0299, 0308, 0406, 0500, 1097, 54913, 57506
PRODUCT	50397	IMIDACLOPRID	ADVANTAGE FOR PUPPIES & SMALL DOGS UP TO 4 KG	0103, 0308, 0406, 0500, 1097, 54915, 57510
PRODUCT	58260	IMIDACLOPRID	ADVANTIX FOR DOGS 10-25KG	0305, 0707, 1004, 44320, 54910, 57500
PRODUCT	58261	IMIDACLOPRID	ADVANTIX FOR DOGS 4-10KG	0305, 0707, 1004, 44321, 54911, 57499
PRODUCT	58262	IMIDACLOPRID	ADVANTIX FOR DOGS OVER 25KG	0305, 0707, 1004, 44322, 54909, 57501
PRODUCT	58259	IMIDACLOPRID	ADVANTIX FOR PUPPIES AND SMALL DOGS UP TO 4KG	0305, 0707, 1004, 44319, 54908, 57498
PRODUCT	55326	IMIDACLOPRID	ADVOCATE FOR CATS OVER 4KG	0403, 0504, 116347, 1203, 1204, 47072, 54926, 57539
PRODUCT	55322	IMIDACLOPRID	ADVOCATE FOR DOGS 10-25 KG	0403, 0504, 1203, 1204, 47075, 54928, 57543
PRODUCT	55321	IMIDACLOPRID	ADVOCATE FOR DOGS 4-10 KG	0403, 0504, 1203, 1204, 47074, 54929, 57542
PRODUCT	55323	IMIDACLOPRID	ADVOCATE FOR DOGS OVER 25KG	0403, 0504, 1203, 1204, 47076, 54931, 57544



Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	55325	IMIDACLOPRID	ADVOCATE FOR KITTENS AND SMALL CATS UP TO 4KG	0403, 0504, 116364, 1203, 1204, 47070, 54927, 57537
PRODUCT	55320	IMIDACLOPRID	ADVOCATE FOR PUPPIES AND SMALL DOGS UP TO 4 KG	0403, 0504, 1203, 1204, 47073, 54930, 57541
PRODUCT	68906	IMIDACLOPRID	AGMATE IMIDACLOPRID 600 FS INSECTICIDE	59355
PRODUCT	85370	IMIDACLOPRID	AGPROTECT IMIDACLOPRID 600 SEED TREATMENT INSECTICIDE	113079
PRODUCT	84066	IMIDACLOPRID	AGRICLOPRID 600FS INSECTICIDE	109616
PRODUCT	69670	IMIDACLOPRID	AGROCN IMIDACLOPRID 350 SC INSECTICIDE	61399
PRODUCT	66649	IMIDACLOPRID	AGRO-ESSENCE IMIDACLOPRID 200 SC INSECTICIDE	54089
PRODUCT	66808	IMIDACLOPRID	AGRO-ESSENCE INSECTICIDE IMIDACLOPRID 600FS	54450
PRODUCT	84075	IMIDACLOPRID	AGROSHINE IMIDA600 SEED TREATMENT INSECTICIDE	109646
PRODUCT	64093	IMIDACLOPRID	AMGROW CONQUER HOSE-ON LAWN INSECTICIDE	0509
PRODUCT	64681	IMIDACLOPRID	AMGROW CONQUER LAWN & GARDEN INSECTICIDE	1209
PRODUCT	61901	IMIDACLOPRID	AMGROW CONQUER READY TO USE INSECTICIDE	0507, 50784
PRODUCT	69195	IMIDACLOPRID	AMGROW PATROL FIXANT ADVANCED ANT CONTROL BAIT	60206
PRODUCT	66405	IMIDACLOPRID	AMGROW ROSE SPRAY ADVANCED READY TO USE	104917, 53577

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	60092	IMIDACLOPRID	AMPARO SEED TREATMENT INSECTICIDE	0406
PRODUCT	86423	IMIDACLOPRID	AMVAC IMIDACLOPRID 600 FLOWABLE SEED DRESSING INSECTICIDE	115735
PRODUCT	64036	IMIDACLOPRID	ANTMASTER LIQUID BAIT	0709
PRODUCT	66888	IMIDACLOPRID	APPARENT COCKY 200 SC INSECTICIDE	102428, 54626
PRODUCT	68402	IMIDACLOPRID	APPARENT EXPUNGE 600 SC INSECTICIDE	102426, 58290
PRODUCT	69499	IMIDACLOPRID	APPARENT PICADOR 350 SC INSECTICIDE	104010, 60944
PRODUCT	82874	IMIDACLOPRID	APPARENT SINISTER LAWN INSECTICIDE	107026
PRODUCT	88090	IMIDACLOPRID	ARISTOPET ANIMAL HEALTH FLEAS, HEARTWORM AND WORMS FOR CATS OVER 4KG	120241
PRODUCT	88085	IMIDACLOPRID	ARISTOPET ANIMAL HEALTH FLEAS, HEARTWORM AND WORMS FOR DOGS 10-25KG	120234
PRODUCT	88086	IMIDACLOPRID	ARISTOPET ANIMAL HEALTH FLEAS, HEARTWORM AND WORMS FOR DOGS 4-10KG	120235
PRODUCT	88078	IMIDACLOPRID	ARISTOPET ANIMAL HEALTH FLEAS, HEARTWORM AND WORMS FOR DOGS OVER 25KG	120218
PRODUCT	88088	IMIDACLOPRID	ARISTOPET ANIMAL HEALTH FLEAS, HEARTWORM AND WORMS FOR KITTENS AND SMALL CATS UP TO 4KG	120238
PRODUCT	88087	IMIDACLOPRID	ARISTOPET ANIMAL HEALTH FLEAS, HEARTWORM AND WORMS FOR PUPPIES AND SMALL DOGS UP TO 4KG	120236

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	64690	IMIDACLOPRID	ARROW PLUS SEED TREATMENT	48981
PRODUCT	86629	IMIDACLOPRID	ARYSTA LIFESCENCE IMIDACLOPRID 200 SC INSECTICIDE	116230
PRODUCT	86628	IMIDACLOPRID	ARYSTA LIFESCENCE IMIDACLOPRID 350 SC INSECTICIDE	116229
PRODUCT	82664	IMIDACLOPRID	ATLAS GARDEN INSECT SPRAY	106388
PRODUCT	86579	IMIDACLOPRID	ATLAS KILLS AND PROTECTS COCKROACH BAITS	116085
PRODUCT	62598	IMIDACLOPRID	AVENGE + FLY BLOWFLY STRIKE PREVENTION AND LOUSICIDE FOR SHEEP SPRAY-ON POUR-ON	0510, 0809, 100418, 100910, 104913, 118235, 55124, 56741
PRODUCT	65640	IMIDACLOPRID	AW INFLICT 600 SEED DRESSING	51476
PRODUCT	65213	IMIDACLOPRID	AW IRRUPT 350 SOIL INSECTICIDE	0710
PRODUCT	61160	IMIDACLOPRID	BARMAC IMIDATURF TURF AND ORNAMENTAL INSECTICIDE	0808
PRODUCT	60328	IMIDACLOPRID	BAYGON FLY CONTROL WINDOW STICKERS FLOWER	0307, 0606
PRODUCT	66870	IMIDACLOPRID	BITHOR DUAL ACTION INSECTICIDE	115128, 54579, 60284
PRODUCT	81581	IMIDACLOPRID	BODYLINE POUR-ON LOUSICIDE FOR SHEEP	103401, 112340
PRODUCT	62924	IMIDACLOPRID	BRUNNINGS IMIDACLOPRID BUG KILL SYSTEMIC INSECT CONTROL	0809, 111057
PRODUCT	64826	IMIDACLOPRID	BRUNNINGS LAWN GRUB & BEETLE KILL	107646, 49383

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	64824	IMIDACLOPRID	BRUNNINGS LAWN GRUB & BEETLE KILL CONCENTRATE	49379
PRODUCT	83012	IMIDACLOPRID	CENTURION POUR-ON LICE TREATMENT FOR SHEEP	107317, 117552
PRODUCT	67304	IMIDACLOPRID	CHAINDRITE UTILITY INSECTICIDE	55725
PRODUCT	65567	IMIDACLOPRID	CHOICE IMMI 600 FLOWABLE SEED DRESSING INSECTICIDE	51308
PRODUCT	85082	IMIDACLOPRID	CHOICE MERGE 200 SC INSECTICIDE	112250
PRODUCT	64847	IMIDACLOPRID	CONFEDERATE 350 SC INSECTICIDE	0210
PRODUCT	50548	IMIDACLOPRID	CONFIDOR 200 SC INSECTICIDE	1199, 0600, 0601, 0602, 0698, 0699, 0701, 0799, 0800, 0900, 0909, 1001, 1004, 1199, 1205, 50935, 61850
PRODUCT	55962	IMIDACLOPRID	CONFIDOR CONCENTRATE INSECTICIDE	0604, 0802, 0902, 1102
PRODUCT	49395	IMIDACLOPRID	CONFIDOR GARDEN INSECTICIDE	01, 0201, 0798, 0799
PRODUCT	55753	IMIDACLOPRID	CONFIDOR GUARD SOIL INSECTICIDE	0606, 0705, 0806, 0808, 0904, 0908, 0909, 102092, 1106, 111567, 1204
PRODUCT	55592	IMIDACLOPRID	CONFIDOR HOSE-ON LAWN INSECTICIDE	0308, 0503

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	60571	IMIDACLOPRID	CONFIDOR LAWN & GARDEN INSECTICIDE	0706, 100190, 106733, 109442
PRODUCT	49394	IMIDACLOPRID	CONFIDOR PLANT INSECTICIDE	01, 0201, 0798, 0799
PRODUCT	60784	IMIDACLOPRID	CONFIDOR READY TO USE INSECTICIDE	0506, 109441, 61818
PRODUCT	63857	IMIDACLOPRID	CONFIDOR TABLETS GARDEN INSECTICIDE	109443, 46758, 55649, 61878
PRODUCT	67428	IMIDACLOPRID	CONQUEST IMIDA 600 SEED TREATMENT INSECTICIDE	56021
PRODUCT	69702	IMIDACLOPRID	CONQUEST IMIDAH 350 SC INSECTICIDE	61467
PRODUCT	60576	IMIDACLOPRID	COUNTRY IMIDACLOPRID 200 SC TERMITICIDE	0607, 107723
PRODUCT	60923	IMIDACLOPRID	COURAZE 200 SC INSECTICIDE	0506
PRODUCT	61591	IMIDACLOPRID	COURAZE CLASSIC INSECTICIDE	0710, 0807, 100679, 1207, 55606, 61393
PRODUCT	68912	IMIDACLOPRID	COVERT COCKROACH GEL BAIT	59367
PRODUCT	85811	IMIDACLOPRID	COVINE KARMA POUR-ON LOUSICIDE FOR SHEEP	114099, 117269
PRODUCT	70392	IMIDACLOPRID	DAVID GRAYS SYSTEMIC BUG KILLER GRANULAR GARDEN INSECTICIDE	103752, 63348
PRODUCT	67208	IMIDACLOPRID	EASYFARM IMIDACLOPRID 350 SOIL INSECTICIDE	55464, 59764
PRODUCT	68874	IMIDACLOPRID	ECHEM IMIDACLOPRID 200 SC INSECTICIDE	59263

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	63312	IMIDACLOPRID	EMERGE FLOWABLE SEED TREATMENT	0908, 1208
PRODUCT	86457	IMIDACLOPRID	ENDURAMID FOR DOGS 10-25 KG	115799
PRODUCT	66253	IMIDACLOPRID	ENVIROMAX IMIDACLOPRID 200SC TERMITICIDE & INSECTICIDE	53082, 55754
PRODUCT	66097	IMIDACLOPRID	ENVIROMAX IMIDACLOPRID 200SC TURF, CROP & ORNAMENTAL INSECTICIDE	52718
PRODUCT	86910	IMIDACLOPRID	ENVIROMAX IMIDACLOPRID FLYBAIT	117014
PRODUCT	81540	IMIDACLOPRID	ERADICATOR POUR-ON BLOWFLY STRIKE PREVENTION AND LOUSICIDE FOR SHEEP	103322, 120862
PRODUCT	87887	IMIDACLOPRID	EUREKA! IMIDACLOPRID 200 INSECTICIDE	119669
PRODUCT	80878	IMIDACLOPRID	EUREKA! IMIDACLOPRID 350 SOIL INSECTICIDE	101867
PRODUCT	81455	IMIDACLOPRID	EUREKA! IMIDACLOPRID 600 INSECTICIDE	103150
PRODUCT	85809	IMIDACLOPRID	EUREKA! IMIDACLOPRID TEBUCONAZOLE FLOWABLE SEED TREATMENT	114097
PRODUCT	80439	IMIDACLOPRID	EXELPET VET SERIES MONTHLY FLEA, INTESTINAL & HEARTWORM TREATMENT FOR CATS OVER 4KG	100862, 108230, 108395
PRODUCT	80436	IMIDACLOPRID	EXELPET VET SERIES MONTHLY FLEA, INTESTINAL & HEARTWORM TREATMENT FOR DOGS 10-25KG	100858, 108227, 108391
PRODUCT	80437	IMIDACLOPRID	EXELPET VET SERIES MONTHLY FLEA, INTESTINAL & HEARTWORM TREATMENT FOR DOGS 4-10KG	100859, 108394

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	80435	IMIDACLOPRID	EXELPET VET SERIES MONTHLY FLEA, INTESTINAL & HEARTWORM TREATMENT FOR DOGS OVER 25KG	100857, 108226, 108389
PRODUCT	80440	IMIDACLOPRID	EXELPET VET SERIES MONTHLY FLEA, INTESTINAL & HEARTWORM TREATMENT FOR KITTENS & SMALL CATS UP TO 4KG	100863, 108231, 108387
PRODUCT	86334	IMIDACLOPRID	EXI-FLEA FOR CATS OVER 4 KG	115507
PRODUCT	86339	IMIDACLOPRID	EXI-FLEA FOR DOGS 10-25 KG	115518
PRODUCT	86337	IMIDACLOPRID	EXI-FLEA FOR DOGS 4-10 KG	115511
PRODUCT	86342	IMIDACLOPRID	EXI-FLEA FOR DOGS OVER 25 KG	115521
PRODUCT	86326	IMIDACLOPRID	EXI-FLEA FOR KITTENS AND SMALL CATS UP TO 4 KG	115480
PRODUCT	86335	IMIDACLOPRID	EXI-FLEA FOR PUPPIES AND SMALL DOGS UP TO 4 KG	115508
PRODUCT	86381	IMIDACLOPRID	EXI-FLEA PLUS FOR CATS OVER 4 KG	115611
PRODUCT	86384	IMIDACLOPRID	EXI-FLEA PLUS FOR DOGS 10-25 KG	115655
PRODUCT	86383	IMIDACLOPRID	EXI-FLEA PLUS FOR DOGS 4-10 KG	115614
PRODUCT	86385	IMIDACLOPRID	EXI-FLEA PLUS FOR DOGS OVER 25 KG	115656
PRODUCT	86378	IMIDACLOPRID	EXI-FLEA PLUS FOR KITTENS AND SMALL CATS UP TO 4 KG	115605
PRODUCT	86382	IMIDACLOPRID	EXI-FLEA PLUS FOR PUPPIES AND SMALL DOGS UP TO 4 KG	115613
PRODUCT	83017	IMIDACLOPRID	EXILICE POUR-ON LOUSICIDE FOR SHEEP	107324
PRODUCT	68673	IMIDACLOPRID	EZYCROP IMIDACLOPRID 200 SC INSECTICIDE	58873

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	68048	IMIDACLOPRID	EZYCROP IMIDACLOPRID 350 SOIL INSECTICIDE	57356
PRODUCT	68096	IMIDACLOPRID	EZYCROP IMIDACLOPRID 600 SEED TREATMENT INSECTICIDE	57477
PRODUCT	87149	IMIDACLOPRID	F.S.A. IMIDACLOPRID 600 FLOWABLE SEED TREATMENT INSECTICIDE	117644
PRODUCT	66920	IMIDACLOPRID	FARMALINX IMI 600 SEED DRESSING INSECTICIDE	54691
PRODUCT	60951	IMIDACLOPRID	FARMOZ DOMINION 200 SC TERMITICIDE	0307, 0706, 0808
PRODUCT	85544	IMIDACLOPRID	FENNEC POUR-ON FOR SHEEP	113561
PRODUCT	69982	IMIDACLOPRID	FLEA CONTROL DEODORISING HOUSEHOLD FLEA SPRAY	62228
PRODUCT	60655	IMIDACLOPRID	FOLIARFLO PLUS SEED TREATMENT	0306, 1106
PRODUCT	69184	IMIDACLOPRID	FORWARD IMIDACLOPRID 600 SEED DRESSING INSECTICIDE	60158
PRODUCT	46227	IMIDACLOPRID	GAUCHO 600 FLOWABLE SEED TREATMENT INSECTICIDE	02, 0505, 0710, 0805, 0899, 0901, 1004, 1099, 1102, 58490, 58490AA
PRODUCT	52320	IMIDACLOPRID	GAUCHO 600 RED FLOWABLE SEED TREATMENT INSECTICIDE	1099, 56958, 58491
PRODUCT	62019	IMIDACLOPRID	GENERO 600 FLOWABLE SEED DRESSING INSECTICIDE	0507
PRODUCT	62165	IMIDACLOPRID	GENFARM IMIDACLOPRID 200SC INSECTICIDE	0708
PRODUCT	84404	IMIDACLOPRID	GENFARM IMIDACLOPRID 350 INSECTICIDE	110316



Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	60884	IMIDACLOPRID	GENFARM IMIDACLOPRID 600 FLOWABLE SEED DRESSING INSECTICIDE	1106
PRODUCT	82416	IMIDACLOPRID	GENFARM IMIDACLOPRID 600 FLOWABLE SEED TREATMENT INSECTICIDE	105703
PRODUCT	84503	IMIDACLOPRID	GENFARM IMIDI T 360 SEED TREATMENT	110533
PRODUCT	87144	IMIDACLOPRID	GLOBACHEM'S IMIDA 200 INSECTICIDE	117636
PRODUCT	86424	IMIDACLOPRID	GLOBACHEM'S IMIDA INSECTICIDE	115736
PRODUCT	63163	IMIDACLOPRID	GRANULAR PRODUCTS IMIDACLOPRID 350 SOIL INSECTICIDE	0908
PRODUCT	80844	IMIDACLOPRID	GROWERS LAWN GRUBBER CONCENTRATE	101767
PRODUCT	81249	IMIDACLOPRID	GROWERS LAWN GRUBBER HOSE ON	102678
PRODUCT	80617	IMIDACLOPRID	GUARDIAN RED SEED TREATMENT INSECTICIDE	101286
PRODUCT	60666	IMIDACLOPRID	GUARDIAN SEED TREATMENT INSECTICIDE	0306, 0809, 1106, 1208, 53363
PRODUCT	84616	IMIDACLOPRID	GUARDIAN SYSTEMIC GARDEN INSECTICIDE	110939
PRODUCT	86745	IMIDACLOPRID	HERCULES POUR ON FOR LICE	116490
PRODUCT	65040	IMIDACLOPRID	HOMBRE ULTRA CEREAL SEED TREATMENT	49942, 56956, 58492
PRODUCT	67089	IMIDACLOPRID	HORTICO INSECT KILLER READY TO SPRAY TREES & SHRUBS	105086, 55171
PRODUCT	67090	IMIDACLOPRID	HORTICO SYSTEMIC INSECT KILLER IMIDACLOPRID CONCENTRATE	55172

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	82335	IMIDACLOPRID	HOVEX ANT GEL	105462
PRODUCT	82077	IMIDACLOPRID	HOVEX COCKROACH GEL	104935, 114107
PRODUCT	59037	IMIDACLOPRID	HUILONG APHID GUARD 200 SC APHICIDE/INSECTICIDE	0608, 107494, 1106
PRODUCT	67302	IMIDACLOPRID	IMIFORCE 200SC TERMITICIDE	55723, 62508
PRODUCT	64198	IMIDACLOPRID	IMIFORCE UTILITY INSECTICIDE	49707, 53502
PRODUCT	86561	IMIDACLOPRID	IMMADOR 350SC INSECTICIDE	116041
PRODUCT	82395	IMIDACLOPRID	IMMIX 600 SEED TREATMENT	105648, 112101
PRODUCT	60465	IMIDACLOPRID	IMTRADE ANNIHILATE 200 SC ALL PURPOSE INSECTICIDE	0807, 1009, 106758
PRODUCT	63795	IMIDACLOPRID	IMTRADE IMIDACLOPRID 350 SC INSECTICIDE	0309, 57865
PRODUCT	84054	IMIDACLOPRID	INDEPENDENTS OWN ENCORE POUR-ON LOUSICIDE FOR SHEEP	109585, 118626
PRODUCT	60391	IMIDACLOPRID	INITIATOR SYSTEMIC PLANT INSECTICIDE AND FERTILISER	0108, 0209, 0806
PRODUCT	81251	IMIDACLOPRID	INSECT AND BUG SPRAY CONCENTRATE	102680
PRODUCT	81252	IMIDACLOPRID	INSECT AND BUG SPRAY READY TO USE	102682
PRODUCT	87848	IMIDACLOPRID	KARMA 35 POUR-ON LOUSICIDE FOR SHEEP	119551, 120413
PRODUCT	86773	IMIDACLOPRID	KARMA POUR-ON LOUSICIDE FOR SHEEP	116541
PRODUCT	63870	IMIDACLOPRID	KENSO AGCARE IMI-KEN 200SC TERMITICIDE	46793
PRODUCT	62062	IMIDACLOPRID	KENSO AGCARE RADICLE 600 FS FLOWABLE SEED DRESSING	0610, 1008, 106079
PRODUCT	60727	IMIDACLOPRID	KENSO AGCARE SAVAGE 200 INSECTICIDE	0610, 0908, 114860

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	81258	IMIDACLOPRID	KENSO AGCARE SAVAGE 350 SC INSECTICIDE	102695
PRODUCT	59559	IMIDACLOPRID	KOHINOR 200 INSECTICIDE	0505, 0705, 0906, 1105, 63157
PRODUCT	69375	IMIDACLOPRID	KOHINOR 350 INSECTICIDE	60631
PRODUCT	68344	IMIDACLOPRID	KOHINOR 350 SC INSECTICIDE	58194
PRODUCT	67913	IMIDACLOPRID	KOMONDOR 200 INSECTICIDE	104936, 114862, 118446, 57065
PRODUCT	87768	IMIDACLOPRID	LOOKOUT 600 SEED DRESSING	119214
PRODUCT	69488	IMIDACLOPRID	MAXFORCE FUSION COCKROACH GEL	113374, 60922
PRODUCT	64123	IMIDACLOPRID	MAXFORCE QUANTUM LIQUID ANT BAIT	0110A, 113609
PRODUCT	61937	IMIDACLOPRID	MAXFORCE WHITE COCKROACH GEL	0407, 53403
PRODUCT	86998	IMIDACLOPRID	MAYAIMIDA 200 SC INSECTICIDE	117268
PRODUCT	86997	IMIDACLOPRID	MAYAIMIDA 600 SEED DRESSING	117267
PRODUCT	59696	IMIDACLOPRID	MERIT TURF AND ORNAMENTAL INSECTICIDE	0410, 0505, 102184, 50036
PRODUCT	66663	IMIDACLOPRID	MISSION IMIDACLOPRID 200 SC ALL PURPOSE INSECTICIDE	54119
PRODUCT	61975	IMIDACLOPRID	MORTEIN NATURGARD FLY CONTROL WINDOW STICKERS	0809, 1007
PRODUCT	70076	IMIDACLOPRID	MOVENTO ENERGY INSECTICIDE	62448
PRODUCT	83604	IMIDACLOPRID	MOXICLEAR FOR CATS OVER 4 KG	108690, 115928, 120021

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	83621	IMIDACLOPRID	MOXICLEAR FOR DOGS 10-25 KG	108736, 115828, 119999
PRODUCT	83620	IMIDACLOPRID	MOXICLEAR FOR DOGS 4-10 KG	108735, 115827
PRODUCT	83622	IMIDACLOPRID	MOXICLEAR FOR DOGS OVER 25 KG	108737, 115829, 120000
PRODUCT	83601	IMIDACLOPRID	MOXICLEAR FOR KITTENS AND SMALL CATS UP TO 4 KG	108686, 115924, 120018
PRODUCT	83619	IMIDACLOPRID	MOXICLEAR FOR PUPPIES AND SMALL DOGS UP TO 4 KG	108734, 115813, 119980
PRODUCT	82172	IMIDACLOPRID	NEOVEDA SPOT-ON FOR CATS OVER 4 KG	105128, 117524
PRODUCT	82168	IMIDACLOPRID	NEOVEDA SPOT-ON FOR DOGS 10 - 25 KG	105124, 117516
PRODUCT	82169	IMIDACLOPRID	NEOVEDA SPOT-ON FOR DOGS 4 - 10 KG	105125, 117523
PRODUCT	82167	IMIDACLOPRID	NEOVEDA SPOT-ON FOR DOGS OVER 25 KG	105123, 117515
PRODUCT	82171	IMIDACLOPRID	NEOVEDA SPOT-ON FOR KITTENS & SMALL CATS UP TO 4 KG	105127, 117527
PRODUCT	82170	IMIDACLOPRID	NEOVEDA SPOT-ON FOR PUPPIES & SMALL DOGS UP TO 4 KG	105126, 117520
PRODUCT	86499	IMIDACLOPRID	NEOVET FOR CATS OVER 4KG	115902
PRODUCT	86496	IMIDACLOPRID	NEOVET FOR DOGS 10 - 25KG	115897
PRODUCT	86497	IMIDACLOPRID	NEOVET FOR DOGS 4 - 10KG	115900
PRODUCT	86494	IMIDACLOPRID	NEOVET FOR DOGS OVER 25KG	115895
PRODUCT	86500	IMIDACLOPRID	NEOVET FOR KITTENS AND SMALL CATS UP TO 4KG	115903

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	86498	IMIDACLOPRID	NEOVET FOR PUPPIES AND SMALL DOGS UP TO 4KG	115901
PRODUCT	67593	IMIDACLOPRID	NOVAGUARD IMIDACLOPRID 200 SC INSECTICIDE	56422
PRODUCT	68212	IMIDACLOPRID	NOVAGUARD IMIDACLOPRID 350 SOIL INSECTICIDE	57770
PRODUCT	67434	IMIDACLOPRID	NOVAGUARD IMIDACLOPRID 600 SEED TREATMENT INSECTICIDE	56035
PRODUCT	60590	IMIDACLOPRID	NUFARM NUPRID 200SC INSECTICIDE	0606
PRODUCT	60587	IMIDACLOPRID	NUFARM NUPRID 350SC INSECTICIDE	0210, 0409, 0706, 54300, 60151
PRODUCT	65887	IMIDACLOPRID	NUFARM NUPRID 700WG INSECTICIDE	52230, 59650
PRODUCT	68445	IMIDACLOPRID	OZCROP IMIDACLOPRID 350 SC INSECTICIDE	58377
PRODUCT	68446	IMIDACLOPRID	OZCROP IMIDACLOPRID 600 FS INSECTICIDE	58378
PRODUCT	65712	IMIDACLOPRID	PACIFIC IMIDACLOPRID 200 SC INSECTICIDE	51678
PRODUCT	68628	IMIDACLOPRID	PASTORAL AG IMIDACLOPRID POUR-ON LICE TREATMENT FOR SHEEP	121470, 58722
PRODUCT	54645	IMIDACLOPRID	PERMATEK IM 30 INSECTICIDE	0103, 0508, 0707, 48472, 56435, 62135
PRODUCT	82836	IMIDACLOPRID	PEST CONTROLLERS OWN IMIDACLOPRID 200 SC TERMITICIDE	106883
PRODUCT	69543	IMIDACLOPRID	PEST CONTROLLERS OWN IMIDACLOPRID 200SC TERMITICIDE	61091

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	61405	IMIDACLOPRID	PICUS SEED TREATMENT INSECTICIDE	0707, 111407, 1207
PRODUCT	82028	IMIDACLOPRID	PONTIAC SEED TREATMENT	104827, 107189
PRODUCT	81485	IMIDACLOPRID	POWERSHIELD POUR-ON LOUSICIDE FOR SHEEP	103201, 114738
PRODUCT	61574	IMIDACLOPRID	PREMINATOR TERMITICIDE	41163
PRODUCT	49098	IMIDACLOPRID	PREMISE 200 SC TERMITICIDE	0198, 0201, 0605, 0802, 0806, 103200, 119427
PRODUCT	59345	IMIDACLOPRID	PREMISE FOAM INSECTICIDE	0107, 0805, 47889
PRODUCT	67342	IMIDACLOPRID	PREVENTOL TM-TERMITICIDE FOR EXPANDED POLYSTYRENE FOAM	55846
PRODUCT	64900	IMIDACLOPRID	PRIDE INSECTICIDE	0410, 115529
PRODUCT	85132	IMIDACLOPRID	PRISMA 20 SC INSECTICIDE	112338
PRODUCT	60657	IMIDACLOPRID	PROGUARD PLUS SEED TREATMENT	0306, 1106
PRODUCT	80593	IMIDACLOPRID	PROGUARD ULTRA CEREAL SEED TREATMENT	101191
PRODUCT	60656	IMIDACLOPRID	PROLEAF PLUS SEED TREATMENT	0306, 1106
PRODUCT	69774	IMIDACLOPRID	PROTECT-US FLY BAIT	61710
PRODUCT	68971	IMIDACLOPRID	PROTECT-US MULTIAG INSECTICIDE	59539
PRODUCT	60558	IMIDACLOPRID	PROTHOR 200 SC TERMITICIDE	0706, 1107, 56005
PRODUCT	57892	IMIDACLOPRID	QUICKBAYT FLY BAIT	0704
PRODUCT	61737	IMIDACLOPRID	QUICKBAYT SPRAY FLY BAIT	0809, 119534, 53623, 58686

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	66688	IMIDACLOPRID	RAINBOW IMIDACLOPRID 350 SC INSECTICIDE	54192
PRODUCT	66508	IMIDACLOPRID	RAINBOW IMIDACLOPRID 600 SC INSECTICIDE	53795
PRODUCT	83783	IMIDACLOPRID	RAYSTAR IMIDACLOPRID 350 SC INSECTICIDE	108967
PRODUCT	86697	IMIDACLOPRID	REDQUEEN 600 INSECTICIDE	116398
PRODUCT	68518	IMIDACLOPRID	RELAY 200 SC TERMITICIDE	58515, 60288
PRODUCT	69383	IMIDACLOPRID	RESOURCE GARDENING SYSTEMIC INSECT CONTROL READY TO USE	60642
PRODUCT	67498	IMIDACLOPRID	RICHGRO BUG KILLA GRANULAR GARDEN INSECTICIDE	104899, 56196
PRODUCT	82056	IMIDACLOPRID	RICHGRO LAWN INSECT KILLA	104885
PRODUCT	63056	IMIDACLOPRID	ROACHKILL HOME COCKROACH GEL BAIT	0608, 59951
PRODUCT	69506	IMIDACLOPRID	ROTAM ALLEZ 350 SC INSECTICIDE	105104, 60955
PRODUCT	62629	IMIDACLOPRID	RYGEL IMIDACLOPRID 200 SC INSECTICIDE	0509
PRODUCT	69122	IMIDACLOPRID	SABAKEM IMIDACLOPRID 350SC SOIL INSECTICIDE	60024, 61963
PRODUCT	68994	IMIDACLOPRID	SABAKEM IMIDACLOPRID 600FS SEED TREATMENT INSECTICIDE	118042, 59587
PRODUCT	64666	IMIDACLOPRID	SEARLES CONGUARD GARDEN & LAWN INSECTICIDE	1209
PRODUCT	63155	IMIDACLOPRID	SEARLES CONGUARD GARDEN INSECTICIDE	0608
PRODUCT	60857	IMIDACLOPRID	SENATOR 600 FLOWABLE SEED TREATMENT	0107, 100330, 52203, 61992

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	61163	IMIDACLOPRID	SENATOR 600 RED FLOWABLE SEED TREATMENT	100398, 1106
PRODUCT	68192	IMIDACLOPRID	SENATOR 700WG INSECTICIDE	101733, 106268, 57747, 62041
PRODUCT	66209	IMIDACLOPRID	SERESTO FOR DOGS AND PUPPIES UP TO 8 KG FLEAS & TICKS COLLAR	101323, 106422, 107255, 108291, 114214, 115865, 121807, 52994
PRODUCT	65875	IMIDACLOPRID	SERESTO FOR DOGS OVER 8 KG FLEAS & TICKS COLLAR	101355, 106421, 107316, 108294, 114215, 115926, 121809, 52208
PRODUCT	80642	IMIDACLOPRID	SERESTO FOR KITTENS AND CATS FLEAS COLLAR	101322, 106453, 108295, 114138, 119876
PRODUCT	61974	IMIDACLOPRID	SHARP SHOOTER COMPLETE BUG & INSECT SPRAY IMIDACLOPRID	0808
PRODUCT	62472	IMIDACLOPRID	SHARP SHOOTER COMPLETE BUG & INSECT SPRAY IMIDACLOPRID CONCENTRATE	0709
PRODUCT	63142	IMIDACLOPRID	SHARP SHOOTER COMPLETE LAWN GRUB & BEETLE KILLER HOSE ON IMIDACLOPRID SYSTEMIC INSECTICIDE	0809



Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	63143	IMIDACLOPRID	SHARP SHOOTER COMPLETE LAWN GRUB & BEETLE KILLER IMIDACLOPRID SYSTEMIC INSECTICIDE CONCENTRATE	0809
PRODUCT	68858	IMIDACLOPRID	SHERWOOD IMIFORCE 200SC TERMITICIDE	59228
PRODUCT	82820	IMIDACLOPRID	SHIELDRITE CRAWLING INSECT FOAM	106857, 111133
PRODUCT	62475	IMIDACLOPRID	SILVASHIELD INJECTABLE TREE INSECTICIDE	0609, 0808, 50660
PRODUCT	67781	IMIDACLOPRID	SINDOR 200 SC INSECTICIDE	57399
PRODUCT	83338	IMIDACLOPRID	SINDOR 350 SC INSECTICIDE	108080
PRODUCT	83389	IMIDACLOPRID	SINDOR 600 FLOWABLE SEED TREATMENT	108166
PRODUCT	80106	IMIDACLOPRID	SINGLESLOT GEL COCKROACH INSECTICIDE	100223
PRODUCT	68892	IMIDACLOPRID	SINOCHEM INTERSECT 200SC INSECTICIDE	59319
PRODUCT	66379	IMIDACLOPRID	SMART IMIDACLOPRID 600 FLOWABLE SEED DRESSING INSECTICIDE	53537
PRODUCT	85059	IMIDACLOPRID	SNIPER POUR-ON LOUSICIDE FOR SHEEP	112210
PRODUCT	68410	IMIDACLOPRID	SOLFAC DUO RESIDUAL INSECTICIDE	58306, 59669, 62059
PRODUCT	87461	IMIDACLOPRID	SOMBRERO 600 SEED DRESSING	118405
PRODUCT	87267	IMIDACLOPRID	SPALDING IMIDACLOPRID 350 SC INSECTICIDE	117997
PRODUCT	85016	IMIDACLOPRID	SPALDING IMIDACLOPRID 600 SC INSECTICIDE	112060
PRODUCT	84841	IMIDACLOPRID	SUBMARINO IMIDACLOPRID 600 SEED TREATMENT INSECTICIDE	111535

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	67010	IMIDACLOPRID	SUPERWAY IMIDACLOPRID 200 INSECTICIDE	54958
PRODUCT	68545	IMIDACLOPRID	SUREFIRE FLYSTAR BAIT	58549
PRODUCT	60124	IMIDACLOPRID	SUREFIRE SPECTRUM 200SC INSECTICIDE	0706, 0909, 118946
PRODUCT	66265	IMIDACLOPRID	SUREFIRE SPECTRUM 350 SC SOIL INSECTICIDE	109642, 113159, 53155
PRODUCT	70098	IMIDACLOPRID	SUSCON MAXI INTEL SOIL INSECTICIDE	102924, 105964, 113649, 62504
PRODUCT	68086	IMIDACLOPRID	SUSCON YELLOW INTEL INSECTICIDE	57457
PRODUCT	62358	IMIDACLOPRID	SYSTEMIC ADVANCED CONTROL YATES ROSE GUN ADVANCED INSECT, MITE & DISEASE CONTROL	0409, 61364
PRODUCT	66046	IMIDACLOPRID	SYSTEMIC ADVANCED CONTROL YATES ROSE SHIELD ADVANCED INSECT, MITE & DISEASE CONTROL	52591
PRODUCT	65525	IMIDACLOPRID	TANALITH TI INSECTICIDE	51121
PRODUCT	64371	IMIDACLOPRID	TEMPRID 75 RESIDUAL INSECTICIDE	102194, 48160, 55633, 58068, 58117, 62534
PRODUCT	61094	IMIDACLOPRID	TIREM 200 SC INSECTICIDE	0107, 0809, 103757, 109237, 113345, 114912
PRODUCT	63238	IMIDACLOPRID	TITAN IMIDACLOPRID 200 INSECTICIDE	0908, 59656

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	86992	IMIDACLOPRID	TITAN IMIDACLOPRID 350 SC INSECTICIDE	117251
PRODUCT	67321	IMIDACLOPRID	TITAN IMIDACLOPRID 600 FLOWABLE SEED DRESSING INSECTICIDE	55797
PRODUCT	68705	IMIDACLOPRID	TRESPASS 350 INSECTICIDE	100733, 58931, 61371
PRODUCT	85057	IMIDACLOPRID	TRIPLUS INSECTICIDAL SEED TREATMENT	112205
PRODUCT	67769	IMIDACLOPRID	ULTRA FORCE2 TERMITE FOAM INSECTICIDE	110094, 56842
PRODUCT	68263	IMIDACLOPRID	VECTOTHOR FLY BAIT	57875
PRODUCT	63978	IMIDACLOPRID	VETERAN PLUS SEED TREATMENT	0210, 100865, 52552
PRODUCT	85254	IMIDACLOPRID	VETMEC BODYGUARD POUR-ON LOUSICIDE FOR SHEEP	112747, 114703
PRODUCT	80438	IMIDACLOPRID	VETS CHOICE FOR PUPPIES AND SMALL DOGS UP TO 4 KG FLEAS, HEARTWORM AND WORMS	100860
PRODUCT	69894	IMIDACLOPRID	VIRIDOR BUG AND INSECT SPRAY	61980
PRODUCT	60848	IMIDACLOPRID	VOODOO 200 INSECTICIDE	1206
PRODUCT	60883	IMIDACLOPRID	VOODOO GUARD SOIL INSECTICIDE	0906, 58202
PRODUCT	70263	IMIDACLOPRID	WELLFARM IMIDACLOPRID 350 SC INSECTICIDE	62846
PRODUCT	70293	IMIDACLOPRID	WELLFARM IMIDACLOPRID 600 SC SEED DRESSING INSECTICIDE	62944
PRODUCT	66871	IMIDACLOPRID	YATES COMPLETE LAWN INSECT CONTROL	54580

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	66602	IMIDACLOPRID	ZOOTER 600 SEED TREATMENT INSECTICIDE	54888
PRODUCT	64210	IMIDACLOPRID	ZOOTER SOIL GUARD INSECTICIDE	0709
PRODUCT	87489	THIACLOPRID	BAYER VIPER POUR-ON LOUSICIDE FOR SHEEP	118497, 120331
PRODUCT	53203	THIACLOPRID	CALYPSO 480 SC INSECTICIDE	0507, 1002, 1103, 1201
PRODUCT	81523	THIACLOPRID	CAMPBELL COBRA 480SC INSECTICIDE	103284
PRODUCT	63388	THIACLOPRID	LINEOUT INSECTICIDE	45483
PRODUCT	63766	THIACLOPRID	PIRANHA DIP FOR SHEEP	100911, 46448, 49430, 60758
PRODUCT	69664	THIACLOPRID	PONDUS INSECTICIDE	61384
PRODUCT	84681	THIACLOPRID	SUREFIRE REGGAE 480 SC INSECTICIDE	111121
PRODUCT	69187	THIACLOPRID	VIPER POUR-ON LOUSICIDE FOR SHEEP	108903, 118276, 60193
PRODUCT	56499	THIAMETHOXAM	ACTARA INSECTICIDE	0709, 0907, 1203, 49286
PRODUCT	56316	THIAMETHOXAM	AGITA 10 FLY BAIT	0607, 1103
PRODUCT	55288	THIAMETHOXAM	AGITA 100 PLUS FLY SPRAY AND PAINT-ON	0510, 0607, 1103
PRODUCT	70237	THIAMETHOXAM	BRUNNINGS TOMATO INSECT & FUNGUS SPRAY	110304, 62796
PRODUCT	80345	THIAMETHOXAM	BRUNNINGS TRIPLE ACTION BUG KILL	100659, 101931
PRODUCT	80400	THIAMETHOXAM	BRUNNINGS TRIPLE ACTION ROSE PRO INSECT, MITE AND DISEASE CONTROL	100777, 101904
PRODUCT	85516	THIAMETHOXAM	CAMPBELL MOXAM 250SC INSECTICIDE	113492, 120487

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	68967	THIAMETHOXAM	COLUMBUS INSECTICIDE	103753, 119103, 59512
PRODUCT	51833	THIAMETHOXAM	CRUISER 350 FS INSECTICIDE SEED TREATMENT	0301, 0706, 109050, 51064
PRODUCT	51832	THIAMETHOXAM	CRUISER 600 FS INSECTICIDE SEED TREATMENT	0502, 0704, 0706, 51063
PRODUCT	64880	THIAMETHOXAM	CRUISER EXTREME INSECTICIDE SEED TREATMENT	49521
PRODUCT	65888	THIAMETHOXAM	CRUISER OPTI INSECTICIDE SEED TREATMENT	116568, 52231, 59058
PRODUCT	63936	THIAMETHOXAM	DURIVO INSECTICIDE	0710, 121655
PRODUCT	85564	THIAMETHOXAM	KENSO AGCARE KENZAR FS FLOWABLE SEED DRESSING INSECTICIDE	113626
PRODUCT	58185	THIAMETHOXAM	MERIDIAN TURF INSECTICIDE	0604, 0907, 52699
PRODUCT	63523	THIAMETHOXAM	OPTIGARD ANT BAIT GEL	0310, 0609, 102318
PRODUCT	63574	THIAMETHOXAM	RESOLVA ALL-IN-ONE BUG AND FUNGUS KILLER WITH TMX PLANTGUARD	45969
PRODUCT	66550	THIAMETHOXAM	RESOLVA ALL-IN-ONE BUG AND FUNGUS KILLER WITH TMX PLANTGUARD FOR YOUR TOMATOES	53854
PRODUCT	64678	THIAMETHOXAM	RESOLVA LIQUID CONCENTRATE BUG KILLER WITH TMX PLANTGUARD FOR YOUR ORNAMENTALS AND TOMATOES	48945, 53365, 53857
PRODUCT	64459	THIAMETHOXAM	RESOLVA PROTECT AND FEED BUG KILLER GRANULES WITH TMX PLANTGUARD	48408, 57183

Type	Approval or Registration Number	Active Constituent	Product Name	Label Approval Number(s) Associated With the Registered Product
PRODUCT	86102	THIAMETHOXAM	RICHGRO ANT KILLER GEL	114681
PRODUCT	66637	THIAMETHOXAM	SPINNER TURF INSECTICIDE	54071
PRODUCT	64987	THIAMETHOXAM	TALON ANT KILL GEL	49792, 54410
PRODUCT	65959	THIAMETHOXAM	TALON ANT KILLER GEL	52384
PRODUCT	86610	THIAMETHOXAM	THIFAST FLY BAIT	116199
PRODUCT	86535	THIAMETHOXAM	THIJET SPRAY FLY BAIT	115990
PRODUCT	69822	THIAMETHOXAM	VIBRANCE EXTREME SEED TREATMENT	61829
PRODUCT	67480	THIAMETHOXAM	VOLIAM FLEXI INSECTICIDE	56156

## **Notice under regulation 59E of the *Agricultural and Veterinary Chemicals Code Regulations 1995***

### **APVMA APPROVED AUDITORS**

The person/s described in Schedule 1 below were authorised on 5 November 2019, in accordance with subregulation 59E and 61(8)(a) of the *Agricultural and Veterinary Chemicals Code Regulations 1995*, as APVMA-Authorised Good Manufacturing Practice (GMP) Auditors for the purposes of the Agvet Codes.

### **SCHEDULE 1—NEW APPOINTMENTS**

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