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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

Application no.:	120940
Product name:	Relyon Airone WG Fungicide
Active constituent/s:	280 g/kg copper present as copper oxychloride & copper hydroxide
Applicant name:	Isagro Australia Pty Limited
Applicant ACN:	066 736 114
Summary of use:	To approve a new label for the product 'RELYON AIRONE WG FUNGICIDE ' with the label name 'AIRONE WG FUNGICIDE'
Date of registration:	2 September 2019
Product registration no.:	81027
Label approval no.:	81027/120940
Application no.:	120939
Product name:	Contrac Soft Bait
Active constituent/s:	0.05 g/kg bromadiolone
Applicant name:	Bell Laboratories Inc
Applicant ACN:	N/A
Summary of use:	To approve a new label for the product 'CONTRAC SOFT BAIT' with the label name 'TOMCAT SOFT BAIT'
Date of registration:	2 September 2019
Product registration no.:	86331
Label approval no.:	86331/120939
Application no.:	120345
Product name:	Surefire Clethodim 240 EC Selective Herbicide
Active constituent/s:	240 g/L clethodim
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of certain grass weeds in agricultural and ornamental crops
Date of registration:	2 September 2019
Product registration no.:	88123
Label approval no.:	88123/120345
Application no.:	120358
Product name:	Kenso Agcare Indy 150 OD Insecticide
Active constituent/s:	150 g/L indoxacarb
Applicant name:	Kenso Corporation (M) Sdn Bhd
Applicant ACN:	N/A
Summary of use:	For the control of various species of insect pests in adzuki beans, chickpeas, cotton, faba beans, mung beans and soybeans
Date of registration:	4 September 2019
Product registration no.:	88131
Label approval no.:	88131/120358

Application no.:	120532
Product name:	Yates Home Pest Cockroach Kill Gel Bait
Active constituent/s:	8 g/kg indoxacarb (75:25) (equivalent to 6 g/kg active S-isomer)
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For control of cockroaches in domestic situations
Date of registration:	4 September 2019
Product registration no.:	88195
Label approval no.:	88195/120532
Application no.:	120529
Product name:	Mortein Powergard The Expert's Multi Insect Killer Household Protection
Active constituent/s:	0.3 g/kg permethrin, 0.7 g/kg imiprothrin, 1 g/kg esbiothrin
Applicant name:	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN:	629 549 506
Summary of use:	For use on flies, mosquitoes, cockroaches, ants, spiders, fleas, silverfish, wasps and moths in and around the home
Date of registration:	5 September 2019
Product registration no.:	88192
Label approval no.:	88192/120529
Application no.:	120240
Product name:	Imtrade Sulfur 800 WG Fungicide & Miticide
Active constituent/s:	800 g/kg sulfur
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control of powdery mildew, rust and mites in pome and stone fruit, citrus, grapevines, kiwifruit, strawberries and some vegetables
Date of registration:	5 September 2019
Product registration no.:	88089
Label approval no.:	88089/120240
Application no.:	118640
Product name:	Scotts Performance Naturals Snail & Slug Pellets
Active constituent/s:	2.8 g/kg iron present as iron(III) phosphate dihydrate
Applicant name:	Evergreen Garden Care Australia Pty Ltd
Applicant ACN:	003 123 162
Summary of use:	For the control of slugs and snails on edible crops, ornamental plants and natural surfaces not intended to bear vegetation
Date of registration:	10 September 2019
Product registration no.:	87545
Label approval no.:	87545/118640
Application no.:	120627
Product name:	F.S.A. Piclopyr 400 Herbicide
Active constituent/s:	100 g/L picloram present as hexyloxypropylamine salt, 300 g/L triclopyr present as butoxyethyl ester
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of a range of environmental and noxious woody and herbaceous weeds
Date of registration:	11 September 2019
Product registration no.:	88238
Label approval no.:	88238/120627

Application no.:	120621
Product name:	Apparent Indoxacarb 150 OC Insecticide
Active constituent/s:	200 g/L indoxacarb (3:1) (equivalent to 150 g/L active S-isomer)
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use:	For the control of various species of insect pests in adzuki beans, chickpeas, cotton, faba beans, mungbeans and soybeans
Date of registration:	11 September 2019
Product registration no.:	88235
Label approval no.:	88235/120621

Application no.:	112642
Product name:	Exilis 5XL Plant Growth Regulator
Active constituent/s:	100 g/L 6-benzyladenine
Applicant name:	Fine Agrochemicals Limited
Applicant ACN:	N/A
Summary of use:	For fruit thinning and improvement of fruit size of apples
Date of registration:	11 September 2019
Product registration no.:	85207
Label approval no.:	85207/112642

Application no.:	118789
Product name:	Conquest Treeminator 200 Herbicide
Active constituent/s:	200 g/kg tebuthiuron
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use:	For the control of brigalow regrowth, tea tree regrowth, <i>Mimosa pigra</i> , and certain problem wood weeds on grazing lands by hand, aerial, and ground application
Date of registration:	13 September 2019
Product registration no.:	87617
Label approval no.:	87617/118789

Application no.:	120434
Product name:	Smart Flumetsulam 800 WG Herbicide
Active constituent/s:	800 g/kg flumetsulam
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use:	For the post-emergence and salvage control of certain broadleaf weeds in winter cereals (including those undersown with clover, lucerne or medics); clover, fenugreek, lathyrus, lucerne, medic, serradella, and vetch (popany only) seed crops and pastures; chickpeas, field peas, lentils, maize, peanuts; and for the pre-emergence control of certain broadleaf weeds in maize and soybeans
Date of registration:	13 September 2019
Product registration no.:	88155
Label approval no.:	88155/120434

Application no.:	121157
Product name:	Tri-form 35 Soil Fumigant
Active constituent/s:	345 g/kg (465 g/L) chloropicrin, 630 g/kg (844 g/L) 1,3-dichloropropene
Applicant name:	Trical Australia Pty Ltd
Applicant ACN:	600 066 966
Summary of use:	To approve a new label for the product 'TRI-FORM 35 SOIL FUMIGANT' with the label name 'STRIKE 35 SOIL FUMIGANT'
Date of registration:	13 September 2019
Product registration no.:	64245
Label approval no.:	64245/121157

Application no.:	121160
Product name:	Tri-form 60 Soil Fumigant
Active constituent/s:	595 g/kg (865 g/L) chloropicrin, 380 g/kg (560 g/L) 1,3-dichloropropene
Applicant name:	Trical Australia Pty Ltd
Applicant ACN:	600 066 966
Summary of use:	To approve a new label for the product 'TRI-FORM 60 SOIL FUMIGANT' with the label name 'STRIKE 60 SOIL FUMIGANT'
Date of registration:	13 September 2019
Product registration no.:	64862
Label approval no.:	64862/121160

2. VARIATIONS OF REGISTRATION

Application no.:	121598
Product name:	Shoo Insect Spray Super Concentrate
Active constituent/s:	20 g/L piperonyl butoxide, 5 g/L n-octyl bicycloheptene dicarboximide, 5 g/L pyrethrins
Applicant name:	Swipe Pty Limited
Applicant ACN:	145 321 295
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Swipe Insect Spray "Swipe-A-Fly" Super Concentrate' to 'Shoo Insect Spray Super Concentrate'
Date of variation:	22 August 2019
Product registration no.:	86939
Label approval no.:	86939/121598

Application no.:	120537
Product name:	Baythroid Advanced Insect Killer For Lawns
Active constituent/s:	25 g/L beta-cyfluthrin
Applicant name:	Bayer CropScience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To add mole crickets and couch mite as pests
Date of variation:	3 September 2019
Product registration no.:	83922
Label approval no.:	83922/120537

Application no.:	121696
Product name:	Barmac Totril Selective Herbicide
Active constituent/s:	250 g/L ioxynil present as ioxynil octanoate
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Totril Selective Herbicide' to 'Barmac Totril Selective Herbicide'
Date of variation:	4 September 2019
Product registration no.:	31729
Label approval no.:	31729/121696

Application no.:	120597
Product name:	AC Pulverize Herbicide
Active constituent/s:	300 g/L 2,4-D as the triisopropanolamine salt, 75 g/L picloram as the triisopropanolamine salt
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of variation:	To incorporate spray drift instructions from the APVMA's reconsideration action on 2,4-D
Date of variation:	5 September 2019
Product registration no.:	64859
Label approval no.:	64859/120597
Application no.:	116253
Product name:	Topas 100 EC Systemic Fungicide
Active constituent/s:	100 g/L penconazole
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To amend the formulation composition and packaging material
Date of variation:	6 September 2019
Product registration no.:	30476
Label approval no.:	30476/116253
Application no.:	120366
Product name:	Surefire Stellar Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of variation:	To add use in garlic, leeks, shallots, spring onions, Brassica vegetables, Brassica leafy vegetables, horseradish, radish, lettuce, almonds, pistachio, beans, citrus, snow peas, sugar snap peas, and garden peas
Date of variation:	6 September 2019
Product registration no.:	66821
Label approval no.:	66821/120366
Application no.:	118826
Product name:	Botector Fungicide
Active constituent/s:	5 x 10 ⁹ CFU/g <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941) (At least 2.5 x 10 ⁹ <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941) at expiry)
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To extend shelf life
Date of variation:	13 September 2019
Product registration no.:	82495
Label approval no.:	82495/118826
Application no.:	120619
Product name:	Titan Butroxydim 250 WG Herbicide
Active constituent/s:	250 g/kg butroxydim
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To amend label critical comments, add crop safety statements and amend compatibility statements
Date of variation:	13 September 2019
Product registration no.:	82121
Label approval no.:	82121/120619

Application no.:	120630
Product name:	Apparent Metribuzin 750 WG Herbicide
Active constituent/s:	750 g/kg metribuzin
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of variation:	To update the scheduling of the product and label signal heading to Poison
Date of variation:	13 September 2019
Product registration no.:	65108
Label approval no.:	65108/120630

3. VARIATION OF LABEL APPROVAL

Application no.:	120342
Product name:	Aphidex WG Aphicide
Active constituent/s:	500 g/kg pirimicarb
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To amend the safety directions, remove knapsack use from the directions for use and to add a restraint to not apply by equipment carried on the back of the user
Date of variation:	30 August 2019
Product registration no.:	61595
Label approval no.:	61595/120342

Application no.:	120374
Product name:	Agro-Essence Fipronil 200SC Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Agro-Alliance (Australia) Pty Ltd
Applicant ACN:	130 864 603
Summary of variation:	To correct the application rate for forestry plantations
Date of variation:	3 September 2019
Product registration no.:	82050
Label approval no.:	82050/120374

Application no.:	120550
Product name:	Pixxaro Arylex Active Herbicide
Active constituent/s:	250 g/L fluroxypyr present as meptyl ester, 16.25 g/L cloquintocet-mexyl, 16.25 g/L halauxifen present as the methyl ester
Applicant name:	Dow Agrosiences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To change scheduling of the solvent N,N-dimethyloctanamide and N,N dimethyldecanamide on the constituent statement panel
Date of variation:	3 September 2019
Product registration no.:	82839
Label approval no.:	82839/120550

Application no.:	120367
Product name:	Affix 250 SC Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of variation:	To add a number of additional claims to the label
Date of variation:	3 September 2019
Product registration no.:	66885
Label approval no.:	66885/120367
Application no.:	120369
Product name:	Macspred Clomac Herbicide
Active constituent/s:	750 g/kg clopyralid present as the potassium salt
Applicant name:	Macspred Pty Ltd
Applicant ACN:	011 029 495
Summary of use:	To remove the state column in the Direction For Use section of the label
Date of registration:	3 September 2019
Product registration no.:	58844
Label approval no.:	58844/120369
Application no.:	120263
Product name:	Barrack Betterstick Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To vary the withholding period
Date of variation:	3 September 2019
Product registration no.:	61016
Label approval no.:	61016/120263
Application no.:	120422
Product name:	Smart Metribuzin 750 WG Herbicide
Active constituent/s:	750 g/kg metribuzin
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of variation:	To update the signal heading on the product label to 'POISON'
Date of variation:	6 September 2019
Product registration no.:	60935
Label approval no.:	60935/120422
Application no.:	120593
Product name:	Kenso Agcare Ken-Star 450 Herbicide
Active constituent/s:	450 g/L 2,4-D present as the isopropylamine salt
Applicant name:	Kenso Corporation (M) Sdn Bhd
Applicant ACN:	N/A
Summary of variation:	To incorporate spray drift instructions from the APVMA's reconsideration action on 2,4-D
Date of variation:	6 September 2019
Product registration no.:	61893
Label approval no.:	61893/120593

Application no.:	118695
Product name:	Serenade Prime Soil Ameliorant and Biofungicide
Active constituent/s:	Not less than 1.0×10^{12} CFU/L <i>Bacillus amyloliquefaciens</i> (formerly <i>Bacillus subtilis</i>) strain QST 713
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To add uses for control of yellow sigatoka and suppression of common leaf speckle in Banana
Date of variation:	13 September 2019
Product registration no.:	85292
Label approval no.:	85292/118695

Application no.:	120625
Product name:	Kendon Slow Grow 270 Growth Regulator
Active constituent/s:	270 g/L maleic hydrazide as potassium salt
Applicant name:	Kendon Plant Care Pty Ltd
Applicant ACN:	065 737 948
Summary of variation:	To add use in garlic
Date of variation:	23 September 2019
Product registration no.:	33375
Label approval no.:	33375/120625

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

Application no.:	120402
Product name:	Purina Totalcare Heartwormer, Allwormer & Flea Control For Cats
Active constituent/s:	60 mg/mL selamectin
Applicant name:	Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of variation:	For the prevention and control of flea infestations, control of flea allergy dermatitis, prevention of heartworm disease, treatment and control of ear mites, intestinal hookworm, roundworm and biting lice in cats and rabbits weight range between 2.6–7.5 kg
Date of variation:	4 September 2019
Product registration no.:	88142
Label approval no.:	88142/120402
Application no.:	116032
Product name:	Tylomix P250 Tylosin Premix
Active constituent/s:	250 g/kg tylosin as the phosphate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of variation:	For use as an aid in controlling enteric diseases caused by organisms susceptible to tylosin in pigs, for the treatment and prevention of ileitis in pigs, for reduction in the incidence of liver abscess in cattle and as an aid in control of necrotic enteritis caused by <i>Clostridium perfringens</i> in broiler and replacement chickens
Date of variation:	5 September 2019
Product registration no.:	86555
Label approval no.:	86555/116032
Application no.:	116585
Product name:	Lifemdab 100
Active constituent/s:	100 g/kg bacitracin methylene disalicylate
Applicant name:	Lifecome Biochemistry Co Ltd
Applicant ACN:	N/A
Summary of variation:	For use in poultry feed for the prevention of necrotic enteritis
Date of variation:	10 September 2019
Product registration no.:	86795
Label approval no.:	86795/116585

Application no.:	120433
Product name:	Cocciprol
Active constituent/s:	200 g/kg amprolium (as amprolium hydrochloride)
Applicant name:	Vetsense Pty Ltd
Applicant ACN:	150 968 871
Summary of variation:	Soluble premix product for the prevention and treatment of coccidiosis in broilers, broiler breeders, replacement pullets, turkeys, ducks and pigeons
Date of variation:	11 September 2019
Product registration no.:	88154
Label approval no.:	88154/120433

Application no.:	119441
Product name:	Ferrari Propofol 10 mg/mL Injection
Active constituent/s:	10 mg/mL propofol
Applicant name:	Ferrari Animal Health Pty Ltd
Applicant ACN:	162 206 671
Summary of variation:	For use as a general anaesthetic agent in dogs and cats
Date of variation:	13 September 2019
Product registration no.:	87803
Label approval no.:	87803/119441

2. VARIATIONS OF REGISTRATION

Application no.:	121634
Product name:	Independents Own Exitraz WP Cattle Dip And Spray
Active constituent/s:	500 g/kg amitraz
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Exitraz Cattle Dip And Spray' to 'Independents Own Exitraz WP Cattle Dip And Spray'
Date of variation:	29 August 2019
Product registration no.:	86911
Label approval no.:	86911/121634

Application no.:	118719
Product name:	Pexion 100 mg Tablets for Dogs
Active constituent/s:	100 mg imepitoin
Applicant name:	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	To add a new indication for dogs and an additional pack size (30 tablets)
Date of variation:	9 September 2019
Product registration no.:	67813
Label approval no.:	67813/118719

Application no.:	118715
Product name:	Pexion 400 mg Tablets for Dogs
Active constituent/s:	400 mg imepitoin
Applicant name:	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	To add a new indication for dogs and an additional pack size (30 tablets)
Date of variation:	9 September 2019
Product registration no.:	67812
Label approval no.:	67812/118715

Application no.:	121725
Product name:	Tylophos 250 Premix
Active constituent/s:	250 g/kg tylosin
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Tylomix P250 Tylosin Premix' to 'Tylophos 250 Premix'
Date of variation:	6 September 2019
Product registration no.:	86555
Label approval no.:	86555/121725

Application no.:	121735
Product name:	Independents Own Levistar LV Oral Drench
Active constituent/s:	80 g/L levamisole hydrochloride
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Levistar LV Oral Drench' to 'Independents Own Levistar LV Oral Drench'
Date of variation:	9 September 2019
Product registration no.:	86346
Label approval no.:	86346/121735

Application no.:	121743
Product name:	Purina Totalcare Heartwormer, Allwormer & Flea Control for Cats
Active constituent/s:	60 mg/mL selamectin
Applicant name:	Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of variation:	To remove all reference to rabbits from the instructions
Date of variation:	10 September 2019
Product registration no.:	88142
Label approval no.:	88142/121743

3. VARIATION OF LABEL APPROVAL

Application no.:	120375
Product name:	Eclipse Combination Pour-on For Cattle
Active constituent/s:	10 mg/mL abamectin, 200 mg/mL levamisole
Applicant name:	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	To amend first aid instructions and safety directions
Date of variation:	2 September 2019
Product registration no.:	60752
Label approval no.:	60752/120375

Application no.:	120525
Product name:	WSD Spurt Off-shears, Pour-on Sheep Lice Control
Active constituent/s:	25 g/L cypermethrin
Applicant name:	WSD Agribusiness Pty Ltd
Applicant ACN:	600 111 135
Summary of variation:	To correct label actives, include a schedule 5 solvent and amend first aid and safety directions
Date of variation:	2 September 2019
Product registration no.:	39065
Label approval no.:	39065/120525

Application no.:	120547
Product name:	WSD Command Pour-on Lousicide For Sheep
Active constituent/s:	25 g/L triflumuron
Applicant name:	WSD Agribusiness Pty Ltd
Applicant ACN:	600 111 135
Summary of variation:	To correct label actives, include a schedule 5 solvent and amend first aid and safety directions
Date of variation:	3 September 2019
Product registration no.:	56254
Label approval no.:	56254/120547

Application no.:	120400
Product name:	Sykes Big L Pour-On
Active constituent/s:	200 g/L levamisole (as levamisole base)
Applicant name:	Sykes Vet (International) Pty Ltd
Applicant ACN:	085 158 434
Summary of variation:	To correct label actives, include a schedule 5 solvent and amend first aid instructions
Date of variation:	6 September 2019
Product registration no.:	56795
Label approval no.:	56795/120400

Application no.:	119006
Product name:	Bravecto 1400 mg Fluralaner Chewable Tablets for Very Large Dogs
Active constituent/s:	136.4 g/kg fluralaner
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of variation:	Extension of use to include the prevention of flea tapeworm infestations
Date of variation:	9 September 2019
Product registration no.:	68873
Label approval no.:	68873/119006

Application no.:	119009
Product name:	Bravecto 500 mg Fluralaner Chewable Tablets for Medium Dogs
Active constituent/s:	136.4 g/kg fluralaner
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of variation:	Extension of use to include the prevention of flea tapeworm infestations
Date of variation:	9 September 2019
Product registration no.:	68871
Label approval no.:	68871/119009

Application no.:	119010
Product name:	Bravecto 250 mg Fluralaner Chewable Tablets for Small Dogs
Active constituent/s:	136.4 g/kg fluralaner
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of variation:	Extension of use to include the prevention of flea tapeworm infestations
Date of variation:	9 September 2019
Product registration no.:	68872
Label approval no.:	68872/119010

Application no.:	119011
Product name:	Bravecto 112.5 mg Fluralaner Chewable Tablets for Very Small Dogs
Active constituent/s:	136.4 g/kg fluralaner
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of variation:	Extension of use to include the prevention of flea tapeworm infestations
Date of variation:	9 September 2019
Product registration no.:	68867
Label approval no.:	68867/119011
Application no.:	119008
Product name:	Bravecto 1000 mg Fluralaner Chewable Tablets for Large Dogs
Active constituent/s:	136.4 g/kg fluralaner
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of variation:	Extension of use to include the prevention of flea tapeworm infestations
Date of variation:	9 September 2019
Product registration no.:	68870
Label approval no.:	68870/119008
Application no.:	120454
Product name:	Fido's Flea and Tick Rinse Concentrate for Dogs
Active constituent/s:	40 g/L permethrin (25:75::cis:trans)
Applicant name:	Mavlab Pty Ltd
Applicant ACN:	009 708 187
Summary of variation:	To amend first aid instructions and safety direction
Date of variation:	12 September 2019
Product registration no.:	63488
Label approval no.:	63488/120454
Application no.:	120493
Product name:	Equis Shoo Fly Insecticidal Spray and Wash Concentrate for Horses
Active constituent/s:	40 g/L permethrin (25:75 cis:trans)
Applicant name:	Mavlab Pty Ltd
Applicant ACN:	009 708 187
Summary of variation:	To amend first aid instructions and safety direction
Date of variation:	12 September 2019
Product registration no.:	59243
Label approval no.:	59243/120493
Application no.:	120637
Product name:	4Farmers Cypermethrin 25 Off-shears, Pour-on Sheep Lice Control
Active constituent/s:	25 g/L cypermethrin
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of variation:	Variation to the constituents listed on the label by adding a schedule 5 solvent and amending first aid and safety directions and to align the additional user safety instructions, trade advice and disposal statement to current vet labelling code
Date of variation:	12 September 2019
Product registration no.:	54370
Label approval no.:	54370/120637

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

Application no.:	118945
Active constituent/s:	penethamate hydriodide
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use:	For use in veterinary chemical products
Date of approval:	2 September 2019
Approval no.:	87678
Application no.:	116422
Active constituent/s:	carbetamide
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	6 September 2019
Approval no.:	86709
Application no.:	118995
Active constituent/s:	prothioconazole
Applicant name:	Yongnong Biosciences Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	6 September 2019
Approval no.:	87693
Application no.:	119084
Active constituent/s:	metribuzin
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	10 September 2019
Approval no.:	87727
Application no.:	118997
Active constituent/s:	iprodione
Applicant name:	Jiangsu Lanfeng Biochemical Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	11 September 2019
Approval no.:	87695

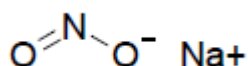
Application no.:	119044
Active constituent/s:	gibberellic acid
Applicant name:	Valent Biosciences a Div of Sumitomo Chemical Australia
Applicant ACN:	081 096 255
Summary of use:	For use in agricultural chemical products
Date of approval:	12 September 2019
Approval no.:	87714

New Agricultural Active Constituent—sodium nitrite

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, sodium nitrite, for use in agricultural products as a vertebrate poison for culling feral pigs.

Common name/IUPAC Name:	Sodium nitrite
Chemical Abstracts Name:	Nitrous acid, sodium salt (1:1)
Manufacturer's Code/s	not applicable
CAS Number:	7632-00-0
Molecular Formula:	NO ₂ Na
Molecular Weight:	69.0

Structure:



Chemical Family:	Sodium salt of nitrous acid
Mode of Action:	Sodium nitrite oxidises ferrous ion to ferric ion in blood and converts haemoglobin to methaemoglobin. Severe methaemoglobinemia is toxic and fatal in susceptible vertebrate animals.

SUMMARY OF THE APVMA'S EVALUATION

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

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

Constituent	Specification	Level
Sodium nitrite	sodium nitrite	990 g/kg minimum

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

The APVMA has considered the toxicological aspects of sodium nitrite, and concluded that there are no toxicological concerns to the approval of this active constituent. Sodium nitrite will be used in a pig bait product which is not intended for use in food producing species and feral pigs culled with this product are not intended for human consumption. As a vertebrate pest control agent, it is unlikely to have future uses in food producing species. Consequently, neither an ADI nor an ARfD have been established for sodium nitrite.

Sodium nitrite is scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Sodium nitrite will be present at 10 per cent (100 g/kg) in the proposed product (HOGGONE Feral Pig Bait). HOGGONE is covered by the existing SUSMP entry in Schedule 6 (when present in formulations at 40 per cent or less, and greater than 1 per cent). The current poison scheduling remains appropriate and no change to the existing entries is proposed.

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

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of sodium nitrite 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 (if available)
- the date you made the submission.

All personal and ***confidential commercial information (CCI)***¹ material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Director of Chemistry and Manufacture
Scientific Assessment and Chemical Review Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

¹ A full definition of 'confidential commercial information' is contained in the Agvet Code.

Hoggone meSN Feral Pig Bait Containing sodium nitrite

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 85028/112112—Hoggone meSN Feral Pig Bait.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	85028/112112—Hoggone meSN Feral Pig Bait
Applicant company:	Animal Control Technologies (Australia) Pty Ltd
Name of active constituent:	Sodium nitrite
Signal heading:	Schedule 6 (POISON)
Summary of proposed use:	For reductions in feral pig populations
Pack sizes:	1.25kg; 5kg

SUMMARY OF THE APVMA'S EVALUATION OF HOGGONE MESN FERAL PIG BAIT 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 Hoggone meSN Feral Pig Bait would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has considered the toxicological aspects of sodium nitrite and concluded that there are no human health toxicological concerns related to the approval of this active constituent. Sodium nitrite will be used in a pig bait product that is not intended for use in food-producing species and feral pigs culled with this product are not intended for human consumption. Furthermore, as a vertebrate pest control agent, it is unlikely to have future uses in food-producing species. Consequently, neither an ADI nor an ARfD have been established for sodium nitrite.

Sodium nitrite is scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Sodium nitrite will be present at 10 per cent (100 g/kg) in the proposed product. Hoggone meSN Feral Pig Bait is covered by the existing SUSMP entry in Schedule 6 (when present in formulations at 40 per cent or less, and greater than 1 per cent). The current poison scheduling remains appropriate and no change to the existing entries is proposed.

The applicant has provided copies of the principal international reviews; published papers on the active ingredient; acute dermal and inhalation toxicity studies on sodium nitrite; and acute toxicity studies on the product. Based upon the APVMA's assessment of this information, the product has low acute oral and dermal toxicity and, as the product is a paste bait, it does not present an inhalation hazard. Although the product is not a skin sensitiser by the Buehler method, it contains a substantial proportion of peanut paste and may therefore present an allergic hazard for peanut-sensitive workers. First Aid and safety directions have been recommended for inclusion on the label. The label carries a warning statement to advise users that people with a peanut sensitivity must not use or handle the product.

After evaluation of the hazards associated with the proposed product and consideration of the exposure profile related to its use, the APVMA is satisfied that Hoggone meSN Feral Pig Bait will 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 Hoggone meSN Feral Pig Bait will not be an undue hazard to the safety of people using anything containing its residues.

The proposed use is not considered a food use as treated feral pigs are not intended for human consumption. In-crop baiting using a pig-specific bait station such as the Hoggone Paste Bait Hopper is considered acceptable because contamination of produce is not likely to occur. Similarly, baiting using a pig-specific bait station eliminates the risk of the baits being accessed by livestock when the product is used according to the label directions. In a worst-case scenario, the data reviewed by the APVMA indicates that a pig fed 500 mg/kg sodium nitrite (LD99) would have mean residues of sodium nitrite in muscle and liver of 3 and 6 mg/kg respectively. The Food Standards Code allows residues of sodium nitrite in cured meats at up to 125 mg/kg; therefore even under a worst-case scenario in which a poisoned pig were inadvertently harvested for human consumption, the residues in meat are unlikely to represent a consumer safety concern.

No withholding period statement is considered necessary.

- (iii) The APVMA is satisfied that the proposed use of Hoggone meSN Feral Pig Bait containing the active constituent sodium nitrite 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 Hoggone meSN Feral Pig Bait is not likely to have an unintended effect that is harmful to animals, plants, or things or the environment if used according to the product label directions.

The APVMA has considered the available environmental fate and effects data in support of the proposed use and has concluded that the risks to the environment are acceptable.

The product formulation and proposed use within a pig-specific bait station, such as the Hoggone Paste Bait Hopper, means there is minimal potential for exposure of the active ingredient, sodium nitrite, to soil, fresh-water, estuarine, or marine environments. Thus, any environmental exposure can be characterised as limited and localised to the ground immediately surrounding the bait station rather than broadcast over the landscape. Additionally, Hoggone meSN Feral Pig Bait is supplied in a plastic tray, which further limits exposure of sodium nitrite to the environment.

Sodium nitrite is a salt comprised of a weak acid and a strong base. In water, sodium nitrite immediately dissociates into sodium (Na^+) and nitrite ion (NO_2^-). The nitrite ion is ubiquitous in the environment, where it forms part of the nitrogen cycle. Sodium nitrite itself is not expected to persist in the soil environment. Nitrite is an intermediary compound formed during nitrification as well as denitrification. It occasionally accumulates in soils and drainage water. Increased environmental exposure through the use of the end use product will be insignificant.

Based on negligible exposure, and limited toxicity, the risk to bees, other non-target arthropods, soil macro- and micro-organisms, terrestrial plants, and aquatic organisms was shown to be acceptable. The main risk arising from the proposed use of Hoggone meSN Feral Pig Bait is the potential for non-target vertebrate exposure through primary consumption of the bait or secondary poisoning from consumption of the feral pig carcass.

Secondary poisoning was shown to be unlikely and, while non-target species could potentially consume a lethal dose directly from the bait, Australian efficacy studies that monitored non-target animal interest in the baits did not identify any mammalian or reptilian species attracted to the bait. Several bird species were observed around the baiting stations but none, with the exception of corvids, appeared to consume the bait. To limit the potential for any non-target species to consume poisoned bait, the proposed label contains the following restraint: DO NOT deploy baits unless within a pig-specific bait station, such as the Hoggone Paste Bait Hopper. This restraint sufficiently limits the risk of non-target exposure to the toxic bait material. Furthermore, prior to deploying Hoggone meSN Feral Pig Bait, users must ensure that feral pigs are actively taking non-poisoned food or placebo bait at the baiting site to reduce exposure of non-target wildlife to unconsumed baits.

Based on an assessment of the environmental data, it is considered that there should be no unacceptable adverse effects to non-target organisms from the use of Hoggone meSN Feral Pig Bait when used in accordance with 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.

Efficacy of Hoggone meSN Feral Pig Bait is supported by seven trials; three conducted in Australia, and four conducted in the United States of America. One trial considered the humaneness and efficacy of the proposed product and concluded that the development of methaemoglobinaemia as a result of sodium nitrite ingestion leads to a state of unconsciousness without a prolonged preliminary excitatory state leading to death within a relatively short period of time.

The proof-of-concept trials and pen trials demonstrate that the optimal effective lethal dose was between 133 mg/kg and 400 mg/kg sodium nitrite. A dose of 250 g–350 g per pig, as specified on the label, provides a small overage of the minimum lethal dose to kill the target animal and the additional amount of bait ensures sufficient bait for other pigs present given a mixed population with juveniles and adults is likely.

Trial design confirmed the importance of pre-feeding to cluster pigs to the feeding point, to allow assessment of mob size, and to increase the uptake rate and consequently the efficacy the product.

Efficacy was well demonstrated in all the trials, with reduction of feral pigs' population by 60 to 100 per cent depending on the trial conditions.

The data indicate that Hoggone meSN Feral Pig Bait will offer effective control of feral pigs when used according to the label directions and support the label claim of "For reductions in feral pig populations".

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of Hoggone meSN Feral Pig Bait would not adversely affect trade between Australia and places outside Australia. As noted in 1 (i) above, as treated feral pigs are not intended for human consumption, the proposed use is not considered a food use.

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 Hoggone meSN Feral Pig Bait 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)² material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

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

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

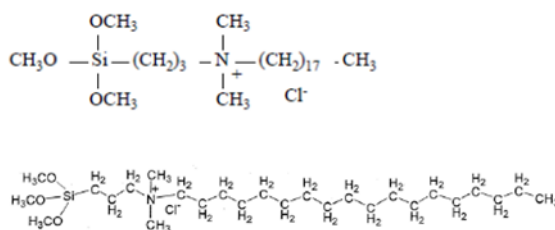
² A full definition of 'confidential commercial information' is contained in the Agvet Code.

New Agricultural Active Constituent—dimethyloctadecyl[3-(trimethoxysilyl)propyl] ammonium chloride manufacturing concentrate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride manufacturing concentrate. Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride manufacturing concentrate (referred to as a Siquat or trimethoxysilyl quat) is a disinfectant used as a preservative and fungicide. The uses proposed for registration are application to polyurethane foam, fibre, and textiles (particularly furniture fabrics) for fungistatic and biostatic protection, and to control dust mites.

Common Name:	Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride
IUPAC Name:	Dimethyl-octadecyl-(3-trimethoxysilylpropyl)azanium chloride
CAS Registry Number:	27668-52-6
Manufacturer's Codes:	ZTrex 72
Minimum Purity:	720 g/kg
Molecular Formula:	C ₂₆ H ₅₈ ClNO ₃ Si
Molecular Weight:	496.30 g/mol

Structure:



Chemical Family: Disinfectant/ antimicrobial

SUMMARY OF THE APVMA'S EVALUATION OF DIMETHYLOCTADECYL[3-(TRIMETHOXYSILYL) PROPYL]AMMONIUM CHLORIDE ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride 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 considered the toxicological aspects of dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride.

Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride was found to have low acute oral, dermal and inhalational toxicity. The compound was a severe eye and skin irritant; but there were no endpoints of concern for repeated oral and dermal exposure to the compound. The compound was not mutagenic or carcinogenic, and it was not a reproductive or developmental toxicant.

An Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) have not been established, considering that the compound is not intended for use in food producing crops or animals, and is of low acute toxicity.

Dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride belongs to the group of quaternary ammonium compounds, classified in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride manufacturing concentrate:

Content shall be declared, and when measured, shall not differ from the declared amount by more than the amount specified in the table below:

Declared content (g/kg)	Allowable deviation from declared content
More than 500	± 25 g/kg
More than 250 up to 500	± 5%
More than 100 up to 250	± 6%
More than 25 up to 100	± 10%
Up to 25	± 15%

Other compounds of toxicological significance are not expected to occur in dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride manufacturing concentrate technical active constituent.

The APVMA is satisfied that the proposed importation and use of dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride manufacturing concentrate would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride manufacturing concentrate should be granted. Submissions should relate only to matters are considered in determining whether the safety criteria set out in section 5A of the Agvet Code are 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 (if available)
- the date you made the submission.

All personal and **confidential commercial information (CCI)**³ material contained in submissions will be treated confidentially.

Submissions should be addressed in writing to:

³ A full definition of 'confidential commercial information' is contained in the Agvet Code.

Director Chemistry and Manufacture
Scientific Assessments and Chemical Review Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

New Chemical Products—Fresche SL Biocide & Material Protectant containing dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride

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 **FRESCHE SL BIOCIDES & MATERIAL PROTECTANT**.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	FRESCHE SL BIOCIDES & MATERIAL PROTECTANT
Applicant company:	FRESCHE BIOSCIENCE PTY LTD
Name of active constituent:	dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride
Signal heading:	Schedule 6
Summary of proposed use:	To protect the treated article against the growth of bacteria, fungus, moulds and mildew, and to control article infestation by house dust mites
Pack sizes:	1 kg, 5 kg, 200 kg, 980 kg, 1000 kg

SUMMARY OF THE APVMA'S EVALUATION OF FRESCHE SL BIOCIDES & MATERIAL PROTECTANT 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 considered the formulation of the product, **FRESCHE SL BIOCIDES & MATERIAL PROTECTANT**. The toxicological profile of all of the FRESCHE SL BIOCIDES & MATERIAL PROTECTANT constituents is well established, and the key health hazards linked to use of the formulated product FRESCHE SL BIOCIDES & MATERIAL PROTECTANT are related to severe eye and skin irritation. First Aid Instructions and Safety Directions (FAISD) to be displayed on the product label have been developed to adequately mitigate the risks resulting from use of the product.

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 **FRESCHE SL BIOCIDES & MATERIAL PROTECTANT** 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 **FRESCHE SL BIOCIDES & MATERIAL PROTECTANT** 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 **FRESCHE SL BIOCIDES & MATERIAL PROTECTANT** containing the active constituent dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride 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 **FRESCHE SL BIOCIDES & MATERIAL PROTECTANT** is not likely to have an unintended effect that is harmful to animals, plants or things 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:

- (v) 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:
- (vi) The APVMA is satisfied that the proposed use of **FRESCHÉ SL BIOCIDÉ & MATERIAL PROTECTANT** would not adversely affect trade between Australia and places outside Australia as the product is not for use in crops or animals that produce food commodities for export.

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 **FRESCHÉ SL BIOCIDÉ & MATERIAL PROTECTANT** 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:

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

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

New Chemical Products—Trebon Insecticide containing etofenprox

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 **TREBON INSECTICIDE**.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	TREBON INSECTICIDE
Applicant company:	SIPCAM Pacific Australia Ltd
Name of active constituent:	Etofenprox
Signal heading:	Schedule - Appendix B (substances considered not to require control by scheduling)
Summary of proposed use:	For the control of Queensland fruit fly and Mediterranean fruit fly on Stone fruit except Cherries.
Pack sizes:	1-1000 L
Withholding period:	3 days

SUMMARY OF THE APVMA'S EVALUATION OF TREBON INSECTICIDE 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 **TREBON INSECTICIDE** would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - (ii) The APVMA is satisfied that the proposed use of **TREBON INSECTICIDE** 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 **TREBON INSECTICIDE** containing the active constituent etofenprox is not likely to be harmful to human beings if used according to the product label directions.
 - (iv) The APVMA is satisfied that the proposed use of the new products **TREBON INSECTICIDE** containing the active constituent etofenprox, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.
2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

- (v) 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:
- (vi) The APVMA is considering whether the proposed use of **TREBON INSECTICIDE** 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, apvma.gov.au/news-and-publications/public-consultations or by contacting the evaluator 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 **TREBON INSECTICIDE** should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

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

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au