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**AGRICULTURAL AND
VETERINARY CHEMICALS**



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

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

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Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Email: communications@apvma.gov.au

Website: www.apvma.gov.au.

GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

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APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4812

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

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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.:	118206
Product name:	Kelpie MCPA LVE 570 EC Herbicide
Active constituent/s:	570 g/L MCPA, present as the 2-ethylhexyl ester
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of use:	For selective control of certain weeds in agricultural crops
Date of registration:	18 February 2019
Product registration no.:	87369
Label approval no.:	87369/118206
Application no.:	118425
Product name:	AC Clatter 900 WG Fungicide
Active constituent/s:	900 g/kg chlorothalonil
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use:	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and vegetables
Date of registration:	18 February 2019
Product registration no.:	87473
Label approval no.:	87473/118425
Application no.:	118408
Product name:	ACP Boll Cracker 900 Growth Regulator
Active constituent/s:	900 g/L ethephon (an anti-cholinesterase compound)
Applicant name:	Australis Crop Protection Pty Ltd
Applicant ACN:	150 711 185
Summary of use:	For crop thinning, loosening or ripening in various crops and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton as specified in the Directions for Use
Date of registration:	18 February 2019
Product registration no.:	87462
Label approval no.:	87462/118408
Application no.:	118121
Product name:	F.S.A. Ammonium Sulphate Spray Adjuvant
Active constituent/s:	980 g/kg ammonium sulphate
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For use with glyphosate-based herbicides to minimise antagonism when tank mixed with flowable herbicides and to improve performance under adverse environmental conditions
Date of registration:	18 February 2019
Product registration no.:	87334
Label approval no.:	87334/118121

Application no.:	118367
Product name:	F.S.A. Simazine 900 WG Herbicide
Active constituent/s:	900 g/kg simazine
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of weeds in chickpea, lupins, triazine tolerant canola, orchards, vineyards and certain other horticultural crops and non-crop situations
Date of registration:	18 February 2019
Product registration no.:	87442
Label approval no.:	87442/118367
Application no.:	118397
Product name:	F.S.A. Triallate 500 Herbicide
Active constituent/s:	500 g/L tri-allate
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of wild oats in wheat, triticale, chickpeas, barley, peas, linseed, lupins, canola, faba beans and safflower
Date of registration:	18 February 2019
Product registration no.:	87456
Label approval no.:	87456/118397
Application no.:	118323
Product name:	F.S.A. MCPA 750 Herbicide
Active constituent/s:	750 g/L MCPA present as the dimethylamine salt
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of broadleaf weeds in cereals, linseed, pastures, rice, sugar cane and turf
Date of registration:	19 February 2019
Product registration no.:	87422
Label approval no.:	87422/118323
Application no.:	118529
Product name:	AC Profuse 800 EC Herbicide
Active constituent/s:	800 g/L prosulfocarb
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use:	For control of annual ryegrass and other grass and broadleaf weeds in barley and wheat
Date of registration:	19 February 2019
Product registration no.:	87498
Label approval no.:	87498/118529
Application no.:	118370
Product name:	F.S.A. Atrazine 900 WG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of weeds and grasses in sorghum, maize, sugar cane, triazine tolerant canola, lucerne, and for fallow area maintenance and other situations
Date of registration:	21 February 2019
Product registration no.:	87443
Label approval no.:	87443/118370

Application no.:	118207
Product name:	Kelpie P-Quat 250 SL Herbicide
Active constituent/s:	250 g/L paraquat present as paraquat dichloride
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of use:	For the control of a wide range of grasses and broadleaf weeds
Date of registration:	21 February 2019
Product registration no.:	87370
Label approval no.:	87370/118207
Application no.:	118587
Product name:	F.S.A. Dry GLY 680 Herbicide
Active constituent/s:	680 g/kg glyphosate (present as the mono-ammonium salt)
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of many annual and perennial weeds in certain situations
Date of registration:	21 February 2019
Product registration no.:	87522
Label approval no.:	87522/118587
Application no.:	118318
Product name:	F.S.A. 75D Herbicide
Active constituent/s:	300 g/L 2,4-D present as the triisopropanolamine salt, 75 g/L picloram present as the triisopropanolamine salt
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of a wide range of annual and perennial broadleaf weeds
Date of registration:	22 February 2019
Product registration no.:	87419
Label approval no.:	87419/118318
Application no.:	118191
Product name:	Maxunitech Carfentrazone-ethyl 400 g/kg WG
Active constituent/s:	400 g/kg carfentrazone-ethyl
Applicant name:	MAX(Rudong) Chemicals Co Ltd
Applicant ACN:	N/A
Summary of use:	For the control of certain annual broadleaf weeds in winter cereals and pyrethrum
Date of registration:	25 February 2019
Product registration no.:	87367
Label approval no.:	87367/118191
Application no.:	118423
Product name:	OzCrop Terbutylazine 875 WG Herbicide
Active constituent/s:	875 g/L terbutylazine
Applicant name:	Ozcrop Pty Ltd
Applicant ACN:	160 656 431
Summary of use:	For the control of weeds in chickpeas, faba beans, fallows, field peas, lentils, lupins, sorghum, and triazine tolerant canola
Date of registration:	25 February 2019
Product registration no.:	87471
Label approval no.:	87471/118423

Application no.:	116067
Product name:	Nemaguard 240 Nematicide/Insecticide
Active constituent/s:	240 g/L oxamyl (an anti-cholinesterase compound)
Applicant name:	Joy Harvest Holding Pty Ltd
Applicant ACN:	130 503 829
Summary of use:	For the control of nematodes in capsicums and tomatoes
Date of registration:	25 February 2019
Product registration no.:	86570
Label approval no.:	86570/116067
Application no.:	118305
Product name:	Nufarm Pinoxaden 100EC Selective Herbicide
Active constituent/s:	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use:	For control of key grass weeds and selective spray topping of wild oats in wheat and barley
Date of registration:	25 February 2019
Product registration no.:	87407
Label approval no.:	87407/118305
Application no.:	118434
Product name:	F.S.A. Dry GLY 700 Herbicide
Active constituent/s:	700 g/kg glyphosate present as the mono-ammonium salt
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of many annual and perennial weeds in certain situations
Date of registration:	26 February 2019
Product registration no.:	87478
Label approval no.:	87478/118434
Application no.:	118418
Product name:	F.S.A. Penetrant Wetter and Sticker
Active constituent/s:	1020 g/L polyether modified polysiloxane
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For use as a non-ionic surfactant with glyphosate and certain brush weed herbicides to improve coverage, penetration and uptake on brush and woody weeds and ryegrass. Also for use with fungicides, insecticides, miticides and foliar micronutrients as per the directions for use table
Date of registration:	26 February 2019
Product registration no.:	87466
Label approval no.:	87466/118418
Application no.:	118530
Product name:	Titan Amine 450 Herbicide
Active constituent/s:	450 g/L 2,4-D present as the isopropylamine salt
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use:	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
Date of registration:	28 February 2019
Product registration no.:	87499
Label approval no.:	87499/118530

Application no.:	118377
Product name:	F.S.A. Fipronil 200 Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane and swede
Date of registration:	28 February 2019
Product registration no.:	87446
Label approval no.:	87446/118377

Application no.:	118227
Product name:	Coles Mosquito Candle
Active constituent/s:	21.1 g/kg piperonyl butoxide, 6 g/kg bioallethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For use to repel and reduce the annoyance of mosquitoes around the home and garden
Date of registration:	28 February 2019
Product registration no.:	87375
Label approval no.:	87375/118227

Application no.:	118381
Product name:	F.S.A. Wetter 1040 Surfactant
Active constituent/s:	1040 g/L octyl phenol ethoxylate
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For use as a non-ionic surfactant with glyphosate herbicides when treating annual ryegrass, silvergrass and perennial grasses
Date of registration:	01 March 2019
Product registration no.:	87450
Label approval no.:	87450/118381

Application no.:	118424
Product name:	Allegiance Fungicide
Active constituent/s:	95 g/L azoxystrobin
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For control of various diseases in turf
Date of registration:	1 March 2019
Product registration no.:	87472
Label approval no.:	87472/118424

Application no.:	112570
Product name:	Smart Pro Grow 420 SC Fungicide
Active constituent/s:	210 g/L prothioconazole, 210 g/L tebuconazole
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use:	For the control of various fungal diseases in wheat, barley, oats, triticale, canola and pyrethrum
Date of registration:	1 March 2019
Product registration no.:	85180
Label approval no.:	85180/112570

2. VARIATIONS OF REGISTRATION

Application no.:	115978
Product name:	Opera Fungicide
Active constituent/s:	85 g/L pyraclostrobin, 62.5 g/L epoxiconazole
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of variation:	To add a new 5 L and 110 L pack size
Date of variation:	7 February 2019
Product registration no.:	62753
Label approval no.:	62753/115978

Application no.:	119055
Product name:	Raid Max Automatic Advanced Multi-Insect System
Active constituent/s:	1.5 g/kg d-phenothrin, 5.6 g/kg transfluthrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RAID AUTOMATIC ADVANCED MULTI-INSECT SYSTEM' to 'RAID MAX AUTOMATIC ADVANCED MULTI-INSECT SYSTEM'
Date of variation:	8 February 2019
Product registration no.:	70363
Label approval no.:	70363/119055

Application no.:	119129
Product name:	Kelpie Alpha-C 300 EC Insecticide
Active constituent/s:	300 g/L alpha-cypermethrin
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MISSION ELLIAS 300 EC INSECTICIDE' to 'KELPIE ALPHA-C 300 EC INSECTICIDE'
Date of variation:	15 February 2019
Product registration no.:	87186
Label approval no.:	87186/119129

Application no.:	119128
Product name:	Kelpie Halox-F 900 EC Herbicide
Active constituent/s:	900 g/L haloxyfop-p present as haloxyfop-p methyl ester
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'IMTRADE LOXY 900 EC HERBICIDE' to 'KELPIE HALOX-F 900 EC HERBICIDE'
Date of variation:	15 February 2019
Product registration no.:	83076
Label approval no.:	83076/119128
Application no.:	119130
Product name:	Kelpie P-Quat Advance Herbicide
Active constituent/s:	250 g/L paraquat present as paraquat dichloride, 10 g/L amitrole
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MISSION PARA-TROOPER SL HERBICIDE' to 'KELPIE P-QUAT ADVANCE HERBICIDE'
Date of variation:	15 February 2019
Product registration no.:	87172
Label approval no.:	87172/119130
Application no.:	118523
Product name:	Slasher Organic Weedkiller
Active constituent/s:	525 g/L nonanoic acid
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To add non-crop uses around buildings, commercial, industrial, domestic and public service areas and rights of way.
Date of variation:	18 February 2019
Product registration no.:	68118
Label approval no.:	68118/118523
Application no.:	118426
Product name:	Sinozeb 750 WG Fungicide
Active constituent/s:	750 g/kg mancozeb
Applicant name:	Sinon Australia Pty Limited
Applicant ACN:	102 741 024
Summary of variation:	To amend the withholding period for bananas
Date of variation:	19 February 2019
Product registration no.:	83438
Label approval no.:	83438/118426

Application no.:	118262
Product name:	Weed Force Holdfast Organosilicone Penetrant and Wetting Agent.
Active constituent/s:	1020 g/L polyether modified polysiloxane
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'WEED FORCE HOLDFAST PENETRANT AND WETTING AGENT' to 'WEED FORCE HOLDFAST ORGANOSILICONE PENETRANT AND WETTING AGENT'. Also, to extend the use of the product when mixed with herbicides to perennial weeds, including blackberry, when recommended to do so on the herbicide label. The rate when mixed with herbicides has changed to hand gun 200 mL/100L spray mixture and boom spray 200-500 mL/100L spray mixture
Date of variation:	19 February 2019
Product registration no.:	83402
Label approval no.:	83402/118262
Application no.:	118076
Product name:	Pool Magic Granular Pool Chlorine
Active constituent/s:	700 g/kg available chlorine (cl) present as calcium hypochlorite
Applicant name:	Klorman Industries Pty Ltd
Applicant ACN:	072 597 650
Summary of variation:	To approve a new label for the product 'POOL MAGIC GRANULAR POOL CHLORINE' with the label name 'POOL MAGIC PRO CALHYPO GRANULAR POOL CHLORINE'
Date of variation:	20 February 2019
Product registration no.:	63955
Label approval no.:	63955/118076
Application no.:	118651
Product name:	Slasher Organic Weedkiller
Active constituent/s:	525 g/L nonanoic acid
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To approve a new label for the product 'SLASHER ORGANIC WEEDKILLER' with the label name 'YATES ZERO RAPID ACTION WEEDKILLER CONCENTRATE'
Date of variation:	20 February 2019
Product registration no.:	68118
Label approval no.:	68118/118651
Application no.:	118354
Product name:	Astro 120 Me Growth Regulator
Active constituent/s:	120 g/L trinexapac-ethyl
Applicant name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of variation:	To make a number of minor variations to the label
Date of variation:	25 February 2019
Product registration no.:	64368
Label approval no.:	64368/118354

Application no.:	118518
Product name:	Smart Ox 240 Herbicide
Active constituent/s:	240 g/L oxyfluorfen
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of variation:	To vary the pack size range to 10 L to 1000L. The label is also updated in accordance with the latest labelling codes
Date of variation:	25 February 2019
Product registration no.:	68379
Label approval no.:	68379/118518
Application no.:	118329
Product name:	Ezycrop 2,4-D IPA 300 Herbicide
Active constituent/s:	300 g/L 2,4-D present as the isopropylamine salt
Applicant name:	Ezycrop Pty Ltd
Applicant ACN:	156 476 827
Summary of variation:	To incorporate spray drift instructions from APVMA reconsideration action
Date of variation:	25 February 2019
Product registration no.:	68049
Label approval no.:	68049/118329
Application no.:	118398
Product name:	Smart Paraquat 250 Herbicide
Active constituent/s:	250 g/L paraquat present as paraquat dichloride
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of variation:	To amend the withholding period for pulses to seven days and include the all other crops withholding period of not required when used as directed
Date of variation:	26 February 2019
Product registration no.:	64588
Label approval no.:	64588/118398
Application no.:	118593
Product name:	Sinon Mancozeb 750 WG Fungicide
Active constituent/s:	750 g/kg mancozeb
Applicant name:	Sinon Australia Pty Ltd
Applicant ACN:	102 741 024
Summary of variation:	To remove the use on apples
Date of variation:	28 February 2019
Product registration no.:	83842
Label approval no.:	83842/118593
Application no.:	115399
Product name:	Intuity Fungicide
Active constituent/s:	250 g/L mandestrobin
Applicant name:	Sumitomo Chemical Australia Pty Ltd
Applicant ACN:	081 096 255
Summary of variation:	To add the use in lettuce and green bean
Date of variation:	28 February 2019
Product registration no.:	69787
Label approval no.:	69787/115399

Application no.:	118446
Product name:	Komondor 200 Insecticide
Active constituent/s:	200 g/L imidacloprid
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of variation:	To include the suppression of silverleaf whitefly in ornamental plants
Date of variation:	1 March 2019
Product registration no.:	67913
Label approval no.:	67913/118446
Application no.:	118534
Product name:	Amgrow Chemspray Weed Control Bin-Die Selective Lawn Weeder
Active constituent/s:	200 g/L bromoxynil present as the n-octanoyl ester, 200 g/L MCPA present as the 2-ethyl hexyl ester
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of variation:	To update the restraints and directions for use to include a restriction on use in ST varieties of buffalo grass
Date of variation:	01 March 2019
Product registration no.:	31456
Label approval no.:	31456/118534
Application no.:	118607
Product name:	Progibb SG Plant Growth Regulator Soluble Granule
Active constituent/s:	400 g/kg gibberellic acid
Applicant name:	Valent Biosciences a Div of Sumitomo Chemical Australia
Applicant ACN:	081 096 255
Summary of variation:	To update a wetting agent restraint
Date of variation:	01 March 2019
Product registration no.:	53027
Label approval no.:	53027/118607

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.:	108303
Product name:	Sulfatrim Oral Paste
Active constituent/s:	400 mg/g sulfadiazine, 86 mg/g trimethoprim
Applicant name:	Randlab Australia Pty Ltd
Applicant ACN:	114 948 837
Summary of use:	For the treatment of infections in horses caused by organisms susceptible to sulfadiazine in combination with trimethoprim
Date of registration:	20 February 2019
Product registration no.:	83452
Label approval no.:	83452/108303
Application no.:	115895
Product name:	Neovet for Dogs over 25kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	NA
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection, the treatment and control of roundworms, hookworms, whipworm, sarcoptic mange, ear mites and lice in dogs weighing over 25 kg
Date of registration:	21 February 2019
Product registration no.:	86494
Label approval no.:	86494/115895
Application no.:	115902
Product name:	Neovet for Cats over 4kg
Active constituent/s:	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	NA
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection, the treatment and control of roundworms, hookworms, ear mites and lungworm for cats weighing over 4 kg
Date of registration:	21 February 2019
Product registration no.:	86499
Label approval no.:	86499/115902
Application no.:	115897
Product name:	Neovet For Dogs 10 – 25kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection, the treatment and control of roundworms, hookworms, whipworm, sarcoptic mange, ear mites and lice in dogs weighing 10 – 25 kg
Date of registration:	21 February 2019
Product registration no.:	86496
Label approval no.:	86496/115897

Application no.:	115900
Product name:	Neovet For Dogs 4 – 10kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection, the treatment and control of roundworms, hookworms, whipworm, sarcoptic mange, ear mites and lice for dogs weighing 4-10 kg
Date of registration:	21 February 2019
Product registration no.:	86497
Label approval no.:	86497/115900
Application no.:	115903
Product name:	Neovet for Kittens And Small Cats up to 4kg
Active constituent/s:	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection, the treatment and control of roundworms, hookworms, ear mites and lungworm for kittens and cats
Date of registration:	21 February 2019
Product registration no.:	86500
Label approval no.:	86500/115903
Application no.:	118787
Product name:	Cattlemax LV Pour-On Endectocide for Cattle
Active constituent/s:	10 mg/mL ivermectin
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the treatment and control of ivermectin sensitive internal and external parasites of beef and dairy cattle
Date of registration:	22 February 2019
Product registration no.:	87615
Label approval no.:	87615/118787
Application no.:	116103
Product name:	Tilmodil 300 Tilmicosin Injection
Active constituent/s:	300 mg/mL tilmicosin
Applicant name:	Emdoka bvba
Applicant ACN:	N/A
Summary of use:	For treatment of Bovine Respiratory Disease (BRD) in lot-fed cattle
Date of registration:	25 February 2019
Product registration no.:	86584
Label approval no.:	86584/116103
Application no.:	118786
Product name:	Independents Own Albemax Broad Spectrum Sheep Lamb and Goat Drench
Active constituent/s:	19 mg/mL albendazole
Applicant name:	Vetpharm Pty Ltd
Applicant ACN:	629 894 086
Summary of use:	For the control of susceptible roundworms, large lungworms, tapeworm and to aid in the control of adult liver fluke and to reduce the output of viable worm and fluke eggs
Date of registration:	25 February 2019
Product registration no.:	87614
Label approval no.:	87614/118786

Application no.:	115676
Product name:	Adaptil Junior Collar for Puppies
Active constituent/s:	50 g/kg synthetic analogue of the canine appeasing pheromone
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For an aid in alleviating or preventing fear related signs in puppies
Date of registration:	01 March 2019
Product registration no.:	86396
Label approval no.:	86396/115676

Application no.:	113778
Product name:	Metacam 40 mg/mL Solution for Injection
Active constituent/s:	40 mg/mL meloxicam
Applicant name:	Boehringer Ingelheim Pty Ltd Vetmedica Division
Applicant ACN:	000 452 308
Summary of use:	For use as an anti-inflammatory, analgesic and antipyretic in cattle
Date of registration:	01 March 2019
Product registration no.:	85634
Label approval no.:	85634/113778

2. VARIATIONS OF REGISTRATION

Application no.:	115036
Product name:	CLiK Extra Spray-On Sheep Blowfly Treatment
Active constituent/s:	65 g/L dicyclanil
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To change the scheduling of the active constituent, dicyclanil, in CLiK Extra Spray-On Sheep Blowfly Treatment containing 6.5% dicyclanil
Date of variation:	11 February 2019
Product registration no.:	81863
Label approval no.:	81863/115036

Application no.:	117417
Product name:	Flusapex Drops Diuretic For Dogs & Cats
Active constituent/s:	10 mg/mL frusemide
Applicant name:	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN:	614 716 700
Summary of variation:	To update the label's contraindication, precaution and side effect statements
Date of variation:	13 February 2019
Product registration no.:	35636
Label approval no.:	35636/117417

Application no.:	116797
Product name:	Dermcare Otoflush
Active constituent/s:	2.0 g/L poly(hexamethylene) biguanidine hydrochloride, 1.2 g/L disodium edetate
Applicant name:	Dermcare-Vet Pty Ltd
Applicant ACN:	010 280 010
Summary of variation:	To add general directions statement for use of the product in cases of ruptured eardrums in dogs
Date of variation:	25 February 2019
Product registration no.:	60080
Label approval no.:	60080/116797

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.:	116579
Active constituent/s:	pyraclostrobin
Applicant name:	Agroshine Australia Pty Ltd
Applicant ACN:	105 873 023
Summary of use:	For use in agricultural chemical products
Date of approval:	14 February 2019
Approval no.:	86792

Application no.:	116522
Active constituent/s:	gleptoferron
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use:	For use in veterinary chemical products
Date of approval:	20 February 2019
Approval no.:	86764

Application no.:	109215
Active constituent/s:	equine immunoglobulin protein
Applicant name:	Padula Serums Pty Ltd
Applicant ACN:	167 348 610
Summary of use:	For use in veterinary chemical products
Date of approval:	22 February 2019
Approval no.:	83901

Application no.:	115121
Active constituent/s:	picaridin
Applicant name:	Synergia Sciences Private Limited
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	25 February 2019
Approval no.:	86247

Application no.:	116487
Active constituent/s:	oxamyl
Applicant name:	Shandong Rainbow International Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	28 February 2019
Approval no.:	86743

Application no.:	116545
Active constituent/s:	chlorfenapyr
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For use in agricultural chemical products
Date of approval:	28 February 2019
Approval no.:	86776

New active constituent and new chemical products CIMALGEX CHEWABLE TABLETS FOR DOGS containing the active cimicoxib

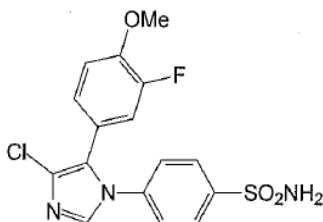
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, cimicoxib, and an application for registration of a suite of new products containing the new active constituent.

The products are CIMALGEX 80 mg CHEWABLE TABLETS FOR DOGS, CIMALGEX 30 mg CHEWABLE TABLETS FOR DOGS and CIMALGEX 8 mg CHEWABLE TABLETS FOR DOGS for use in the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery, in dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name:	Cimicoxib
IUPAC name:	4-[4-Chloro-5-(3-fluoro-4-methoxyphenyl)imidazol-1-yl]benzenesulfonamide
Chemical abstracts name:	Benzenesulfonamide, 4-[4-chloro-5-(3-fluoro-4-methoxyphenyl)-1H-imidazol-1-yl]
CAS number:	265114-23-6
Molecular formula:	C ₁₆ H ₁₃ ClFN ₃ O ₃ S
Molecular weight:	381.8

Structure:



Chemical family:	Benzene sulfonamide
Mode of action:	Non-steroidal anti-inflammatory drug, acting via inhibition of the enzyme cyclooxygenase 2 (COX-2)

EVALUATION OF THE ACTIVE CONSTITUENT CIMICOXIB 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 cimicoxib (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. There is currently no pharmacopoeia monograph for cimicoxib.

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

The APVMA has considered the toxicological aspects of cimicoxib, and concluded that there are no toxicological concerns to the approval of this active constituent. No ADI or ARfD was established, as cimicoxib is not currently proposed for use in food producing animals.

The Scheduling Delegate for the Poisons Standard (*Standard for the Uniform Scheduling of Medicines and Poisons – SUSMP*) made a final decision regarding cimicoxib to include it in Schedule 4 of the SUSMP.

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

PARTICULARS OF THE PRODUCT

Applicant company:	VETOQUINOL AUSTRALIA PTY LTD
Name of active constituent:	Cimicoxib
Signal heading:	Schedule 4
Summary of proposed use:	For use in the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery, in dogs.
Pack sizes:	8, 32, 144 tablets (each strip containing 8 tablets)
Withholding period:	NA

SUMMARY OF THE APVMA'S EVALUATION OF CIMALGEX CHEWABLE 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 CIMALGEX CHEWABLE 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 CIMALGEX CHEWABLE TABLETS FOR DOGS would not be an undue hazard to the safety of people exposed to them during their handling or use, from handling the excreta or vomitus of treated dogs, or from the accidental ingestion of the tablets.

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.

The APVMA estimated the acute toxicity of CIMALGEX CHEWABLE TABLETS FOR DOGS was ascertained 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 (cimicoxib) and non-actives estimation the products present a low acute oral, dermal and inhalation toxicity, are slightly irritating to the skin, are moderately irritating to the eyes and demonstrate the potential for skin sensitisation. Administration of CIMALGEX CHEWABLE TABLETS FOR DOGS will primarily be conducted by pet owners rather than by a Veterinarian.

- (ii) Pet owners may be exposed to the product when administering the tablet. There will be 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. To mitigate the acute and repeat-dose risks associated with CIMALGEX CHEWABLE TABLETS FOR DOGS, the reviewer has recommended first aid statement (a)–*If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.*

Based on the product formulation and use pattern it was determined that dermal exposure to CIMALGEX CHEWABLE TABLETS FOR DOGS, as well as ocular and inhalation would be negligible under normal conditions of use. The proposed safety direction "*Wash hands after use*" would mitigate the risk of ocular exposure (including hand to eye exposure) and both skin and eye irritation occurring. The product is a skin sensitiser therefore the APVMA recommends the standard safety direction statement "*Repeated exposure may cause allergic disorders*". The APVMA is satisfied that the proposed use of CIMALGEX CHEWABLE TABLETS FOR DOGS will not be an undue hazard to the safety of people using anything containing its 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 CIMALGEX CHEWABLE TABLETS FOR DOGS is not likely to be harmful to human beings if used according to the product label directions.

The active cimicoxib 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 CIMALGEX CHEWABLE 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 cimicoxib into the environment. Cimicoxib 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 cimicoxib will not present a significant risk to the environment.

Disposal instructions 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.*

An external reviewer has assessed the target animal safety of CIMALGEX CHEWABLE TABLETS FOR DOGS in a target animal safety study which administered Cimalgex to dogs at 1X, 3X and 5X the recommended dose rate (2.0 mg/kg daily) for 26 weeks, compared to a control (placebo) group of dogs. A total of 32 dogs were enrolled in the study. All dogs survived until week 26, although the 3X and 5X treatment groups had a greater incidence of liquid faeces and occasional mucus or red traces in the faeces. There were no treatment-related effects on cardiovascular functions, ophthalmological testing, body weight, food or water consumption. There were also no treatment-related abnormalities in the stomach and duodenum of any dog. There was a dose-related decrease in red cell parameters (red cell count, haemoglobin concentration and packed cell volume), platelet count and fibrinogen, particularly in the 5X treatment group. A similar response was reported for the white blood cell count. The 3X and 5X treatment groups also had changes in clinical chemistry, with a decrease in calcium, protein and albumin concentrations and an increase in amylase activity. Degenerative changes in the gastrointestinal system (erosions, ulcerations and villous atrophy) and mild renal papillary necrosis were observed, which appeared to be dose-related.

Overall it was concluded that the 5X dose rate is the maximum tolerated dose due to the marked haematological changes and histopathological findings in the digestive tract. It was also noted that the 1X dose rate was well tolerated clinically, and only induced a minimal papillary necrosis in the kidney of 1 animal out of 8.

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

- Contraindication statements relating to animals suffering from gastrointestinal disorders, haemorrhagic disorders, hypersensitivity to cimicoxib and use with other corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Precaution statements relating to young animals, breeding, pregnant or lactating animals, animals suffering from impaired cardiac or hepatic function, animals which are dehydrated, hypovolaemic or hypotensive, animals with history of gastric ulceration and animals with intolerance to NSAID's.
- Side effects relating to gastro-intestinal disorders (vomiting and/or diarrhoea), haemorrhage and ulcer formation, impaired renal function, hepatic biochemistry parameters changes, anorexia and lethargy.

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) The APVMA is satisfied that the proposed use of CIMALGEX CHEWABLE TABLETS FOR DOGS would be effective when used as directed.

The suite of products, CIMALGEX CHEWABLE TABLETS FOR DOGS is intended for the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery, in dogs. The product is a tablet to be administered orally with or without a small quantity of food at the recommended dose of 2.0 mg/kg/day cimicoxib. For management of peri-operative pain due to orthopaedic or soft tissue surgeries, one dose two hours prior to surgery, followed by three to seven days of treatment are recommended, based on the judgement of the attending veterinarian. For relief of pain and inflammation associated with osteoarthritis, administration for six months is recommended.

The supporting information included a number of scientific publications, research or clinical studies in dogs (including dose confirmation, pharmacokinetic and pharmacodynamic studies) and clinical efficacy and safety studies in dogs.

A number of pharmacokinetic studies were performed in dogs, which showed that a dose rate of ~ 2 mg/kg/day was appropriate for analgesia and anti-inflammatory effects.

Two clinical studies were performed to demonstrate the efficacy of the product. Study 1 was a double-blinded randomised study comparing cimicoxib with firocoxib in 167 dogs over a 3 month period. The dogs were administered either cimicoxib (2 mg/kg/day) or firocoxib (5 mg/kg/day) and efficacy was assessed by clinical examination, assessment of pain and locomotion (days 0, 7, 15, 30, 60 and 90), plus blood was collected for haematology and biochemistry. Non-inferiority was demonstrated for cimicoxib in terms of efficacy, based on improvement in lameness and pain score.

Study 2 was a confirmatory clinical field study in which 237 dogs were enrolled from 28 veterinary clinics. The dogs were randomly assigned to receive either cimicoxib (2 mg/kg; n=114) or carprofen (4 mg/kg; n=123) 2 hr prior to surgery, with the type of surgery stratified evenly between the two treatment groups. Standard anaesthetic and post-operative care protocols were maintained between all facilities. The dogs underwent either soft tissue or orthopaedic surgery and the efficacy and safety of cimicoxib was compared to carprofen. There was a slight but non-significant improvement in analgesia in the cimicoxib group, with overall non-inferiority demonstrated between the two drugs.

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 CIMALGEX CHEWABLE TABLETS FOR DOGS would not adversely affect trade between Australia and places outside 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 cimicoxib should be approved and whether the application for registration of the products CIMALGEX 80 mg CHEWABLE TABLETS FOR DOGS, CIMALGEX 30 mg CHEWABLE TABLETS FOR DOGS and CIMALGEX 8 mg CHEWABLE 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
- date you made the submission.

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

Written submissions should be addressed in writing to:

Enquiries
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4701

Fax: +61 2 6210 4721

Email: enquiries@apvma.gov.au

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 www.apvma.gov.au.

1. NEW LICENCES

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

Nil

2. CHANGES TO EXISTING LICENCES

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

ARTHROPHARM PTY LTD

ACN: 003 261 907

105 -113 Bronte Road

BONDI JUNCTION NSW 2022

Licence number: 1107

Product types: *

- *Category 1:* Sterile products for injection

Steps of manufacture: Quality Assurance (QA) of raw materials, formulation including blending, aseptic filling, packaging, secondary packaging, labelling, sterilisation (heat, filtration), analysis and testing (physical, chemical, endotoxin, microbiological), storage and release for supply.

Amended licence issued: 4 February 2019

WESTERN AUSTRALIAN AGRICULTURE AUTHORITY

ABN: 86 611 226 341

Animal Health Laboratories

Department of Agriculture &
Food

444 Albany Highway

ALBANY WA 6330

Licence number: 1091

Product types: *

- *Category 1:* Immunobiologicals

Steps of manufacture: Quality assurance (QA) of raw materials, collection and preparation of mature nematodes, antigen extraction, formulation including blending, wet milling, sterilisation (heat, filtration), microbiological reduction treatment (filtration), aseptic filling, packaging, labelling, analysis and testing (physical, chemical, immunobiological, endotoxin, serological), storage and release for supply.

Amended licence issued: 5 February 2019

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

3. LICENCE CANCELLATIONS

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

AUSTRALIAN PET BRANDS **Licence number:** 4089
PTY LTD

ACN: 138 614 150 **Date cancelled:** 26 February 2019
12 Williamson Road
INGLEBURN NSW 2565

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
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4899

Email: mls@apvma.gov.au

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