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**Gazette**

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**AGRICULTURAL AND  
VETERINARY CHEMICALS**



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

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

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

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

Website: [www.apvma.gov.au](http://www.apvma.gov.au).

## GENERAL INFORMATION

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

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

## DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website,

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## APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4988

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

<b>Application no.:</b>	105648
<b>Product name:</b>	Relyon Immix 600 Seed Treatment
<b>Active constituent/s:</b>	600 g/L imidacloprid
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the control of various insect pests in a range of crops and the protection of the spread of barley yellow dwarf virus in cereal crops
<b>Date of registration/approval:</b>	18 May 2016
<b>Product registration no.:</b>	82395
<b>Label approval no.:</b>	82395/105648
<b>Application no.:</b>	105955
<b>Product name:</b>	Ozcrop Carfentrazone 240 EC Herbicide
<b>Active constituent/s:</b>	240 g/L carfentrazone-ethyl
<b>Applicant name:</b>	Ozcrop Pty. Ltd
<b>Applicant ACN:</b>	160 656 431
<b>Summary of use</b>	For improvement in the control of marshmallow and certain other broadleaf weeds prior to establishment of crops, fallows or forest plantations, in commercial, industrial and public service areas, around agricultural buildings and yards, in tree fruits, nuts, grape vines in tank mixture with knockdown herbicides; control of marshmallow and annual nettles in grass pastures and rough grass/turf areas; and control of volunteer cotton seedlings including Roundup Ready cotton and desiccation of cotton re-growth
<b>Date of registration/approval:</b>	18 May 2016
<b>Product registration no.:</b>	82510
<b>Label approval no.:</b>	82510/105955
<b>Application no.:</b>	105644
<b>Product name:</b>	Relyon Epoxicon 125SC Fungicide
<b>Active constituent/s:</b>	125 g/L epoxiconazole
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of use</b>	For the control of certain fungal diseases including stripe rust of wheat and specified fungal diseases of barley
<b>Date of registration/approval:</b>	20 May 2016
<b>Product registration no.:</b>	82392
<b>Label approval no.:</b>	82392/105644

<b>Application no.:</b>	102549
<b>Product name:</b>	Tomcat All-Weather Rat & Mouse Block Baits
<b>Active constituent/s:</b>	0.05 g/kg bromadiolone
<b>Applicant name:</b>	Scotts Australia Pty Limited
<b>Applicant ACN:</b>	003 123 162
<b>Summary of use</b>	For control of rats and mice in domestic situations
<b>Date of registration/approval:</b>	24 May 2016
<b>Product registration no.:</b>	81206
<b>Label approval no.:</b>	81206/102549
<b>Application no.:</b>	103208
<b>Product name:</b>	Newk 540 Glyphosate Herbicide
<b>Active constituent/s:</b>	540 g/L glyphosate present as the potassium salt
<b>Applicant name:</b>	Polygon (NZ) Limited
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For the control of a wide range of annual and perennial weeds
<b>Date of registration/approval:</b>	24 May 2016
<b>Product registration no.:</b>	81493
<b>Label approval no.:</b>	81493/103208
<b>Application no.:</b>	106120
<b>Product name:</b>	Abscission Plant Growth Regulator
<b>Active constituent/s:</b>	20 g/L 6-benzyladenine
<b>Applicant name:</b>	Agritrading Pty Limited
<b>Applicant ACN:</b>	134 291 295
<b>Summary of use</b>	For reducing fruit set, increasing fruit size and improving firmness of harvested apples
<b>Date of registration/approval:</b>	24 May 2016
<b>Product registration no.:</b>	82577
<b>Label approval no.:</b>	82577/106120
<b>Application no.:</b>	102786
<b>Product name:</b>	Hy-Clor Saltactiv Salt Water Pool Booster
<b>Active constituent/s:</b>	504 g/kg available chlorine (Cl) present as sodium dichloroisocyanurate
<b>Applicant name:</b>	Hy-Clor (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 655 381
<b>Summary of use</b>	For control of algae and bacteria in outdoor pools
<b>Date of registration/approval:</b>	25 May 2016
<b>Product registration no.:</b>	81307
<b>Label approval no.:</b>	81307/102786
<b>Application no.:</b>	106001
<b>Product name:</b>	Abamcol Insecticide
<b>Active constituent/s:</b>	18 g/L abamectin
<b>Applicant name:</b>	Premier Shukuroglou AU Pty Ltd
<b>Applicant ACN:</b>	603 303 939
<b>Summary of use</b>	For the control of certain mites on cotton, citrus, apples, capsicums, hops, pears, tomatoes, ornamentals and strawberries and native budworm on cotton
<b>Date of registration/approval:</b>	26 May 2016
<b>Product registration no.:</b>	82529
<b>Label approval no.:</b>	82529/106001

<b>Application no.:</b>	105096
<b>Product name:</b>	Rotam LVE MCPA 570 Herbicide
<b>Active constituent/s:</b>	570 g/L MCPA present as the 2-ethylhexyl ester
<b>Applicant name:</b>	Rotam Agrochemical Co., Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For selective control of certain weeds in agricultural crops
<b>Date of registration/approval:</b>	26 May 2016
<b>Product registration no.:</b>	82147
<b>Label approval no.:</b>	82147/105096
<b>Application no.:</b>	101520
<b>Product name:</b>	Fendona Plus 60 SC Insecticide
<b>Active constituent/s:</b>	60 g/L alpha-cypermethrin
<b>Applicant name:</b>	BASF Australia Ltd
<b>Applicant ACN:</b>	008 437 867
<b>Summary of use</b>	For control of ants, cockroaches, silverfish, fleas, flies, mosquitos, bed bugs, meal moths and spiders in domestic, industrial, commercial and public health situations
<b>Date of registration/approval:</b>	27 May 2016
<b>Product registration no.:</b>	80739
<b>Label approval no.:</b>	80739/101520
<b>Application no.:</b>	105079
<b>Product name:</b>	Adama Bonanza Elite Herbicide
<b>Active constituent/s:</b>	500 g/L diflufenican
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use</b>	For the control of certain weeds in clover-based pasture field peas, lentils, lupins and oilseed poppy
<b>Date of registration/approval:</b>	27 May 2016
<b>Product registration no.:</b>	82143
<b>Label approval no.:</b>	82143/105079
<b>Application no.:</b>	105658
<b>Product name:</b>	Rygel Bromoxynil MCPA Selective Herbicide
<b>Active constituent/s:</b>	200 g/L bromoxynil present as the n-octanoyl ester 200 g/L MCPA present as the ethyl hexyl ester
<b>Applicant name:</b>	Profeng Australia Pty Ltd
<b>Applicant ACN:</b>	156 055 533
<b>Summary of use</b>	For the control of broadleaf weeds in wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf
<b>Date of registration/approval:</b>	27 May 2016
<b>Product registration no.:</b>	82402
<b>Label approval no.:</b>	82402/105658

<b>Application no.:</b>	102453
<b>Product name:</b>	Tyllanex 800 WG Herbicide
<b>Active constituent/s:</b>	800 g/kg terbuthylazine
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use</b>	For the control of weeds, crops chickpeas, faba beans, field peas, lupins and triazine-tolerant canola
<b>Date of registration/approval:</b>	30 May 2016
<b>Product registration no.:</b>	81161
<b>Label approval no.:</b>	81161/102453
<b>Application no.:</b>	102249
<b>Product name:</b>	Fendona Pressurised Insecticide
<b>Active constituent/s:</b>	0.5 g/kg alpha-cypermethrin
<b>Applicant name:</b>	BASF Australia Ltd.
<b>Applicant ACN:</b>	008 437 867
<b>Summary of use</b>	For the control of ants, cockroaches, silverfish, spiders, fleas, Indian meal moth, red flour beetle, bed bugs, flies and mosquitoes in various situations
<b>Date of registration/approval:</b>	30 May 2016
<b>Product registration no.:</b>	81056
<b>Label approval no.:</b>	81056/102249
<b>Application no.:</b>	105291
<b>Product name:</b>	Agitator 700 Surfactant
<b>Active constituent/s:</b>	350 g/L soyal phospholipids, 350 g/L propionic acid
<b>Applicant name:</b>	Stotras Pty Ltd
<b>Applicant ACN:</b>	164 590 167
<b>Summary of use</b>	For use as an acidifying and penetrating surfactant
<b>Date of registration/approval:</b>	31 May 2016
<b>Product registration no.:</b>	82253
<b>Label approval no.:</b>	82253/105291
<b>Application no.:</b>	106119
<b>Product name:</b>	Super Seed 25T Fungicide/Insecticide Seed Treatment
<b>Active constituent/s:</b>	25 g/L tebuconazole 4 g/L triflumuron
<b>Applicant name:</b>	Premier Shukuroglou AU Pty Ltd
<b>Applicant ACN:</b>	603 303 939
<b>Summary of use</b>	For control of bunt, flag smut and loose smut in wheat, for control of covered and loose smut in barley and oats and for protection against insect pests of stored grain
<b>Date of registration/approval:</b>	31 May 2016
<b>Product registration no.:</b>	82576/106119
<b>Label approval no.:</b>	106119

<b>Application no.:</b>	63462
<b>Product name:</b>	Perox395 Chlorine Free Pool Sanitiser
<b>Active constituent/s:</b>	395 g/L hydrogen peroxide
<b>Applicant name:</b>	Waterco Limited
<b>Applicant ACN:</b>	002 070 733
<b>Summary of use</b>	For control of bacteria in private (domestic) spas and pools
<b>Date of registration/approval:</b>	1 June 2016
<b>Product registration no.:</b>	70441
<b>Label approval no.:</b>	70441/63462
<b>Application no.:</b>	105669
<b>Product name:</b>	Rotriafol 500 Fungicide
<b>Active constituent/s:</b>	500 g/L flutriafol
<b>Applicant name:</b>	Rotam Agrochemical Co., Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser
<b>Date of registration/approval:</b>	1 June 2016
<b>Product registration no.:</b>	82407
<b>Label approval no.:</b>	82407/105669
<b>Application no.:</b>	105060
<b>Product name:</b>	Cutlass 500 Herbicide
<b>Active constituent/s:</b>	500 g/L dicamba present as the dimethylamine salt
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use</b>	For the control of certain broadleaf weeds in winter cereals, pastures, conservation tillage, sugarcane, turf, rice, and non-crop areas
<b>Date of registration/approval:</b>	2 June 2016
<b>Product registration no.:</b>	82128
<b>Label approval no.:</b>	82128/105060
<b>Application no.:</b>	105570
<b>Product name:</b>	Paul Munn The Lawn Specialist B6 Bindii & Clover Selective Lawn Herbicide
<b>Active constituent/s:</b>	200 g/L bromoxynil present as n-octanoyl ester 200 g/L MCPA present as 2-ethylhexyl ester
<b>Applicant name:</b>	Paul Munn's Garden Centre Pty Ltd
<b>Applicant ACN:</b>	008 270 031
<b>Summary of use</b>	For the control of bindii and other weeds in buffalo and other lawns
<b>Date of registration/approval:</b>	3 June 2016
<b>Product registration no.:</b>	82364
<b>Label approval no.:</b>	82364/105570
<b>Application no.:</b>	106115
<b>Product name:</b>	Premodione 500SC Fungicide
<b>Active constituent/s:</b>	500 g/L iprodione
<b>Applicant name:</b>	Premier Shukuroglou Au Pty Ltd
<b>Applicant ACN:</b>	603 303 939
<b>Summary of use</b>	For the control of certain fungal diseases in various crops and situations
<b>Date of registration/approval:</b>	3 June 2016
<b>Product registration no.:</b>	82573
<b>Label approval no.:</b>	82573/106115



<b>Application no.:</b>	103933
<b>Product name:</b>	Prompt 750 WG Herbicide
<b>Active constituent/s:</b>	750 g/kg tribenuron-methyl
<b>Applicant name:</b>	Grow Choice Pty Limited
<b>Applicant ACN:</b>	069 839 961
<b>Summary of use</b>	For the control of certain broadleaf weeds in fallows and pre-crop situations
<b>Date of registration/approval:</b>	6 June 2016
<b>Product registration no.:</b>	81740
<b>Label approval no.:</b>	81740/103933

<b>Application no.:</b>	105158
<b>Product name:</b>	Sherwood Vectorforce ULV & Thermal Fogging Insecticide Concentrate
<b>Active constituent/s:</b>	25 g/L cypermethrin 862 g/L hydrocarbon
<b>Applicant name:</b>	Sherwood Chemicals Australasia Pty Ltd
<b>Applicant ACN:</b>	136 993 630
<b>Summary of use</b>	For the knockdown control of adult mosquitoes, biting midges, flies and cockroaches in and around domestic, public service areas, agricultural buildings, commercial and industrial areas, refuse tips and breeding areas
<b>Date of registration/approval:</b>	6 June 2016
<b>Product registration no.:</b>	82195
<b>Label approval no.:</b>	82195/105158

<b>Application no.:</b>	105607
<b>Product name:</b>	Titan Clethodim 360 Herbicide
<b>Active constituent/s:</b>	360 g/L clethodim
<b>Applicant name:</b>	Titan AG Pty Ltd
<b>Applicant ACN:</b>	122 081 574
<b>Summary of use</b>	For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans
<b>Date of registration/approval:</b>	7 June 2016
<b>Product registration no.:</b>	82380
<b>Label approval no.:</b>	82380/105607

## 2. VARIATIONS OF REGISTRATION

<b>Application no:</b>	106296
<b>Product Name:</b>	Imtrade Chlorpyrifos 500 Insecticide
<b>Active constituent/s:</b>	500 g/L chlorpyrifos
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of variation:</b>	To include a pack size range of 5 L–1000 L
<b>Date of variation:</b>	13 April 2016
<b>Product registration no.:</b>	51190
<b>Label approval no.:</b>	51190/106296

<b>Application no:</b>	106294
<b>Product name:</b>	Imtrade MCPA LVE 500 EC Herbicide
<b>Active constituent/s:</b>	500 g/L MCPA present as the iso-octyl ester
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of variation:</b>	To amend the distinguishing and label name from 'CHEMAG LVE MCPA 500 HERBICIDE' to 'IMTRADE MCPA LVE 500 EC HERBICIDE'
<b>Date of variation:</b>	13 April 2016
<b>Product registration no.:</b>	51687
<b>Label approval no.:</b>	51687/106294

<b>Application no:</b>	106424
<b>Product name:</b>	Comet 400 Herbicide
<b>Active constituent/s:</b>	400 g/L fluroxypyr as the methylheptyl ester
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'NUFARM COMET 400 HERBICIDE' to 'COMET 400 HERBICIDE'
<b>Date of variation:</b>	26 April 2016
<b>Product registration no.:</b>	61667
<b>Label approval no.:</b>	61667/106424

<b>Application no:</b>	106426
<b>Product name:</b>	Rifle 440 Herbicide
<b>Active constituent/s:</b>	440 g/L pendimethalin
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'NUFARM RIFLE 440 HERBICIDE' to 'RIFLE 440 HERBICIDE'
<b>Date of variation:</b>	26 April 2016
<b>Product registration no.:</b>	54599
<b>Label approval no.:</b>	54599/106426

<b>Application no:</b>	106428
<b>Product name:</b>	Trooper 75-D Herbicide
<b>Active constituent/s:</b>	75 g/L picloram as the triisopropanolamine salt, 300 g/L 2,4-D as the triisopropanolamine salt
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'NUFARM TROOPER 75-D HERBICIDE' to 'TROOPER 75-D HERBICIDE'
<b>Date of variation:</b>	27 April 2016
<b>Product registration no.:</b>	62751
<b>Label approval no.:</b>	62751/106428

<b>Application no:</b>	106429
<b>Product name:</b>	Trooper 242 Herbicide
<b>Active constituent/s:</b>	26 g/L picloram present as the potassium salt, 420 g/L MCPA present as the potassium salt
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'NUFARM TROOPER 242 HERBICIDE' to 'TROOPER 242 HERBICIDE'
<b>Date of variation:</b>	27 April 2016
<b>Product registration no.:</b>	55555
<b>Label approval no.:</b>	55555/106429
<b>Application no:</b>	106446
<b>Product name:</b>	Archer Herbicide
<b>Active constituent/s:</b>	300 g/L clopyralid present as the triisopropanolamine salt
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'NUFARM ARCHER HERBICIDE' to 'ARCHER HERBICIDE'
<b>Date of variation:</b>	27 April 2016
<b>Product registration no.:</b>	52139
<b>Label approval no.:</b>	52139/106446
<b>Application no:</b>	106447
<b>Product name:</b>	Conqueror Herbicide
<b>Active constituent/s:</b>	100 g/L picloram present as the hexyloxypropylamine salt, 300 g/L triclopyr present as the butoxyethyl ester
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'NUFARM CONQUEROR HERBICIDE' to 'CONQUEROR HERBICIDE'
<b>Date of variation:</b>	27 April 2016
<b>Product registration no.:</b>	57783
<b>Label approval no.:</b>	57783/106447
<b>Application no:</b>	106448
<b>Product name:</b>	Collide 700 Adjuvant
<b>Active constituent/s:</b>	350 g/L soyal phospholipids, 350 g/L propionic acid
<b>Applicant name:</b>	NUFARM AUSTRALIA LIMITED
<b>Applicant ACN:</b>	004 377 780
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'NUFARM NU 700 SURFACTANT' to 'COLLIDE 700 ADJUVANT'
<b>Date of variation:</b>	27 April 2016
<b>Product registration no.:</b>	70329
<b>Label approval no.:</b>	70329/106448

<b>Application no:</b>	106482
<b>Product name:</b>	Weed Force Ground Keeper Herbicide
<b>Active constituent/s:</b>	750 g/kg sulfometuron methyl
<b>Applicant name:</b>	Weed Force Pty Ltd
<b>Applicant ACN:</b>	602 207 152
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'WEED FORCE GUSTO HERBICIDE' to 'WEED FORCE GROUND KEEPER HERBICIDE'
<b>Date of variation:</b>	2 May 2016
<b>Product registration no.:</b>	80733
<b>Label approval no.:</b>	80733/106482

<b>Application no:</b>	106525
<b>Product name:</b>	Relyon Nero 250WG Herbicide
<b>Active constituent/s:</b>	250 g/kg butoxydim
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'FMC VULCAN 250WG HERBICIDE' to 'RELYON NERO 250WG HERBICIDE'
<b>Date of variation:</b>	4 May 2016
<b>Product registration no.:</b>	70456
<b>Label approval no.:</b>	70456/106525

<b>Application no:</b>	106537
<b>Product name:</b>	Relyon Carpenter 240EC Herbicide
<b>Active constituent/s:</b>	240 g/L carfentrazone-ethyl
<b>Applicant name:</b>	Ruralco Holdings Limited
<b>Applicant ACN:</b>	009 660 879
<b>Summary of variation:</b>	To change the distinguishing product name and the name that appears on the label from 'RELYON SLEDGE 240EC HERBICIDE' to 'RELYON CARPENTER 240EC HERBICIDE'
<b>Date of variation:</b>	5 May 2016
<b>Product registration no.:</b>	81904
<b>Label approval no.:</b>	81904/106537

<b>Application no.:</b>	105797
<b>Product name:</b>	AC Carbine 240 Herbicide
<b>Active constituent/s:</b>	240 g/L clethodim
<b>Applicant name:</b>	Axichem Pty Ltd
<b>Applicant ACN:</b>	131 628 594
<b>Summary of use:</b>	To change pack sizes
<b>Date of variation:</b>	27 May 2016
<b>Product registration no.:</b>	64760
<b>Label approval no.:</b>	64760/105797

<b>Application no:</b>	103062
<b>Product name:</b>	Brumby 480 SC Fungicide
<b>Active constituent/s:</b>	480 g/L prothioconazole
<b>Applicant name:</b>	Bayer Cropscience Pty Ltd
<b>Applicant ACN:</b>	000 226 022
<b>Summary of variation:</b>	To add a pack size range and to extend registration to include aerial application to peanuts
<b>Date of variation:</b>	31 May 2016
<b>Product registration no.:</b>	68332
<b>Label approval no.:</b>	68332/103062

<b>Application no:</b>	104210
<b>Product name:</b>	Terbyne Xtreme 875 WG Herbicide
<b>Active constituent/s:</b>	875 g/kg terbuthylazine
<b>Applicant name:</b>	Sipcam Pacific Australia Pty Ltd
<b>Applicant ACN:</b>	073 176 888
<b>Summary of variation:</b>	To extend use for the control of black bindweed / climbing buckwheat ( <i>fallopia convolvulus</i> ) on an existing legume crop, chickpeas, when used in a mandatory tank-mix combination, within NSW, VIC, SA,WA and QLD only
<b>Date of variation:</b>	31 May 2016
<b>Product registration no.:</b>	68613
<b>Label approval no.:</b>	68613/104210

<b>Application no:</b>	105062
<b>Product name:</b>	Concentrate Roundup Path Weedkiller
<b>Active constituent/s:</b>	143 g/L glyphosate as the isopropylamine salt, 15.1 g/L triclopyr as the triethylamine salt
<b>Applicant name:</b>	Monsanto Australia Ltd
<b>Applicant ACN:</b>	006 725 560
<b>Summary of variation:</b>	To replace existing uses with new use on hard surfaces
<b>Date of variation:</b>	6 June 2016
<b>Product registration no.:</b>	69980
<b>Label approval no.:</b>	69980/105062

<b>Application no.:</b>	103622
<b>Product name:</b>	Mainman 500 WG Insecticide
<b>Active constituent/s:</b>	500 g/kg flonicamid
<b>Applicant name:</b>	Ishihara Sangyo Kaisha, Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	To remove a restraint against application by aircraft, add no-spray zone information and add a pack size
<b>Date of variation:</b>	6 June 2016
<b>Label approval no.:</b>	66373/103622

### 3. LABEL APPROVAL

<b>Application no.:</b>	106064
<b>Product name:</b>	Santalum Estate Mosquito Repellent Original Incense Sandalwood Sticks
<b>Active constituent/s:</b>	15 g/kg citronella oil, 15 g/kg eucalyptus oil
<b>Applicant name:</b>	Mayo Hardware Pty Ltd
<b>Applicant ACN:</b>	071 517 176
<b>Summary of use:</b>	To add an additional label name to the product under 'WAXWORKS OUTDOOR STYLE THAT PROTECTS! MOSQUITO REPELLENT ORIGINAL INCENSE SANDALWOOD STICKS'
<b>Date of approval:</b>	30 May 2016
<b>Label approval no.:</b>	69167/106064
<b>Application no.:</b>	106065
<b>Product name:</b>	Santalum Estate Mosquito Repellent Incense Sandalwood Sticks
<b>Active constituent/s:</b>	15 g/kg citronella oil, 15 g/kg eucalyptus oil
<b>Applicant name:</b>	Mayo Hardware Pty Ltd
<b>Applicant ACN:</b>	071 517 176
<b>Summary of use:</b>	To add an additional label name to the product under 'WAXWORKS OUTDOOR STYLE THAT PROTECTS! MOSQUITO REPELLENT INCENSE SANDALWOOD STICKS'
<b>Date of approval:</b>	31 May 2016
<b>Label approval no.:</b>	81388/106065
<b>Application no.:</b>	105543
<b>Product name:</b>	Colony Killer Termite Bait
<b>Active constituent/s:</b>	1 g/kg chlorfluazuron
<b>Applicant name:</b>	Termi-Fix Pty. Ltd
<b>Applicant ACN:</b>	138 213 224
<b>Summary of use:</b>	To add an additional label name to the product under 'TUCKERBAG TERMITE BAIT'
<b>Date of approval:</b>	7 June 2016
<b>Label approval no.:</b>	64714/105543

## Veterinary Chemical Products and Approved Labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

### 1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

<b>Application no.:</b>	62953
<b>Product name:</b>	Loxicom 1 mg Chewable Tablets for Dogs
<b>Active constituent/s:</b>	Each tablet contains 1 mg meloxicam
<b>Applicant name:</b>	Norbrook Laboratories Australia Pty Limited
<b>Applicant ACN:</b>	080 972 596
<b>Summary of use</b>	For the use in dogs for the alleviation of inflammation and pain in acute and chronic musculoskeletal disorders
<b>Date of registration/approval:</b>	9 May 2016
<b>Product registration no.:</b>	70299
<b>Label approval no.:</b>	70299/62953

## 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 CONSITUTENT

<b>Application no.:</b>	103073
<b>Active constituent/s:</b>	Thiophanate-methyl
<b>Applicant name:</b>	Sanonda (Australia) Pty Ltd
<b>Applicant ACN:</b>	059 813 973
<b>Summary of use:</b>	For use in Agricultural chemical products
<b>Date of approval:</b>	31 May 2016
<b>Approval no.:</b>	81426



## Licensing of Veterinary Chemical Manufacturers

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Pursuant to Part 8 of the Agricultural and Veterinary Chemical Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action, with respect to the licensing of the following veterinary chemical manufacturers, with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the APVMA's website [www.apvma.gov.au](http://www.apvma.gov.au).

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### 1. NEW LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code]

**APEX LABORATORIES PTY LTD**

**ACN:** 000 397 240

2 Cal Close

SOMERSBY NSW 2250

**LICENCE NO:** 2241

**Product Types:** \*

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

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

**Licence Issued:** 6 May 2016

**SD & TM PTY LTD ACTING AS TRUSTEE FOR CHEM-CHROM LABORATORIES AND SERVICES**

**ACN:** 605 216 840

Unit 15, 10–12 Montore Road

MINTO NSW 2566

**LICENCE NO:** 6208

**Product Types:**\*

- *Category 6:* Single step

**Step(s) of Manufacture:** Analysis and testing (physical and chemical)

**Licence Issued:** 30 May 2016

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

## 2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code]

### **ECOLAB PTY LTD**

**ACN:** 000 449 990

350 Reserve Road

CHELTENHAM VIC 3192

**LICENCE NO:** 2128

**Product Types:** \*

- *Category 2:* Liquids

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

**Amended Licence Issued:** 6 May 2016

### **GMP PHARMACEUTICALS PTY LIMITED**

**ACN:** 063 353 006

7–9 Amax Avenue

GIRRAWEE NSW 2145

**LICENCE NO:** 2205

**Product Types:** \*

- *Category 2:* Tablets, pellets, capsules (hard shell and soft gel), creams/lotions, ointments, pastes, powders, spray and liquids

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister and sachet packaging, soft gelatine capsule manufacture, tableting, pellet extrusion, capsule filling from bulk, analysis and testing (physical), storage and release for supply

**Amended Licence Issued:** 9 May 2016

### **MICRONISERS PTY. LTD.**

**ACN:** 006 825 538

6–8 England Street

DANDENONG VIC 3175

**LICENCE NO:** 6011

**Product Types:** \*

- *Category 6:* Single step

**Step(s) of Manufacture:** wet milling of powders, dry milling of powders

**Amended Licence Issued:** 12 May 2016

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

**THE STATE OF VICTORIA  
ACTING THROUGH THE  
DEPARTMENT OF ECONOMIC  
DEVELOPMENT JOBS  
TRANSPORT AND  
RESOURCES**

**ABN:** 69 981 208 728

PIG SERVICES CENTRE

Corner Taylor Street and  
Midland Highway

EPSOM VIC 3551

**LICENCE NO:** 1071

**Product Types:** \*

- *Category 1:* Bacterial vaccines

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, bacterial fermentation, formulation including blending, aseptic filling, packaging, labelling, sterilisation (heat), analysis and testing (physical, chemical, microbiological, sterility, immunobiological, serological and haemolysin assay), storage and release for supply.

**Amended Licence Issued:** 16 May 2016

**PHARMPLEX PTY LTD**

**ACN:** 145 071 165

914 Croobyar Road

MILTON NSW 2538

**LICENCE NO:** 2207

**Product Types:** \*

- *Category 2:* Capsules, pellets/boluses, powders, granules, liquids and hormone impregnated foam sponges.

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, granulation, filling, packaging, labelling, tableting, pellet extrusion, capsule filling from bulk, analysis and testing (physical), storage and release for supply.

**Amended Licence Issued:** 16 May 2016

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

**RADPHARM SCIENTIFIC, A  
DIVISION OF GLOBAL  
MEDICAL SOLUTIONS  
AUSTRALIA PTY LIMITED**

**ACN:** 072 147 561

54–59 Oatley Court

BELCONNEN ACT 2617

**LICENCE NO:** 1073

**Product Types:** \*

- *Category 1: Sterile products*

**Step(s) of Manufacture:** Formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat, filtration), microbiological reduction treatment (heat, filtration), analysis and testing (physical, chemical, Limulus Amoebocyte Lysate test [LAL]), storage and release for supply

**Amended Licence Issued:** 26 May 2016

**BIOPROTON PTY. LTD.**

**ACN:** 059 093 417

55 Dulacca Street

ACACIA RIDGE QLD 4110

**LICENCE NO:** 4096

**Product Types:** \*

- *Category 4: Enzyme supplements*

**Step(s) of Manufacture:** Quality assurance (QA) of raw materials, formulation including blending, packaging, labelling, analysis and testing (physical and enzyme assay), storage, and release for supply.

**Amended Licence Issued:** 31 May 2016

### 3. LICENCE CANCELLATIONS

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

**AUSTRALIAN CONTRACT  
MANUFACTURING (ACM) PTY  
LTD**

**ACN:** 052 052 196

92 Antimony Street

CAROLE PARK QLD 4300

**LICENCE NO:** 2065

**Date Cancelled:** 25 May 2016

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

#### 4. LICENCE SUSPENSIONS

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

**HESLOP CONTRACT**

**LICENCE NO:** 6125

**CASTERS PTY LTD**

**ACN:** 116 308 233

**Date Suspended:** 18 May 2016 to 28 April 2017

8 Pitt Street

RESERVOIR VIC 3073

#### 5. REVOCATION OF LICENCE CANCELLATION

The APVMA has revoked the cancellation of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

#### 6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

#### APVMA CONTACT

Manufacturing Quality and Licensing Section  
Legal and Compliance Program  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

**Phone:** +61 2 6210 4899

**Fax:** +61 2 6210 4813

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

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

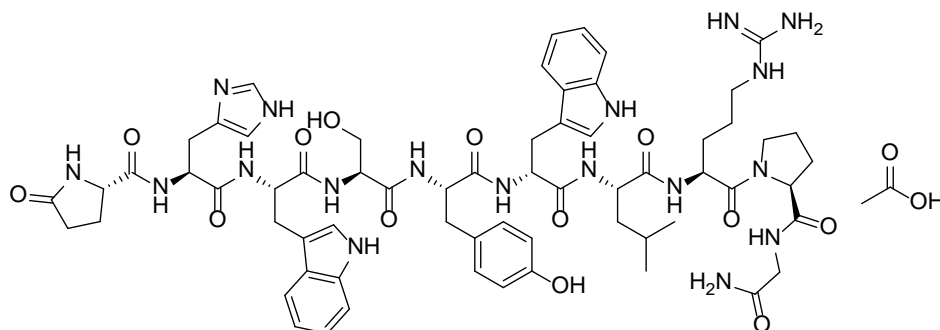
## New Active Constituent and New Veterinary Chemical Product—Elanco Ovugel (Triptorelin Acetate) Gel for Intravaginal use in Sows Containing Triptorelin Acetate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, triptorelin acetate, and an application for registration of a new product containing the new active constituent. The product is ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS.

### PARTICULARS OF THE ACTIVE CONSTITUENT

<b>Common name:</b>	Triptorelin acetate
<b>IUPAC name:</b>	L-pyroglutamyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-tryptophyl-L-leucyl-L-arginyl-L-prolyl-glycinamide, acetate salt
<b>CAS name:</b>	Luteinizing hormone-releasing factor (swine), 6-D-tryptophan, acetate (1:?)
<b>CAS registry number:</b>	160296-12-8
<b>Manufacturer's codes:</b>	D-Trp6-LH-RH
<b>Minimum purity:</b>	950 g/kg
<b>Molecular formula:</b>	C <sub>64</sub> H <sub>82</sub> N <sub>18</sub> O <sub>13</sub> .C <sub>2</sub> H <sub>4</sub> O <sub>2</sub>
<b>Molecular weight:</b>	1371.6

#### Structure:



<b>Chemical family:</b>	Synthetic analogues of the Gonadotropin releasing hormone
<b>Mode of Action:</b>	Responsible for the release of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) from the anterior pituitary.

### SUMMARY OF THE APVMA'S EVALUATION OF TRIPTORELIN ACETATE ACTIVE CONSTITUENT

Triptorelin acetate is a new active constituent for which there is no compendial specification available.

The APVMA has evaluated the chemistry aspects of triptorelin acetate active constituent. The assessment includes consideration of the manufacturing process and quality control procedures, the impurities, analysis of the chemical composition (batch analysis and analytical method inclusive), specifications, stability and packaging. The APVMA found these details of the active constituent acceptable.

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

An external reviewer has completed a toxicology evaluation of triptorelin acetate. The reviewer found that triptorelin acetate is not a skin or eye irritant. Nor is it a skin sensitiser. The submitted information and information from the literature indicates negligible dermal and oral bioavailability of the active even at very high oral doses. Triptorelin embonate is not carcinogenic in CD-1 mice. However, it induces adenomas in the anterior pituitary of Sprague-Dawley rats. Summary reports for various studies with triptorelin indicate no genotoxic potential was evident at concentrations up to the limit of toxicity or solubility.

Conventional reproductive or developmental toxicity studies were not available. It has been reported that Triptorelin 12 had no effect on fertility or general reproductive performance of female rats. Treatment did not elicit embryotoxicity, teratogenicity, or any effects on the development of the offspring (F1 generation) or their reproductive performance. Another report concludes there was no evidence that parental treatment of rats with triptorelin acetate affected fertility, general reproductive performance, or behaviour of the F1 animals. Nor did the administration of triptorelin acetate to sexually mature female rabbits induce effects on the ovaries.

An Acceptable Daily Intake and an Acute Reference Dose for triptorelin are not considered necessary since the active is likely to have a short elimination half-life in pigs. As the active is administered prior to pregnancy, there will be no biologically active material in the sow by the time it is slaughtered. In addition, triptorelin has negligible oral bioavailability. Should humans consume a pig within a few hours of it being dosed with triptorelin, it is very unlikely persons will receive orally or systemically an active dose of triptorelin.

Triptorelin is already listed in Schedule 4 of the Australian Standard for Uniform Scheduling of Medicines and Poisons, with no exceptions.

The APVMA accepts the findings and recommendations of its reviewers on the safety criteria. The APVMA is satisfied that the proposed use of triptorelin acetate would not be an undue hazard to the safety of people exposed to it during its handling and use.

#### **PARTICULARS OF THE APPLICATION**

<b>Proposed product name:</b>	ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS
<b>Applicant company:</b>	ELANCO ANIMAL HEALTH A DIV OF ELI LILLY AUST PTY LTD
<b>Name of active constituent:</b>	TRIPTORELIN ACETATE
<b>Signal heading:</b>	Schedule 4
<b>Summary of proposed use:</b>	For the synchronisation of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination in sows.
<b>Pack sizes:</b>	52.5 mL; 6 x 52.5 mL
<b>Withholding period:</b>	Zero (0) days

**SUMMARY OF THE APVMA'S EVALUATION OF ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS 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 ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS would not be an undue hazard to the safety of people exposed to it during its handling and use.

An external toxicology reviewer has conducted a risk assessment on the product and concluded that it can be used safely.

The external reviewer has estimated the acute toxicity of ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS based on information provided by the applicant. The product is not a skin or eye irritant, and is expected to have low toxicity via all routes of exposure.

An operator qualitative risk assessment concluded that exposure to the product during proposed use may occur but would result in very low to negligible exposure. Exposure via other routes was considered unlikely.

To mitigate the acute and repeat-dose risks associated with ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS, the reviewer has recommended first aid statement (a)—*If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26*. This first aid instruction will be included on the product label. No specific safety directions have been recommended.

The APVMA has considered and has accepted the findings and recommendations of the reviewer.

- (ii) The APVMA is satisfied that the proposed use of ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS will not be an undue hazard to the safety of people using anything containing its residues.

The applicant has proposed that the use of triptorelin for inducing ovulation in sows is eligible for a Table 5 entry in the MRL Standard.

Triptorelin residues should not occur in pig commodities since only very small quantities of the product are used; treated pigs are unlikely to be made available for human consumption in the short term since they will be used for breeding; the dose is administered intravaginally and the vagina is removed at slaughter.

If commodities from treated animals are consumed, triptorelin residues in these commodities will be of no toxicological significance since triptorelin is absorbed and rapidly metabolised by the animal into small peptides with negligible biological activity. Triptorelin has low oral bioavailability since triptorelin is rapidly inactivated by the gastrointestinal enzymes.

The APVMA proposes to include triptorelin acetate in Table 5 of the *MRL Standard* under "Gonadotrophin Releasing Hormone (GnRH) and analogues". This entry supports the proposed withholding period of zero (0) days.

- (iii) The APVMA is satisfied that the proposed use of ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS containing the active constituent triptorelin acetate is not likely to be harmful to human beings if used according to the product label directions.



Triptorelin is approved for therapeutic use in humans, and is listed in Schedule 4 of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP), with no exceptions. ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS contains 100 µg/mL triptorelin as the acetate and is classified as a Schedule 4 prescription animal drug. Based on the concentration of triptorelin and the toxicological profile of the product, this scheduling is considered appropriate.

- (iv) The APVMA is satisfied that the proposed use of the new product ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS containing the active constituent triptorelin acetate, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The APVMA has conducted a risk assessment to consider the environmental safety ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS. The standard environmental release scenario for treatment of intensively reared sows was considered in a Phase 1 assessment according to EMA Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH Guidelines GL6 and GL38 (2008).

The predicted environmental concentration of triptorelin in soil (PEC soil initial) was 0.0052 µg/kg, which is well below the limit of concern (100 µg/kg). Therefore, it is not required that the environmental risk assessment proceed to Phase II. The label will contain a disposal statement as follows: *Dispose of empty container by wrapping with paper and putting in garbage.*

An external reviewer has assessed the safety of ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS in a margin of safety study in pigs, with single intravaginal application at 1X and 7X the recommended dose. A 4.5% decrease in live-weight was associated with the regression of mammary tissue following weaning and some minor (non-dose related) vaginal inflammation was observed. However, no dose-related abnormalities were detected in results for serum chemistry, haematology, urinalysis, or serum endocrine function.

A review of reproductive safety parameters from a number of proof-of-concept studies demonstrated that ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS did not adversely affect fertilisation or embryo survival. No adverse drug experiences or association with health problems have been noted in the non-pivotal or pivotal efficacy studies. Comparison of health-related observations for numerous sows treated with the proposed product in the multi-site pivotal efficacy study with sows receiving vehicle gel indicated that none of the health issues observed and recorded were associated with triptorelin treatment.

The APVMA is satisfied that ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS would not have an unintended effect that is harmful to the target animals (sows). Appropriate contraindication and precaution statements will be included on the label.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

- (i) In relation to its assessment of efficacy, 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.

ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS is intended for use in sows for the synchronisation of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination. The product is applied as an intravaginal gel four days after weaning to facilitate a single fixed-time artificial insemination of sows 22 hours later.

The efficacy studies include non-pivotal laboratory model efficacy studies, dose determination studies, dose confirmation studies, field studies and a pivotal field study conducted in the USA in accordance with Good Clinical Practice, as well as supporting published information. These studies were conducted in similar pork production systems to those used in Australia, and with similar genotypes of pigs. Consequently, the studies are applicable to Australian production systems.

The series of pivotal and non-pivotal efficacy studies demonstrated that 200 µg of triptorelin gel in the proposed product administered intravaginally at 96 hours post-weaning advanced and synchronised ovulation and normal fertility was achieved with a single fixed-time insemination.

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:

- (ii) The APVMA is considering whether the proposed use of ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS would not adversely affect trade between Australia and places outside Australia.

Triptorelin residues should not occur in foods and is of no toxicological significance if humans consume treated animals. Therefore, there are no residues related risks to Australia's export trade in pork.

The APVMA proposes to be satisfied that use of ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS, in accordance with the recommended relevant label particulars, meets the trade criteria, provided the following Trade Advice statement is included on the relevant label particulars: *Export Slaughter Interval (ESI): Zero (0) days.*

#### **FURTHER INFORMATION**

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

#### **MAKING A SUBMISSION**

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

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether ELANCO OVUGEL (TRIPTORELIN ACETATE) GEL FOR INTRAVAGINAL USE IN SOWS 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:

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