



**Commonwealth
of Australia**

Gazette

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Published by The Australian Pesticides & Veterinary Medicines Authority

**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*.

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GENERAL INFORMATION

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

Pursuant to section 53(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

From February 2010, the APVMA will publish the *APVMA Gazette* in electronic format only. The *APVMA Gazette* and information about subscribing to the gazette alert service are available on the APVMA website, www.apvma.gov.au.

Copies of the *APVMA Gazette* from November 1999 until July 2009 will remain available from the APVMA website.

APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4871

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

CONTENTS

Notice of Registrations	4
Agricultural Chemical Products	4
Veterinary Chemical Products	8
Notice – New Agricultural Active Constituent	14
Metrafenone	14
Other Notices	17
Licensing of Veterinary Chemical Manufacturers	17
Application Summaries	21
Amendments to the MRL Standard	24

NOTICE OF REGISTRATIONS

Agricultural Chemical Products

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 registration in respect of the following products, with effect from the dates shown.

1. RESTRICTED PRODUCT

No entries

2. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

No entries

3. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name:	Ozcrop Terbutryn Herbicide
Active Constituent/s:	500g/L terbutryn
Applicant Name:	CMS Trade Pty Ltd
Applicant ACN:	086 927 157
Summary of Use:	For control of certain early competing broadleaf weeds in wheat, barley, triticale, pastures and some varieties of oats and field peas.
Date of Registration:	01 November 2010
Label Approval No:	65057/10L/0510, 65057/10LL/0510, 65057/0510

Product Name:	Rainbow Triasulfuron 750 WG Herbicide
Active Constituent/s:	750g/kg triasulfuron
Applicant Name:	Shandong Rainbow International Co., Ltd.
Applicant ACN:	N/A
Summary of Use:	For pre-plant control of annual ryegrass, paradoxa grass and certain broadleaf weeds in wheat and for post-emergent control of wild radish in wheat, oats and barley.
Date of Registration:	10 November 2010
Label Approval No:	65252/50525

Product Name:	AC Nutless Herbicide
Active Constituent/s:	750g/kg halosulfuron-methyl
Applicant Name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of Use:	For the control of nutgrass in various crops (sugarcane, corn/maize, sorghum and cotton) and for the control of mullumbimby couch and nutgrass in turf.
Date of Registration:	18 November 2010
Label Approval No:	65484/51027

Product Name:	Rygel ClearUp Bio 360 SL Herbicide
Active Constituent/s:	360g/L glyphosate present as the monoethanolamine salt
Applicant Name:	Rygel Australia Pty. Ltd.
Applicant ACN:	106 839 007
Summary of Use:	For non-selective control of many annual, perennial and woody weeds in a wide variety of situations.
Date of Registration:	18 November 2010
Label Approval No:	65468/50997

Product Name:	Amgrow Caterpillar and Insect Spray
Active Constituent/s:	50g/L esfenvalerate
Applicant Name:	Ecofertiliser Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For use in home and garden situations for control of caterpillars and other insect pests.
Date of Registration:	18 November 2010
Label Approval No:	65410/50857

Product Name:	Amgrow Garden Insect Control
Active Constituent/s:	50g/L esfenvalerate
Applicant Name:	Ecofertiliser Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For use in home and garden situations for control of insect pests.
Date of Registration:	18 November 2010
Label Approval No:	65411/50858

Product Name:	Amgrow Home Pest Control
Active Constituent/s:	50g/L esfenvalerate
Applicant Name:	Ecofertiliser Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For use in domestic, public service, commercial, industrial building/premises to control insects.
Date of Registration:	19 November 2010
Label Approval No:	65413/50860

Product Name:	Masmart Carbendazim Systemic Fungicide
Active Constituent/s:	500g/L carbendazim
Applicant Name:	Masmart Pty Ltd
Applicant ACN:	001 807 441
Summary of Use:	For the control of fungal diseases in various crops
Date of Registration:	22 November 2010
Label Approval No:	65561/51293

Product Name:	Cosamil Fungicide Miticide
Active Constituent/s:	800g/kg sulfur (s) as wettable sulphur.
Applicant Name:	Sumil Chemical Industries Pvt Ltd
Applicant ACN:	N/A
Summary of Use:	For the control of certain fungal diseases, mites and white louse scale in grape vines, ornamentals, pome fruit, stone fruit, citrus and vegetables as per the directions for use.
Date of Registration:	24 November 2010
Label Approval No:	65406/50848

Product Name:	Rygel ClearUp 510 Herbicide
Active Constituent/s:	510g/L glyphosate present as the isopropylamine salt
Applicant Name:	Rygel Australia Pty. Ltd.
Applicant ACN:	106 839 007
Summary of Use:	For the control of a wide range of annual and perennial weeds in a variety of situations.
Date of Registration:	24 November 2010
Label Approval No:	61509/50479

Product Name:	Pureblue Spa Protector
Active Constituent/s:	190g/L hydrogen peroxide
Applicant Name:	United Eastern Chemicals Pty Ltd
Applicant ACN:	099 897 177
Summary of Use:	For use as a spa clarifier and bactericide
Date of Registration:	25 November 2010
Label Approval No:	65577/51342

Product Name:	Trio Trifluralin 480 Herbicide
Active Constituent/s:	480g/L trifluralin
Applicant Name:	5 Heads Pty Ltd T/A Trio Manufacturing
Applicant ACN:	098 396 546
Summary of Use:	For the control of certain annual grasses and broadleaf weeds in some horticultural and agricultural crops.
Date of Registration:	25 November 2010
Label Approval No:	64509/48535

Product Name:	Naturalure* Home Garden Fruit Fly Bait Concentrate
Active Constituent/s:	0.24g/L spinosad
Applicant Name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of Use:	For the control of fruit flies on fruit and vegetables in the home garden.
Date of Registration:	25 November 2010
Label Approval No:	65685/51575

Product Name:	Pic Plus Soil Fumigant
Active Constituent/s:	847g/kg chloropicrin
Applicant Name:	Trical Incorporated
Applicant ACN:	N/A
Summary of Use:	For the control of certain soil-borne pests and diseases in agricultural soils.
Date of Registration:	30 November 2010
Label Approval No:	64383/48184

Product Name:	PQ Premium Quality No Ducks
Active Constituent/s:	23.5g/L alcohol ethoxylate, 100g/L benzalkonium chloride
Applicant Name:	Zodiac Group Australia Pty Ltd
Applicant ACN:	002 641 965
Summary of Use:	For discouraging ducks from entering swimming pools.
Date of Registration:	30 November 2010
Label Approval No:	65564/51296

Product Name:	Dairy Power Acid Liquid Detergent
Active Constituent/s:	370g/L nitric acid, 127g/L ortho phosphoric acid
Applicant Name:	Campbell Brothers Limited T/A Campbell Cleantec
Applicant ACN:	009 657 489
Summary of Use:	For use as an acid liquid detergent for milking equipment.
Date of Registration:	30 November 2010
Label Approval No:	64949/49671

Product Name:	Buzz Wipes! Insect Repellent Wipes Low Scent
Active Constituent/s:	49g/kg diethyltoluamide
Applicant Name:	Bloop Products Pty Limited
Applicant ACN:	131 296 092
Summary of Use:	For use as a personal insect repellent to repel mosquitoes and other biting insects.
Date of Registration:	01 December 2010
Label Approval No:	64424/200g/0610

4. LISTED REGISTRATIONS

No Entries

5. VARIATIONS

Product Name:	Topik 240 EC Selective Herbicide
Applicant Name:	Syngenta Crop Protection Pty Limited
Applicant ACN:	002 933 717
Summary of Variation:	To extend registration to Tasmania.
Date of Variation:	8 November 2010
Label Approval No:	49344/50572

Product Name:	Deflecta Stabilizer Antimicrobial Concrete Sealant
Applicant Name:	Vet-Ag Pathogen Control Pty Ltd
Applicant ACN:	068 618 931
Summary of Variation:	To include suppression of ' <i>Salmonella salford</i> ' and delete restraint for use in potable water supplies and additional formulation site.
Date of Variation:	9 November 2010
Label Approval No:	60195/48699

Product Name:	Permatek IM 30 Insecticide
Applicant Name:	Zelam Pty Ltd
Applicant ACN:	082 428 028
Summary of Variation:	To extend the label claims to the envelope treating of reconstituted wood-based products (RWBP) with a maximum thickness of 12.5mm in hazard class H2-after the wood product had been manufactured and the envelope treating of solid dimensional timber, both for the control of termites and other wood boring insects in the hazard class H2F.
Date of Variation:	29 November 2010
Label Approval No:	54645/48472

6. RESTRICTED PRODUCT VARIATION

No Entries

Veterinary Chemical Products

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 registration in respect of the following products, with effect from the dates shown.

7. RESTRICTED PRODUCT

No entries

8. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

No entries

9. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name:	Elanco Component TE-S Growth And Finishing Implants For Steers
Active Constituent/s:	Each pellet contains: 140mg trenbolone acetate, 28mg oestradiol
Applicant Name:	Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd
Applicant ACN:	000 233 992
Summary of Use:	For improved growth promotion and finishing in steers.
Date of Registration:	18 November 2010
Label Approval No:	65449/50957

Product Name:	Holistic Select Small & Mini Breed Nourish Puppy Health Anchovy, Sardine & Chicken Meals Recipe																														
Active Constituent/s:	Containing: <table border="0"> <tr> <td>Omega 3 Fatty Acid</td> <td>Min</td> <td>0.6%</td> </tr> <tr> <td>Omega 6 Fatty Acid</td> <td>Min</td> <td>3%</td> </tr> <tr> <td>Glucosamine Hydrochloride</td> <td>Min</td> <td>41mg/cup</td> </tr> <tr> <td>Lactic Acid</td> <td></td> <td>240 million CFU/LB</td> </tr> <tr> <td>Amylase</td> <td></td> <td>5 Dextrin Units/LB</td> </tr> <tr> <td>Cellulase</td> <td>100 Cellulase Units/LB</td> <td></td> </tr> <tr> <td>Protease</td> <td></td> <td>280 HUT/LB</td> </tr> <tr> <td>Carotene-Beta</td> <td>Min</td> <td>5 mg/kg</td> </tr> <tr> <td>Carnitine –I</td> <td>Min</td> <td>5 mg/kg</td> </tr> <tr> <td>Total Bacillus Organisms</td> <td></td> <td>7 million CFU/LB</td> </tr> </table>	Omega 3 Fatty Acid	Min	0.6%	Omega 6 Fatty Acid	Min	3%	Glucosamine Hydrochloride	Min	41mg/cup	Lactic Acid		240 million CFU/LB	Amylase		5 Dextrin Units/LB	Cellulase	100 Cellulase Units/LB		Protease		280 HUT/LB	Carotene-Beta	Min	5 mg/kg	Carnitine –I	Min	5 mg/kg	Total Bacillus Organisms		7 million CFU/LB
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Carotene-Beta	Min	5 mg/kg																													
Carnitine –I	Min	5 mg/kg																													
Total Bacillus Organisms		7 million CFU/LB																													
Applicant Name:	Eagle Pack Pet Food Pty Ltd																														
Applicant ACN:	107 481 783																														
Summary of Use:	Puppy pet food for small and mini breeds of dogs containing glucosamine, direct fed microbes and enzymes.																														
Date of Registration:	18 November 2010																														
Label Approval No:	63687/46276																														

Product Name:	Feline Holistic Select Radiant Adult Health Anchovy, Sardine & Salmon Meal Recipe
Active Constituent/s:	Omega 3 Fatty Acid Min 1.3% Omega 6 Fatty Acid Min 3.3% Taurine Min 0.17% Glucosamine Hydrochloride Min 41mg/cup Lactic Acid 240 million CFU/LB Amylase5 Dextrin Units/LB Cellulase 100 Cellulase Units/LB Protease 280 HUT/LB Carotene-Beta 5 mg/kg Total Bacillus Organisms 7 million CFU/LB.
Applicant Name:	Eagle Pack Pet Food Pty Ltd
Applicant ACN:	107 481 783
Summary of Use:	Pet food for normal adult cats containing glucosamine, direct fed microbes and enzymes.
Date of Registration:	19 November 2010
Label Approval No:	63704/46292
Product Name:	Netvax Vaccine For Poultry
Active Constituent/s:	4TCP U/mL clostridium perfringens type A alpha toxoid, 0.31mL light mineral oil per dose, 0.035-0.05mg thiomersal per dose.
Applicant Name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of Use:	For the active immunisation of broiler breeder birds to provide passive immunity in the progeny as an aid in the control of mortality and lesions caused by Clostridium perfringens Type A induced necrotic enteritis.
Date of Registration:	19 November 2010
Label Approval No:	62842/44103
Product Name:	M+PAC Mycoplasma Hypopneumoniae Inactivated Vaccine for Pigs
Active Constituent/s:	End of shelf life (EOSL) 1RP unit mycoplasma hypopneumoniae strain j
Applicant Name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of Use:	As an aid in the prevention of Mycoplasma hypopneumoniae induced pneumonia in pigs.
Date of Registration:	23 November 2010
Label Approval No:	62077/42286
Product Name:	Protrace Multi Combination Copper, Cobalt And Selenium Capsules For Cattle
Active Constituent/s:	Each 112g capsule contains 6.3g cobalt oxide, 16.8g copper (as copper oxide), 6g selenium (elemental)
Applicant Name:	Agvantage Pty Ltd
Applicant ACN:	097 970 280
Summary of Use:	For the treatment and prevention of copper, cobalt and selenium deficiencies and the treatment of responsive conditions in cattle over 200kg bodyweight.
Date of Registration:	24 November 2010
Label Approval No:	62946/44374

Product Name:	RWR Glucosamine IV Injection
Active Constituent/s:	200mg/mL glucosamine hydrochloride
Applicant Name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of Use:	For use in selected cases to help improve joint function in horses.
Date of Registration:	24 November 2010
Label Approval No:	64585/48712

Product Name:	Prid Delta 1.55g Vaginal Delivery System
Active Constituent/s:	1.55g per device progesterone
Applicant Name:	Ceva Sante Animale S.A.
Applicant ACN:	N/A
Summary of Use:	For the control of oestrus in heifers and cows.
Date of Registration:	25 November 2010
Label Approval No:	64665/48902

Product Name:	Holistic Select Radiant Adult Health Lamb Meal Recipe
Active Constituent/s:	Omega 3 Fatty Acids Min 0.5% Omega 6 Fatty Acids Min 2.3% Taurine Min 11% Glucosamine Hydrochloride 41mg/cup Amylase 5.DXU/LB Cellulase 100CU/LB Protease 280HUT/LB Carotene-Beta 5mg/kg Total Bacillus Organisms 7 million CFU/LB Total Lactic Acid Producing Organisms 240 million CFU/LB
Applicant Name:	Eagle Pack Pet Food Pty Ltd
Applicant ACN:	107 481 783
Summary of Use:	Adult dog pet food for normal mature dogs containing glucosamine, direct fed microbes and enzymes.
Date of Registration:	26 November 2010
Label Approval No:	63693/4682

Product Name:	Eagle Pack Natural Dog Food Fortified With Vitamins And Minerals Reduced Fat Adult
Active Constituent/s:	Crude Protein Min 20% Crude Fat Max 11.0% Crude Fiber Max 4.3% Moisture Max 10% Calcium Min 1.0% Phosphorus Min 0.8% Vitamin A Min 22000 IU/kg Vitamin E Min 165 IU/kg Ascorbic Acid (Vitamin C) Min 30 mg/kg Omega 6 Fatty Acids Min 1.8% Omega 3 Fatty Acids Min 0.4% Total Lactic Acid Producing Organisms 240 million CFU/LB Total Bacillus Organisms 7 million CFU/LB Protease 280 HUT/LB Cellulase 100 Cellulase Units/LB Amylase 5 Dextrin Units/LB
Applicant Name:	Eagle Pack Pet Food Pty Ltd
Applicant ACN:	107 481 783
Summary of Use:	Adult dog pet food for normal mature dogs containing direct fed microbes and enzymes.
Date of Registration:	29 November 2010
Label Approval No:	63689/46278

Product Name:	Holistic Select Vitalize Senior Health Chicken Meal & Rice Recipe
Active Constituent/s:	Crude Protein Min 26% Crude Fat Min 10.0% Crude Fiber Max 3.5% Moisture Max 10% Calcium Min 1.0% Phosphorus Min 0.7% Vitamin A Min 22,000 IU/kg Vitamin E Min 165 IU/kg Ascorbic Acid (Vitamin C) Min 30mg/kg Omega 6 Fatty Acids Min 2.6% Omega 3 Fatty Acids Min 0.5% Beta-Carotene Min 5.0 mg/kg L-Carnitine Min 150.0 mg/kg Taurine Min 0.11% Glucosamine Hydrochloride Min 41 mg/cup Total Lactic Acid Producing Organisms 240 million CFU/LB Total Bacillus Organisms 7 million CFU/LB Protease 280 HUT/LB Cellulase 100 Cellulase Units/LB Amylase 5 Dextrin Units/LB
Applicant Name:	Eagle Pack Pet Food Pty Ltd
Applicant ACN:	107 481 783
Summary of Use:	Adult dog pet food for normal elderly dogs containing direct fed microbes and enzymes.
Date of Registration:	29 November 2010
Label Approval No:	63690/46270

Product Name:	Holistic Select Small & Mini Breed Radiant Adult Health Anchovy, Sardine & Chicken Meals Recipe
Active Constituent/s:	Crude Protein Min 30% Crude Fat Min 18% Crude Fiber Max 3.0% Moisture Max 10% Calcium Min 1.3% Phosphorus Min 0.85% Vitamin A Min 22,000 IU/kg Vitamin E Min 165 IU/kg Ascorbic Acid (Vitamin C) Min 30mg/kg DHA Min 0.05% Omega 6 Fatty Acids Min 3.0% Omega 3 Fatty Acids Min 0.75% Beta-Carotene Min 5.0 mg/kg L-Carnitine Min 150.0 mg/kg Taurine Min 0.11% Glucosamine Hydrochloride Min 41 mg/cup Total Lactic Acid Producing Organisms 240 million CFU/LB Total Bacillus Organisms 7 million CFU/LB Protease 280 HUT/LB Cellulase 100 Cellulase Units/LB Amylase 5 Dextrin Units/LB
Applicant Name:	Eagle Pack Pet Food Pty Ltd
Applicant ACN:	107 481 783
Summary of Use:	Pet food for small and mini breeds of dogs containing glucosamine, direct fed microbes and enzymes.
Date of Registration:	29 November 2010
Label Approval No:	63688/46277

Product Name:	Feline Holistic Select Radiant Adult Health Duck Meal Recipe
Active Constituent/s:	Omega 3 Fatty Acid Min 0.52 % Omega 6 Fatty Acid Min 3.60 % Glucosamine hydrochloride 41 mg/cup Lactic acid 240 million CFU/lb Cellulase 100 Cellulase Units/lb Protease 280 HUT/lb Carotene-beta 5.00 mg/kg Total bacillus organisms 7 million CFU/lb Amylase 5 Dextrin Units/lb
Applicant Name:	Eagle Pack Pet Food Pty Ltd
Applicant ACN:	107 481 783
Summary of Use:	Adult cat pet food for normal mature cats containing direct fed microbes and enzymes.
Date of Registration:	01 December 2010
Label Approval No:	63694/46283

Product Name:	Eagle Pack Natural Dog Food Fortified With Vitamins & Minerals Original Adult Pork Meal & Chicken Meal Formula		
Active Constituent/s:	Omega 3 Fatty Acid		Min .3%
	Omega 6 Fatty Acid		Min 3%
	Lactic acid		240 million CFU/lb
	Amylase		5 Dextrin Units/lb
	Cellulase		100 Cellulase Units/lb
	Protease		280 HUT/lb
	Total bacillus organisms		7 million CFU/lb
Applicant Name:	Eagle Pack Pet Food Pty Ltd		
Applicant ACN:	107 481 783		
Summary of Use:	Adult dog pet food for normal mature dogs containing direct fed microbes and enzymes.		
Date of Registration:	01 December 2010		
Label Approval No:	63695/46284		

10. LISTED REGISTRATIONS

No entries

11. VARIATIONS

Product Name:	CHLORASONE EYE OINTMENT
Applicant Name:	Jurox Pty Limited
Applicant ACN:	000 932 230
Summary of Variation:	Of registration to change product name from VR CHLORASONE EYE OINTMENT to CHLORASONE EYE OINTMENT.
Date of Variation:	5 November 2010
Label Approval No:	36329/51268

12. RESTRICTED PRODUCT VARIATION

No entries

NOTICE – NEW AGRICULTURAL ACTIVE CONSTITUENT

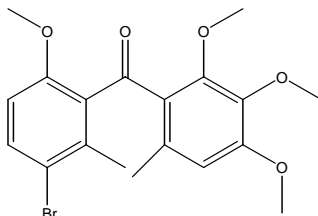
Metrafenone

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, metrafenone for use in grapevines and cucurbits for the control of powdery mildew.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	Metrafenone
IUPAC Name:	3'-Bromo-2,3,4,6'-tetramethoxy-2',6-dimethylbenzophenone
CAS Name:	(3-Bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)-methanone
CAS Registry Number:	220899-03-6
Manufacturer's Codes:	CL 375839; BAS 560 F
Minimum Purity:	975 g/kg
Molecular Formula:	C ₁₉ H ₂₁ BrO ₅
Molecular Weight:	409.280

Structure:



Chemical Family: Aryl phenyl ketone fungicides

SUMMARY OF THE APVMA'S EVALUATION OF METRAFENONE ACTIVE CONSTITUENT

The Chemistry Section of the APVMA has evaluated the chemistry aspects of active constituent metrafenone (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. Metrafenone is a new active constituent and there are no compendial specifications available for metrafenone.

On the basis of the data provided it is proposed that the following minimum compositional standard be established for metrafenone:

Constituent	Specification	Level
Metrafenone	White to beige coloured solid	Minimum 975 g/kg

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

The Office of Chemical Safety and Environmental Health of the Department of Health and Ageing has considered the toxicological aspects of metrafenone, and advised that there are no objections on human health grounds to the approval of metrafenone.

An acceptable daily intake (ADI) of 0.25 mg/kg bw/day is recommended based on a no observable effect level (NORL) of 24.9 mg/kg bw/day in a 24-month rat study and using a 100-fold safety factor. An acute reference dose (ARfD) for metrafenone has not been established, as there is no sufficient data to enable an ARfD to be set. The National Drugs and Poisons Schedule Committee (NDPSC) has agreed that (i) the benign liver tumours in metrafenone-administered mice and rats are unlikely be encountered in humans considering the proposed product use pattern, and (ii) metrafenone has low acute toxicity, it is non-irritating to eyes and skin, and has no skin sensitization potentials. Therefore, the NDPSC recommended to include metrafenone in Schedule 6, with a cut-off to Schedule 5 for preparation containing 50 percent or less of metrafenone, of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

The APVMA accepts the findings and recommendations of its advisors on these criteria.

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of **metrafenone** should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. These grounds include **chemistry and manufacture, and toxicity**. 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

- Contact name
- Company or Group name (if relevant)
- Postal Address
- Email Address (if available)
- The date you made the submission.

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

Written submissions on the APVMA's proposal to grant approval for metrafenone that relate to the **grounds for approval** should be addressed in writing to:

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

Pesticides Chemistry Evaluation Manager
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4936
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Email: john.hughes@apvma.gov.au

OTHER NOTICES

Licensing of Veterinary Chemical Manufacturers

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.

1. NEW LICENCES

**BIOTEST LABORATORIES
PTY. LTD.**

ACN: 010 924 571

2 Darnick Street

UNDERWOOD QLD 4119

LICENCE NO: 1089

Product Types:*

- *Category 1:* Autologous equine mesenchymal stem cells from bone marrow

Step(s) of Manufacture: Quality assurance (QA) of raw materials, isolation and expansion of equine mesenchymal stem cells from bone marrow, microbiological reduction treatment (filtration), aseptic filling, packaging, secondary labelling, storage and release for supply.

Licence Issued: 20/10/2010

With special conditions

* 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

AGRICURE PTY. LTD.**LICENCE NO:** 2161**ACN:** 000 178 790

End Gantry Place

Braemar

Via MITTAGONG NSW 2575

Product Types: *

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

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

Amended Licence Issued: 12/10/2010

Changes to licence scope.

AUSVETLAB PTY LTD**LICENCE NO:** 1063**ACN:** 001 611 516

Kays Lane

ALSTONVILLE NSW 2477

Product Types: *

- *Category 1:* (Immunobiologicals and sterile products) – Immunobiologicals (tick antiserum), Immunobiologicals (snake antivenoms)

Step(s) of Manufacture: Quality assurance (QA) of raw materials, serum collection, management and immunisation of donor animals, formulation including blending, aseptic filling, sterilisation (heat and filtration), microbiological reduction treatment (heat and filtration), packaging, labelling, analysis and testing (physical), storage and release for supply.

Amended Licence Issued: 12/10/2010

Addition of licence condition.

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

**ENSIGN LABORATORIES
PROPRIETARY LIMITED****ACN:** 004 395 242

490-500 Wellington Road

MULGRAVE VIC 3170

LICENCE NO: 2040**Product Types: ***

- *Category 2:* Sprays, suspensions and liquids
- *Category 3:* Liquids and sprays
- *Category 4:* Premixes and supplements

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, sachet packaging, labelling, aerosol filling from bulk, analysis and testing (physical, chemical and microbiological), storage and release for supply.

Amended Licence Issued: 22/10/2010

Change to licence scope, change to key personnel.

3. LICENCE CANCELLATIONS

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

**RTH SCIENTIFIC SERVICES
PTY LTD****ACN:** 112 358 915

47 Oak Place

MACKENZIE QLD 4156

LICENCE NO: 2185**Date Cancelled:** 21/10/2010**Reason for Cancellation:** S127 (1) (d)**4. LICENCE SUSPENSIONS**

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

Nil

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

5. REVOCATION OF LICENCE CANCELLATION

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

Nil

6. REVOCATION OF LICENCE SUSPENSION

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

Nil

APVMA CONTACT

Dounia Houzaife
GMP Officer
Manufacturing Quality and Licensing Section
Australian Pesticides and Veterinary Medicines Authority
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KINGSTON ACT 2604

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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*

Application Summaries

The APVMA publishes complete application summaries on the APVMA website, www.apvma.gov.au. They are published in weekly instalments using the date the application was accepted for assessment. If an application summary has been amended, the APVMA will publish the amended version on the website and list it separately in the APVMA Gazette Notice for Application Summaries.

As a requirement of Regulations 8C and E of the Agvet Code, some product names will appear as 'NOT AVAILABLE'.

A summary will be removed from the website 28 days after the application has been finalised. Therefore, some summaries published in this notice may have already been removed prior to the Gazette being published.

APPLICATION SUMMARIES PUBLISHED SINCE THOSE PUBLISHED IN APVMA GAZETTE NO. 22, 23 NOVEMBER 2010.

Application No.	Name
49649	NOT AVAILABLE
49936	CHICK-SAN CRESOL
50443	AQUA-HEALTH CONCIDE ALGAECIDE
50557	RONOZYME NP (L)
50602	NUFARM FILAN FUNGICIDE
50637	PREDDY GRANULES ORAL ANTI-INFLAMMATORY, ANTI-ALLERGY, ANTI-PRURITIC AGENT FOR HORSES
50710	SULFOSULFURON
50790	EMAMECTIN BENZOATE
50797	TASER PRO 125 SC INSECTICIDE
50912	THIFENSULFURON-METHYL
50980	GENFARM PANZER 680 DRY HERBICIDE
51112	METACAM 2.5 MG CHEWABLE TABLETS FOR DOGS
51117	METACAM 1 MG CHEWABLE TABLETS FOR DOGS
51149	SANONDA HERBICIDE DIURON 900WG
51150	SANONDA HERBICIDE PARAQUAT 250SL
51206	PRO STICKUP SPRAY ADJUVANT
51207	TRIO CHARGEUP SPRAY ADJUVANT
51274	RAINBOW CHLORPYRIFOS 500 INSECTICIDE
51408	CHOICE CLODINAFOP 240EC HERBICIDE
51436	INTERNATIONAL INTERSPEED 642 TIN FREE ANTIFOULING TOPCOAT

Application No.	Name
51449	FARMALINX MEPIDEF COTTON GROWTH REGULANT
51475	NOT AVAILABLE
51490	IMIDACLOPRID
51542	BLACK FLAG DO-IT-YOURSELF CONTROL BOMB INSECT KILLER
51558	BLACK FLAG AUTOMATIC OUTDOOR INSECT CONTROL SYSTEM
51561	HEARTGARD 30 PLUS (IVERMECTIN/PYRANTEL) CHEWABLES EACH CHEWABLE CONTAINS 272UG IVERMECTIN AND 227MG PYRANTEL (AS EMBONATE SALT)
51626	NUFARM FENITROTHION 1000 INSECTICIDE
51677	PACIFIC DIFLUFENICAN 500 SC SELECTIVE HERBICIDE
51708	FARMOZ SOPRANO FUNGICIDE
51714	TITAN THIDIAZURON + DIURON COTTON DEFOLIANT
51717	AW ETHEPHON GROWTH REGULATOR
51719	AW THIDIAZURON SC COTTON DEFOLIANT
51731	OPAL PIC-M HERBICIDE
51759	KILLS FAST! WOOLWORTHS SELECT FAST KNOCKDOWN INSECT SPRAY
51795	RAINBOW QUIZALOFOP-P-ETHYL 200 EC SELECTIVE HERBICIDE
49007	FOSTERRA PARAQUAT / DIQUAT HERBICIDE
49125	SYKES BIG L WORM DRENCH FOR SHEEP & CATTLE
49937	CHICK-SAN FORMALIN
50079	PROPICONAZOLE
50138	SAGEWASH SANITIZER
50185	NO ROT GEL INDUSTRIAL
50374	VAPORMATE FUMIGANT
50731	FLAZASULFURON
50734	FIPRONIL
50808	RHYME INSECTICIDE
50816	AMISTAR TOP FUNGICIDE
50844	IMTRADE BIFENTHRIN ULTRA 400 EC TERMITICIDE & INSECTICIDE
51013	NOT AVAILABLE
51130	BULLDOCK DUO INSECTICIDE

Application No.	Name
51133	BUCTRIL MA SELECTIVE HERBICIDE
51350	NOT AVAILABLE
51351	NOT AVAILABLE
51352	NEMESIS TERMITE BAIT
51355	THISTLE-KILLEM 750 SELECTIVE HERBICIDE
51553	BLACK FLAG DO-IT-YOURSELF OUTDOOR & INDOOR SURFACE SPRAY HOUSEHOLD PROTECTION
51554	BLACK FLAG AUTOMATIC INDOOR INSECT CONTROL SYSTEM
51574	RENTOKIL LABYRINTH TERMITE BAIT
51628	BARMAC OUT OF BOUNDS INSECTICIDE AND TERMITICIDE
51631	DISECT 100 EC INSECTICIDE/MITICIDE
51674	PACIFIC TRICLOPYR 600 HERBICIDE
51679	PACIFIC PARAQUAT 250 HERBICIDE
51738	IMTRADE REGAL 800 WG INSECTICIDE
51779	SABERO ACEPHATE 970SG INSECTICIDE
51792	RAINBOW PLANT GROWTH REGULATOR
51794	RAINBOW SULFOMETURON 750 WG HERBICIDE
51799	RAINBOW TRIFLURALIN-ORYZALIN 250 EC SELECTIVE HERBICIDE
51868	CROP CARE MIDAS HERBICIDE FOR CLEARFIELD WHEAT

A change or correction has been made to the following summaries:

Application No.	Product/Active Constituent Name
46493	FIPFORCE AQUA TERMITICIDE

APVMA CONTACT

For further information please contact:

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Amendments to the MRL Standard

AMENDMENT NO. 6N

The Australian Pesticides and Veterinary Medicines Authority (APVMA) sets maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. These MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. At the same time the APVMA is satisfied, from dietary exposure assessment, that the levels are not an undue hazard to human health.

The MRL Standard lists MRLs of substances which may arise from the approved use of those substances or other substances, and provides the relevant residue definitions to which these MRLs apply.

The evaluation process takes into account studies on chemistry, metabolism, analytical methodology, residues, good agricultural practice, toxicology and dietary exposure. From time to time the evaluation process results in amendments to the MRL Standard. It should be noted that relevant MRLs are referred to Food Standards Australia New Zealand for incorporation into Standard 1.4.2 of the Food Standards Code entitled "Maximum Residue Limits".

Note: "*" denotes that the maximum residue limit (MRL) has been set at or about the limit of analytical quantitation (see: Residue Guideline No.4, *Maximum Residue Limit Proposals 'At or about the Limit of Analytical Quantitation'*, published in NRA Gazette No.9, p44, 5/9/95).

'T' denotes that the MRL, residue definition or use is temporary to enable further experimental work to be carried out in Australia or overseas, and will be reconsidered at some future date.

The MRL Standard is also accessible via the APVMA website, www.apvma.gov.au

TABLE 1: MAXIMUM RESIDUE LIMITS OF PESTICIDES, AGRICULTURAL CHEMICALS, FEED ADDITIVES, VETERINARY MEDICINES AND ASSOCIATED SUBSTANCES IN FOOD COMMODITIES

Residues of substances which may occur in food commodities and for which the following maximum residue limits (MRLs) apply.

COMPOUND	FOOD	MRL (mg/kg)
Carbaryl		
DELETE:		
GC 0080	Cereal grains	T5
SO 0691	Cotton seed	1
ADD:		
GC 0640	Barley	15
GC 0080	Cereal grains [except Barley and Sorghum]	5
SO 0691	Cotton seed	3

COMPOUND	FOOD	MRL (mg/kg)
GC 0651	Sorghum	10
Prohexadione-calcium		
ADD:		
FS 0013	Cherries	*0.01

TABLE 4: MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN ANIMAL FEED COMMODITIES

Residues of substances which may occur in animal feed commodities and for which the following maximum residue limits (MRLs) apply.

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Carbaryl		
DELETE:		
AF 0080	Forage of cereal grains	T100
AS 0081	Straw and fodder (dry) of cereal grains	T100
ADD:		
AF 0080	Forage of cereal grains	100
	Grass pastures	400
AS 0162	Hay or fodder (dry) of grasses	300
	Legume forage	400
	Legume fodder	100
AM 0165	Miscellaneous fodder and forage crops	300
	Sorghum bran	20
AS 0081	Straw and fodder (dry) of cereal grains	100
Terbutylazine		
DELETE:		
	Canola fodder (dry)	*0.05
	Canola forage (green)	5
ADD:		

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
	Rape seed [canola] fodder	0.5
	Rape seed [canola] forage	5

TABLE 5: USES OF SUBSTANCES WHERE MAXIMUM RESIDUE LIMITS ARE NOT NECESSARY

SUBSTANCE	USE
ADD:	
S-Abscisic acid	For use on grapevines to accelerate or increase the colouration of berries

APVMA CONTACT

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