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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.

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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.

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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. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name: GP Flupropanate Granular Herbicide

Active Constituent/s: 86.9g/kg Flupropanate present as the Sodium Salt

Applicant Name: Granular Products Pty Ltd

Applicant ACN: 110 555 952

Summary of Use: For the control of serrated tussock and certain other grass weeds in pastures and non-crop

situations.

Date of Registration: 24 May 2011 Label Approval No: 61689/41383

Product Name: Ozcrop Haloxyfop 520 EC Herbicide

Active Constituent/s: 520g/L haloxyfop present as the haloxyfop-r methyl ester

Applicant Name: CMS Trade Pty Ltd

Applicant ACN: 086 927 157

Summary of Use: For use in grain legume and oilseed crops, lucerne, medic and clover pasture and seed

crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical

fruit and nut crops to control annual and perennial grass weeds.

Date of Registration: 25 May 2011 Label Approval No: 65912/52282

Product Name: Omni Algistop Algaecide

Active Constituent/s: 400g/L Benzalkonium Chlorine present as Alkyl Dimethylbenzlammonium Chloride.

Applicant Name: Chemtura Australia Pty Ltd

Applicant ACN: 005 225 507

Summary of Use: For control of algae in swimming pools.

Date of Registration: 25 May 2011 Label Approval No: 65818/52096

Product Name: ProGuard Dichlor Granules Pool Sanitiser

Active Constituent/s: 560g/kg chlorine present as sodium dichloroisocyanurate dihydrate

Applicant Name:2 Chemtura Australia Pty Ltd

Applicant ACN: 005 225 507

Summary of Use: For the control of algae and bacteria in swimming pools.

Date of Registration: 25 May 2011 Label Approval No: 66131/52789 Product Name: Hy-Clor Hy-Tech Long Lasting Swimming Pool Tablets Active Constituent/s:

850g/kg Chlorine present as Trichloroisocyanuric Acid

Hy-Clor (Australia) Pty Ltd Applicant Name:

000 655 381 Applicant ACN:

Summary of Use: For the control of algae and bacteria in outdoor swimming pools.

Date of Registration: 25 May 2011 Label Approval No: 66189/52955

Product Name: Ravensdown Oat-X Herbicide

Active Constituent/s: 60g/L Cloquintocet-Mexyl, 240g/L Clodinafop-Propargyl.

Applicant Name: Ravensdown Fertiliser Co-Operative Limited

Applicant ACN: 128 889 814

Summary of Use: For the control of Wild Oats, Paradoxa grass (Annual Phalaris), Canary Grass and Annual

Ryegrass in Wheat.

Date of Registration: 25 May 2011 Label Approval No: 66092/52711

Product Name: Tyrant 500 Fungicide Active Constituent/s: 500g/L Propiconazole.

Applicant Name: Crop Care Australasia Pty Ltd

Applicant ACN: 061 362 347

Summary of Use: For use in a range of crops including bananas, peanuts, pineapples, stone fruit, sugarcane,

winter cereals, and turf for the control of various diseases as per the directions for use.

Date of Registration: 25 May 2011 Label Approval No: 66183/52940

Product Name: Chemtura Fix 38 Cotton Growth Regulant Active Constituent/s: 38g/L mepiquat present as the chloride

Applicant Name: Chemtura Australia Pty Ltd

Applicant ACN: 005 225 507

Summary of Use: For use in cotton to control fruiting and excessive vegetative growth.

Date of Registration: 25 May 2011 Label Approval No: 66201/52981

Product Name: Aako Tepee 240 SL Herbicide

Active Constituent/s: 240g/L Imazapic as the Ammonium Salt

Aako Australia Pty Limited Applicant Name:

122 279 109 Applicant ACN:

Summary of Use: For use in fallow situations, sugarcane and peanuts for pre-emergence control of certain

annual grasses and broadleaf weeds and early post-emergence control of certain annual grasses and broadleaf weeds in peanuts and sugarcane as specified in the directions for use.

Date of Registration: 26 May 2011 66244/53057 Label Approval No:

Product Name: Duramite Miticide
Active Constituent/s: 480g/L Bifenazate.

Applicant Name: Chemtura Australia Pty Ltd

Applicant ACN: 005 225 507

Summary of Use: For use in apples, pears, apricots, nectarines, peaches and plums to control

Two-spotted Mite, European Red Mite and Bryobia Mite.

Date of Registration: 26 May 2011 Label Approval No: 66204/52987

Product Name: Promalin Plant Regulator Solution

Active Constituent/s: 19g/L 6-Benzyladenine, 19g/L Gibberellin A4 and Gibberellin A7.

Applicant Name: Valent Biosciences A Div Of Sumitomo Chemical Australia

Applicant ACN: 081 096 255

Summary of Use: For improved fruit shape/typiness in apples and other uses as per the directions for use.

Date of Registration: 26 May 2011 Label Approval No: 66238/53039

Product Name: Rainbow Metolachlor 720 EC Herbicide

Active Constituent/s: 720g/kg Metolachlor

Applicant Name: Shandong Rainbow International Co., Ltd.

Applicant ACN: N/A

Summary of Use: For the control of certain annual grasses and broadleaf weeds in various crops.

Date of Registration: 26 May 2011 Label Approval No: 65863/52188

Product Name: Omni Spa Sanitising Tablets Sanitiser

Active Constituent/s: 650g/kg Bromine, 280g/kg Chlorine present as Bromo-Chloro-Dimethylhydantoin.

Applicant Name: Biolab Australia Pty Ltd

Applicant ACN: 586 695 893

Summary of Use: For the control of algae and bacteria in spas.

Date of Registration: 26 May 2011 Label Approval No: 66019/53174

Product Name: Omni Algikill Algaecide

Active Constituent/s: 40g/L Copper (Cu) present as Copper Sulfate.

Applicant Name: Biolab Australia Pty Ltd

Applicant ACN: 005 878 017

Summary of Use: For use in swimming pools to kill and control all forms of algae.

Date of Registration: 27 May 2011 Label Approval No: 66025/52499

Product Name: Titan Diclofop-Methyl 500 EC Selective Herbicide

Active Constituent/s: 500g/L Diclofop-Methyl.

Applicant Name: Titan Ag Pty Ltd
Applicant ACN: 122 081 574

Summary of Use: For post-emergent control of annual ryegrass and wild oats in wheat, barley, triticale and

cereal rye.

Date of Registration: 27 May 2011 Label Approval No: 66100/52726 Product Name: Canyon 600 WG Herbicide

Active Constituent/s: 600g/kg Metsulfuron-Methyl.

Applicant Name: Hextar Chemicals Pty Ltd

Applicant ACN: 114 525 709

Summary of Use: For the control of certain brush and broadleaf species in native pastures, rights of way,

commercial and industrial areas and for the control of certain broadleaf weeds in winter

cereal crops, grass pastures and pasture renovation.

Date of Registration: 27 May 2011 Label Approval No: 66199/52978

Product Name: DeLaval Cidisan Acid Milking Machine And Bulk Milk Tank Detergent Sanitiser

Active Constituent/s: 117g/L sulphuric acid, 214g/L phosphoric acid

Applicant Name: DeLaval Pty Ltd
Applicant ACN: 004 210 459

Summary of Use: Registration of a 214 g/L phosphoric acide and 117 g/L sulphuric acid aqueous concentrate

product for cleaning and sanitising, milk harvesting and storage equipment on Australian

dairy farms.
31 May 2011

Date of Registration: 31 May 2011 Label Approval No: 63290/45248

Product Name: Crop Care Surfact 700 Adjuviant

Active Constituent/s: 350g/L soyal phospholipids, 350g/L propionic acid

Applicant Name: Crop Care Australasia Pty Ltd

Applicant ACN: 061 362 347

Summary of Use: For use as a surfactant.

Date of Registration: 31 May 2011 Label Approval No: 66203/52985

Product Name: Ryzup SG Plant Growth Regulator Soluble Granule

Active Constituent/s: 400g/kg gibberellic acid

Applicant Name: Valent Biosciences A Div Of Sumitomo Chemical Australia

Applicant ACN: 081 096 255

Summary of Use: For use in winter dormant grass-dormant pastures to increase production.

Date of Registration: 31 May 2011 Label Approval No: 66252/53079

Product Name: Chick-San Formalin
Active Constituent/s: 400g/L formaldehyde
Applicant Name: Sopura Australia Pty Ltd

Applicant ACN: 080 038 062

Summary of Use: For use in poultry farms and hatcheries as a disinfectant.

Date of Registration: 31 May 2011 Label Approval No: 65035/49937 Product Name: Kenso Agcare Imi-Ken 200 SC Termiticide

Active Constituent/s: 200g/L imidacloprid

Applicant Name: Kenso Corporation (M) Sdn. Bhd.

Applicant ACN: N/A

Summary of Use: For use in the management of subterranean termites in a range of situations.

Date of Registration: 1 June 2011 Label Approval No: 63870/46793

REISSUE 66238

Product Name: Promalin Plant Growth Regulator Solution

Active Constituent/s: 19g/L 6-Benzyladenine, 19g/L Gibberellin A4 and Gibberellin A7.

Applicant Name: Valent Biosciences A Div Of Sumitomo Chemical Australia

Applicant ACN: 081 096 255

Summary of Use: For improved fruit shape/typiness in apples and other uses as per the directions for use.

Date of Registration: 26 May 2011 Label Approval No: 66238/53039

REISSUE - 64109

Product Name: Success Neo Insecticide
Active Constituent/s: 120g/L spinetoram

Applicant Name: Dow Agrosciences Australia Limited

Applicant ACN: 003 771 659

Summary of Use: For the control of certain insect pests in fruit, herbs, ornamentals, vegetables and forestry.

Date of Registration: 12 April 2011 Label Approval No: 64109/47522

2. VARIATIONS

Product Name: Crop Care Thiram 600 Flowable Fungicide

Applicant Name: Crop Care Australasia Pty Ltd

Applicant ACN: 061 362 347

Summary of Variation: Variation to label approval to include sunflower seeds for export only.

Date of Variation: 20 May 2011 Label Approval No: 61586/52615

Product Name: Imtrade Sodium Free Envirofume Soil Fumigant

Applicant Name: Imtrade Australia Pty Ltd

Applicant ACN: 090 151 134

Summary of Variation: Variation of registration and label approval to amend product name.

Date of Variation: 24 May 2011 Label Approval No: 55785/52748 Product Name: Agro-Essence Trifluralin 480EC
Applicant Name: Agro-Alliance (Australia) Pty Ltd

Applicant ACN: 130 864 603

Summary of Variation: Variation of registration and label approval to change the name of the product from

ALLIANCE HERBICIDE TRIFLURALIN 480EC to AGRO-ESSENCE TRIFLURALIN 480EC.

Date of Variation: 26 May 2011 Label Approval No: 64732/53448

Product Name: Agro-Essence Paraquat 250SL
Applicant Name: Agro-Alliance (Australia) Pty Ltd

Applicant ACN: 130 864 603

Summary of Variation: Variation of registration and label approval to change the name of the product from

ALLIANCE HERBICIDE PARAQUAT 250SLto AGRO-ESSENCE PARAQUAT 250SL.

Date of Variation: 26 May 2011 Label Approval No: 64731/53446

Product Name: Agro-Essence Simazine 900WG
Applicant Name: Agro-Alliance (Australia) Pty Ltd

Applicant ACN: 130 864 603

Summary of Variation: | Variation of registration and label approval to change the name of the product from

ALLIANCE HERBICIDE SIMAZINE 900WG to AGRO-ESSENCE SIMAZINE 900WG.

Date of Variation: 26 May 2011 Label Approval No: 64729/53447

Product Name: Agro-Essence 2,4-D 625SL
Applicant Name: Agro-Alliance (Australia) Pty Ltd

Applicant ACN: 130 864 603

Summary of Variation: | Variation of registration and label approval to change the name of the product from

ALLIANCE HERBICIDE 2,4-D 625SL to AGRO-ESSENCE 2,4-D 625SL.

Date of Variation: 26 May 2011 Label Approval No: 64728/53443

Product Name: Agro-Essence Glyphosate 450SL
Applicant Name: Agro-Alliance (Australia) Pty Ltd

Applicant ACN: 130 864 603

Summary of Variation: Variation of registration and label approval to change the name of the product from

ALLIANCE HERBICIDE GLYPHOSATE 450SL to AGRO-ESSENCE GLYPHOSATE 450SL.

Date of Variation: 26 May 2011 Label Approval No: 64733/53445

Product Name: Agro-Essence Clethodim 240EC
Applicant Name: Agro-Alliance (Australia) Pty Ltd

Applicant ACN: 130 864 603

Summary of Variation: Variation of registration and label approval to change the name of the product from

ALLIANCE HERBICIDE CLETHODIM 240EC to AGRO-ESSENCE CLETHODIM 240EC.

Date of Variation: 26 May 2011 Label Approval No: 65740/53444 Product Name: Agro-Essence Atrazine 900WG
Applicant Name: Agro-Alliance (Australia) Pty Ltd

Applicant ACN: 130 864 603

Summary of Variation: Variation of registration and label approval to change the name of the product from

ALLIANCE ATRAZINE 900WG to AGRO-ESSENCE ATRAZINE 900WG.

Date of Variation: 26 May 2011 Label Approval No: 65181/53442

Product Name: Tussock Herbicide
Applicant Name: Grow Choice Pty Limited

Applicant ACN: 069 839 961

Summary of Variation: Variation of registration to change MRL of Flupropanate in milk and to amend the withholding

period.

Date of Variation: 30 May 2011 Label Approval No: 51909/48606

Product Name: Kenso Agcare Para-Ken 250 Herbicide
Applicant Name: Kenso Corporation (M) Sdn. Bhd.

Applicant ACN: N/A

Summary of Variation: To add an additional pack size (1000L) and update storage and disposal instructions.

Date of Variation: 30 May 2011 Label Approval No: 56102/53089

Product Name: Lorox Linuron Flowable Herbicide

Applicant Name: Tessenderlo Kerley, Inc

Applicant ACN: N/A

Summary of Variation: To change product name from LINURON FLOWABLE HERBICID to LOROX LINURON

FLOWABLE HERBICIDE.

Date of Variation: 01 June 2011 Label Approval No: 60490/52311

Product Name: Lorox Linuron DF Herbicide
Applicant Name: Tessenderlo Kerley, Inc

Applicant ACN: N/A

Summary of Variation: To change product name from LINURON DF HERBICIDE to LOROX LINURON DF

HERBICĬDĖ.

Date of Variation: 01 June 2011 Label Approval No: 60222/52310

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.

3. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Product Name: Buzz Off Antiseptic & Fly Repellent Cream

Active Constituent/s: 8.3g/kg n-octyl bicycloheptene dicarboximide, 25g/kg di-n-propyl isocinchomeronate, 10g/kg

piperonyl butoxide, 66.6g/kg diethyltoluamide, 1g/kg pyrethrins

Applicant Name: Value Plus Animal Health Care Products Pty Ltd

Applicant ACN: 094 221 913

Summary of Use: Antiseptic fly and mosquito repellent for dogs, cats and horses.

Date of Registration: 20 May 2011 Label Approval No: 65155/50301

Product Name: Hill's Prescription Diet c/d Multicare Feline Bladder Health With Chicken

Active Constituent/s:

Applicant Name: Hill's Pet Nutrition Inc

Applicant ACN: N/A

Summary of Use: A complete pet diet which is intended to assist in the nutritional management of cats suffering

from Feline Lower Urinary Tract Disease (FLUTD) caused by struvite uroliths or urethral

plugs, oxalate uroliths or feline idiopathic cystitis (FIC).

Date of Registration: 23 May 2011 Label Approval No: 63669/46213

Hill's Prescription Diet c/d Multicare Feline Bladder Health With Seafood Product Name:

Active Constituent/s: N/A

Applicant Name: Hill's Pet Nutrition Inc

Applicant ACN:

A complete pet diet which is intended to assist in the nutritional management of cats suffering Summary of Use:

from Feline Lower Urinary Tract Disease (FLUTD) caused by struvite uroliths or urethral

plugs, oxalate uroliths or feline idiopathic cystitis (FIC).

23 May 2011 Date of Registration: Label Approval No: 63670/46216

Product Name: Hill's Prescription Diet D/D Canine Skin Support Salmon Formula

Active Constituent/s:

N/A

Hill's Pet Nutrition Inc Applicant Name:

Applicant ACN: N/A

Summary of Use: Registration of a therapeutic pet diet for managing symptoms of food allergies in dogs.

Date of Registration: 30 May 2011 Label Approval No: 64717/370g/0511

4. VARIATIONS

Product Name: ADAPTIL DIFFUSER
Applicant Name: Ceva Sante Animale S.A.

Applicant ACN: N/A

Summary of Variation: Variation to registered particulars to change the packaging of the product and change

product name from D.A.P. DIFFUSER DOG APPEASING PHEROMONE to ADAPTIL

DIFFUSER.

Date of Variation: 23 May 2011 Label Approval No: 59307/52264

Product Name: Hill's Prescription Diet z/d Canine Ultra Allergen-Free

Applicant Name: Hill's Pet Nutrition Inc

Applicant ACN: N/A

Summary of Variation: Variation to registration particulars to change the product name from HILL'S PRESCRIPTION

DIET CANINE Z/D ULTRA ALLERGEN-FREE to HILL'S PRESCRIPTION DIET Z/D CANINE

ULTRA ALLERGEN-FREE and variation to label approval.

Date of Variation: 27 May 2011

Label Approval No: 59791/2kg/1010, 59791/3.6kg/1010, 59791/7.98kg/1010, 59791/11.3kg/1010

Product Name: Tikdip Cattle Dip And Spray

Applicant Name: Agvantage Pty Ltd
Applicant ACN: 097 970 280

Summary of Variation: To allow use of product for tick control (three species) on cattle in WA.

Date of Variation: 30 May 2011 Label Approval No: 65721/53441

NEW VETERINARY CHEMICAL PRODUCT

Pasteurella multocida Strain PMP-1 in the product Vaxsafe PM Vaccine (living)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bioproperties Pty Ltd, for the approval of a new active constituent, *Pasteurella multocida* Strain PMP-1. The APVMA also has before it an application from the same applicant, for the registration of a new product, VAXSAFE PM VACCINE (LIVING) ('the product') containing the above active constituent. The product is to be used as an aid in the control of fowl cholera due to infection with virulent homologous and heterologous strains of *Pasteurella multocida*.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name: Pasteurella multocida Strain PMP-1

Manufacturer: Bioproperties Pty Ltd

11 Moores Rd

Glenorie NSW 2157

Potency: Manufacturer's standard

Appearance and Identity: As per European Pharmacopoeia

Sterility: As per European Pharmacopoeia

Extraneous agents: As per European Pharmacopoeia

Mycoplasma: As per European Pharmacopoeia

Gene technology: Not applicable

Mode of Action: Inducing immunological response

PARTICULARS OF THE APPLICATION

Proposed Product Name(s): VAXSAFE PM VACCINE (LIVING)

Applicant Company: Bioproperties Pty Ltd

36 Charter St

Ringwood Victoria 3134

Manufacturer: Bioproperties Pty Ltd

11 Moores Rd

Glenorie NSW 2157

Name of Active Constituent: Pasteurella multocida Strain PMP-1

Adjuvant: NIL

Signal Heading: Schedule 0

Summary of Proposed Use: As an aid in the control of fowl cholera due to infection with virulent

homologous and heterologous strains of Pasteurella multocida.

Pack Sizes: 500 dose, 1000 dose and 2000 dose- borosilicate type I neutral glass

vials.

Amounts to be administered and

route of administration:

Vaxsafe PM Vaccine (Living) should be administered to growing birds from 8-14 weeks of age at 0.2mL per dose intramuscularly. A second vaccination should be administered 4 weeks after the first vaccination. Homologous challenge: Duration of immunity has been demonstrated to be at least 26 weeks after second and final dose of Vaxsafe PM.

Heterologous challenge: Duration of immunity has been demonstrated to

rieterologous challenge. Duration of infinitrity has been demonstrated

at least 4 weeks after second and final dose of Vaxsafe PM

Withholding Period: Nil

SUMMARY OF THE APVMA'S EVALUATION OF VAXSAFE PM VACCINE (LIVING) IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994

The APVMA has assessed the chemistry and manufacturing aspects of *Pasteurella multocida* Strain PMP-1 and the product, including starting materials, master seed organism (source, isolation, identification, testing), culture media, vaccine production, storage, quality control and batch release analysis, and found them to meet APVMA standard. The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

The APVMA is satisfied that the proposed use of the new product VAXSAFE PM VACCINE (LIVING) containing the active constituent *Pasteurella multocida* Strain PMP-1 would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment. The excipients used in the product have been previously assessed and found to be safe. They are already present in several vaccines registered for use in Australia.

In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

FUTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Consultation' section, www.apvma.gov.au or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for the approval for the active constituent **PASTEURELLA MULTOCIDA STRAIN**

PMP-1 and the registration of **VAXSAFE PM VACCINE (LIVING)** should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds include **occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade** and **efficacy**. 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include:

- 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 the application for registration that relate to the **grounds for registration** should be addressed in writing to:

Dr John Owusu Principal Evaluator Veterinary Medicines Program Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

Phone: (02) 6210 4736 **Fax:** (02) 6210 4741

Email: john.owusu@apvma.gov.au

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¹ A full definition of 'confidential commercial information' is contained in the HAgvet CodeH.

OTHER NOTICES

Proposal to Amend Standard 1.4.2 of the Australia New Zealand Food Standards Code

In the previous notice, the APVMA gazetted particular amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*.

Under Section 82 of the *Food Standards Australia New Zealand Act 1991* the APVMA is proposing to incorporate these variations (numbered 12N) to MRLs into Standard 1.4.2 - Maximum Residue Limits of the Australia New Zealand Food Standards Code.

MRLs contained in Standard 1.4.2 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Standard 1.4.2 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA is satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this Notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Standard 1.4.2 in the APVMA *Gazette*. The variations will take effect as from the date of that subsequent notice.

DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

Note: The following amendments are in a format that accords with the proposed amending Legislative Instrument which, in turn, has to be consistent with the existing format of Standard 1.4.2 (Maximum Residue Limits) of the *Australia New Zealand Food Standards Code*.

PROPOSED AMENDMENT NO. 12N

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunsetting.

To commence: on gazettal of variation

Standard 1.4.2 of the Australia New Zealand Food Standards Code is varied by -

1 inserting in Schedule 1 –

-	Propylene oxide Propylene oxide	
Almonds		T100

2 inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals –

Isoxaflutole		
The sum of isoxaflutole, 2-cyclopropylcarconyl-3-(2-		
methylsulfonyl-4-trifluoromethylphenyl)-3-		
oxopropanenitrile and 2-methylsulfonyl-4-		
trifluoromethylbenzoic acid expressed as isoxaflutole		
Poppy seed	*0.02	
Metosulam		
Metosulam		
Poppy seed	*0.01	

INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Standard 1.4.2 - Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

All personal and *confidential commercial information* (CCI)² material contained in submissions to the APVMA will be treated confidentially.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Standard 1.4.2' and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 12 July 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

For further information please contact:

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

Phone: (02) 6210 4837 **Fax:** (02) 6210 4840

Email: residues@apvma.gov.au

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² A full definition of "confidential commercial information" is contained in the Agricultural and Veterinary Chemicals Code (Agvet Code), which is scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *MRL Standard* published by the APVMA. The *MRL Standard* lists MRLs of substances which may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, based on dietary exposure assessments and current health standards, that the limits are not harmful to public health.

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

The APVMA has varied the MRL Standard as set out below with effect from the date of this notice.

For further information please contact:

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

Phone: (02) 6210 4837 **Fax:** (02) 6210 4840

Email: residues@apvma.gov.au

AMENDMENT No. 12N, 2011

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.

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.

COMPOU	ND	FOOD	MRL (mg/kg)
Isoxafluto	le		
ADD:			
so	0698	Poppy seed	*0.02
Metosular	n		
ADD:			
so	0698	Poppy seed	*0.01
ADD:			
Propylene	oxide		
TN	0660	Almonds	T100

TABLE 3: RESIDUE DEFINITION

Where MRL(s) are recommended, the following residue definitions are applicable.

COMPOUND	RESIDUE
ADD:	
Propylene oxide	{T} Propylene oxide

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)
Flutriafol		
DELETE:		
AF 0081	Forage of cereal grains	3
AS 0081	Straw and fodder (dry) of cereal grains	2
ADD:		
	Forage and fodder of cereal grains	3
	Straw of cereal grains	2

Cancellation of Product Registration at the Request of the Registrant

At the request of the registrant, the APVMA has cancelled the registration and the associated label approval(s) of the following product(s):

Product No.	Product Name	Registrant	Date of Effect
46375	OLD TIMER'S WHITE SALVE	VIRBAC (AUSTRALIA) PTY LDT	19 MAY 2013
	ZINC AND CASTOR OIL		
	EMOLLIENT FOR HORSES		

The following instructions set out how a person can deal with the cancelled product(s).

SUPPLY

A person may supply or cause to be supplied product(s) manufactured prior to 19 May 2011 at wholesale and retail level, until the 19 May 2013.

After 19 May 2013 it will be an offence against the Agvet Codes to have possession or custody of the product(s) with the intention to supply, or to supply the product(s).

USE

A person may continue to use the product(s) according to its label instructions until 19 May 2013.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product(s) in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product after the registration has been cancelled until 19 May 2013.

The supply and use of the product(s) must be in accordance with the conditions of registration, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product listed in the table in a manner that contravenes the above instructions.

APVMA CONTACT

For any enquiries or further information about this matter, please contact:

Chemical Review/AERP Contact Officer Pesticides Program Australian Pesticides and Veterinary Medicines Authority PO Box 6182

SYMONSTON ACT 2609 **Phone:** (02) 6210 4749 **Fax:** (02) 6210 4840

Email: chemicalreview@apvma.gov.au

Addendum to the Record of Approved Active Constituents

The current *Record of Approved Active Constituents for Registered Chemical Products* is also accessible from the APVMA website, www.apvma.gov.au

APPROVED SINCE GAZETTE NO. 2, FEBRUARY 1 2011

For use in agricultural and/or veterinary chemical products:

Common Name	Approval Holder	Manufacturer Site	Approval No
Sulfosulfuron	MONSANTO AUSTRALIA LTD	SUMITOMO CHEMICAL COMPANY LTD OITA WORKS 2200 TSURUSAKI, OITA-CITY OITA 870-0106 JAPAN	65330
Mancozeb	SINON AUSTRALIA PTY LIMITED	SINON CORPORATION 65333 NO 111, CHUNG SHAN RDTA-TU HSIANGTAICHUNG HSIEN 432 TAIWAN	
Glyphosate	AGROSHINE AUSTRALIA PTY LTD	CHONGQING PESTICIDE & CHEMICAL INDUSTRY (GROUP) CO, LTD NO. 30 JING JI QIAO, JING KOU SHAPINGBA DISTRICT CHONGQING, CHINA	
Chlormequat chloride	TAMINCO NV AUSTRALIA	TAMINCO N.V 66342 PANTSERSCHIPSTRAAT 207B-9000 GENT BELGIUM	
Fenbuconazole	DOW AGROSCIENCES AUSTRALIA LIMITED	DECCAN FINE CHEMICALS (INDIA) PRIVATE LIMITED PLOT NO. 74 A ROAD NO:9, JUBILEE HILLS HYDERABAD- 500 033 INDIA	
Diuron	SHARDA WORLDWIDE EXPORTS PVT LTD	NINGXIA SANXI CHEMICAL CO., LTD 65351 FINE INDUSTRIAL PARK PINGLUO NING XIAPR CHINA	
Thifensulfuron-methyl	DU PONT (AUSTRALIA) LTD	DUPONT AGRICULTURAL CHEMICALS LTD 65432 SHANGAI (DUPAC), 3055 PUDONG BEI LUPUDON SHANGAI 200137 PR CHINA	
Metham-sodium	NUFARM AUSTRALIA LIMITED	TAMINCO N.V. PANTSERSCHIPSTRAAT 207B-9000 GENT BELGIUM	66259

APVMA CONTACT

For further information please contact:

Application Management & Enquiries Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

Phone: (02) 6210 4701 **Fax:** (02) 6210 4721

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. 10, 20 MAY 2011.

Application No.	Name
50205	DAVID GRAYS TOMATO DUST 3 IN 1
49523	MAESTRO CRACK AND CREVICE PROFESSIONAL AEROSOL SPRAY
49524	SUMIBLAST WATER-BASED AEROSOL 2.5/2.5 HOUSEHOLD INSECT RESIDUAL SPRAY
50591	NOT AVAILABLE
51460	PROTECTANT TERMITE BARRIER
51832	BOB MARTIN SINCE 1892 FLEA RID FOR LARGE DOGS SPOT ON
51834	BOB MARTIN SINCE 1892 FLEA RID FOR SMALL DOGS AND PUPPIES SPOT ON
52214	4FARMERS FIPRONIL 800 WDG
52301	CALTEX SUMMER SPRAY OIL
52780	TRIPLE TIME HERBICIDE
52790	CAMPBELL CHEERS 500SC FLOWABLE FUNGICIDE
52894	KENSO AGCARE KEN-PAM 423 FUMIGANT
52946	NOT AVAILABLE
53033	RODENTHOR BLOCK RODENTICIDE
53081	COUNTRY CHLORPYRIFOS 500 INSECTICIDE
53089	KENSO AGCARE PARA-KEN 250 HERBICIDE
53090	KENSO AGCARE SPEEDY 250 HERBICIDE
53173	AGRISMART AMMONIUM SULPHATE SPRAY GRADE
53220	AMGROW ORGANIX WEED BLITZ READY TO USE
53391	AGSPRAY ATRAZINE 900 WDG HERBICIDE
51590	VIRKILL PLUS (+)

Application No.	Name
53016	ZODIAC EZY PURIFIER EASY TO USE BUILT IN WATER CONDITIONER UV BLOCKOUT FOR LONGER LASTING PROTECTION CONTROLS BACTERIA, VIRUSES AND ALGAE IN SWIMMING POOLS THIS PRODUCT IS STABILISED TO INCREASE THE
53060	OVUPROST INJECTION
41496	BARMAC THIRAM DG FUNGICIDE
48438	YATES ZALETON DUAL ACTION SYSTEMIC FUNGICIDE
48937	PROGIBB G.A. GROWTH REGULANT
49596	4FARMERS TRIFLURALIN 600 SELECTIVE HERBICIDE
50301	NOT AVAILABLE
51658	ECOPAR FORTE HERBICIDE
52365	RAID AUTOMATIC ADVANCED INSECT CONTROL SYSTEM DO IT YOURSELF EXPERT
52557	RIZOLEX TURF FUNGICIDE
52615	CROP CARE THIRAM 600 FLOWABLE FUNGICIDE
52779	COUNTRY TRIADIMENOL 250 FUNGICIDE
52870	BLUE LINE BETTER POOL CHLORINE FAST DISSOLVING 2-IN-1 GRANULES
52871	BLUE LINE BEST POOL CHLORINE POWERFUL 5-IN-1 GRANULES
52873	BLUE LINE BEST POOL CHLORINE TABLETS CONTROLLED RELEASE 5-IN-1 TABLETS
53031	CYCOSTAT 10G
53082	ENVIROMAX IMIDACLOPRID 200SC TERMITICIDE
53096	MATTER 240EC SELECTIVE HERBICIDE
53215	CHLORASONE EYE OINTMENT
53222	AMACIN EYE & EAR OINTMENT
53234	TRICIN EYE & EAR OINTMENT
53318	AGSPRAY CHLORULFURON 750 WDG HERBICIDE
53323	AGSPRAY PROPICONAZOLE 250 EC FUNGICIDE
53390	AGSPRAY GLUFOSINATE 200 NON-SELECTIVE HERBICIDE
53397	TITAN METHAM SOIL FUMIGANT
53423	RAINBOW LVE MCPA 500 SELECTIVE HERBICIDE
53441	TIKDIP CATTLE DIP AND SPRAY
53468	HEINIGER LIQUID CARBARYL INSECT SPRAY
53500	NOT AVAILABLE

Application No.	Name
53511	MILO'S EAR CLEANSER
53525	PACIFIC ETHEPHON 720 GROWTH REGULATOR
53567	NOT AVAILABLE

APVMA CONTACT

For further information please contact:

Application Management and Enquiries Team (AME)
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