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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 Chemicals 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 & Veterinary Medicines Authority) Gazette* is published monthly and contains details of the registration of agricultural and veterinary chemical 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, web site and subscription

From November 1999, the APVMA is providing the printed version of the *APVMA Gazette* free of charge to APVMA registrants. It is also now freely available on the APVMA web site:

<http://www.apvma.gov.au>

APVMA CONTACTS

Distribution to APVMA registrants and general enquiries:

tel: 02 6210 4871

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

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New Agricultural & Veterinary Chemical Products

Copper citrate hemipentahydrate and Sodium dichloroisocyanurate in the product: BioGuard Smart Shock Pool Oxidiser

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Chemtura Australia Pty Ltd for registration of a new product containing the active constituents copper citrate hemipentahydrate and sodium dichloroisocyanurate. The product is BIOGUARD SMART SHOCK POOL OXIDISER. The product is for use as a swimming pool sanitiser and algaecide.

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 registration should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Application

Proposed product name:	BIOGUARD SMART SHOCK POOL OXIDISER
Applicant company:	Chemtura Australia Pty Ltd
Name of active constituents:	copper citrate hemipentahydrate sodium dichloroisocyanurate
Signal heading:	Schedule 6
Statement of claims:	For sanitisation and control of algae in swimming pools
Pack sizes:	500g, 10kg, 20kg
Withholding period:	Not applicable

Summary of the APVMA's evaluation of BIOGUARD SMART SHOCK POOL OXIDISER 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 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:

- (i) The APVMA is satisfied that the proposed use of BIOGUARD SMART SHOCK POOL OXIDISER would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Commonwealth Department of Health and Ageing Office of Chemical Safety (OCS) has conducted a risk assessment on BIOGUARD SMART SHOCK POOL OXIDISER and concluded that it can be used safely.

BIOGUARD SMART SHOCK POOL OXIDISER is of low to moderate acute oral toxicity and low dermal toxicity. It is corrosive to the skin and eyes and is a skin sensitiser. No acute inhalational toxicity studies were provided. The main route of exposure is dermal and this route has low toxicity but is corrosive. The use of personal protective equipment (rubber gloves) during application of the product will mitigate the risk to users.

The APVMA accepts the findings and recommendations of the OCS evaluation.

The product will be formulated overseas or in Australia; repackaging may be required in Australia.

- (ii) The APVMA is satisfied that the proposed use of BIOGUARD SMART SHOCK POOL OXIDISER will not be an undue hazard to the safety of people using anything containing its residues. The product is not intended for use on food commodities that may be consumed by humans.
- (iii) The APVMA is satisfied that the proposed use of the BIOGUARD SMART SHOCK POOL OXIDISER is not likely to be harmful to human beings if used according to the product label directions.

The active constituents have been evaluated and approved and the product is included in Schedule 6. The appropriate Signal Heading is on the label. First Aid and Safety Directions for copper citrate hemipentahydrate and sodium dichloroisocyanurate have been recommended by the Commonwealth Department of Health and Ageing Office of Chemical Safety and have been included on the label.

The APVMA accepts the findings and recommendations of its advisers on this criteria.

- (iv) **The APVMA is satisfied that the proposed use of BIOGUARD SMART SHOCK POOL OXIDISER in swimming pools is not likely to have an unintended effect that is harmful to animals, plants or the environment.**

The Commonwealth Department of the Environment and Water Resources (DEW) has assessed data in support of BIOGUARD SMART SHOCK POOL OXIDISER and believes that the application contains adequate data to demonstrate that the use of BIOGUARD SMART SHOCK POOL OXIDISER according to the label is unlikely to result in primary poisonings of wildlife, fish or other non-target organisms. Pool water is expected to be retained and not regularly replenished, so there is only limited environmental impact from use according to the label.

The APVMA accepts the findings and recommendations of its advisers on this criteria.

- (v) **The APVMA is satisfied that the proposed use of BIOGUARD SMART SHOCK POOL OXIDISER would not adversely affect trade between Australia and places outside Australia as the product is not for use on any Australian export commodities.**

In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:

- (i) The APVMA is satisfied the data from trials supporting the efficacy of BIOGUARD SMART SHOCK POOL OXIDISER adequately demonstrates that under local conditions this product is effective for the proposed use.

Submissions

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration must be received by the APVMA by 1 September 2009 and should be addressed in writing to:

Ken Young
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority

PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4763
Fax: (02) 6210 4776

Other Notices

AMENDMENT No. 2M: Amendments to the MRL Standard

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 web page.

<http://www.apvma.gov.au/residues/mrl.shtml>

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)
Abamectin		
ADD:		
FB 0264	Blackberries	T0.1
FB 0272	Raspberries, Red, Black	T0.1
Cyprodinil		
ADD:		
FB 0275	Strawberry	T5
Dimethomorph		
ADD:		
VL 0054	Brassica leafy vegetables	T2
Fludioxonil		
ADD:		
FB 0275	Strawberry	T5
Glufosinate-ammonium		
ADD:		
DH 1100	Hops, dry	T0.2
Sethoxydim		
DELETE:		
VS 0627	Rhubarb	T0.1
ADD:		
VS 0627	Rhubarb	0.1

For further information please contact:

Michelle Hemming
Residues Contact Officer
Australian Pesticides & Veterinary Medicines Authority

PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4837
Fax: (02) 6210 4840
Email: michelle.hemming@apvma.gov.au

Application Summaries

The APVMA publishes complete application summaries on the APVMA website (http://www.apvma.gov.au/data_protection/appl_summaries.shtml). 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. 7, 7th July 09

Application No.	Name
42746	WIDESTRIKE TM INSECT PROTECTION
42864	DES-O-GERM SP VEG AGRICULTURAL DISINFECTANT
43540	BLOCKADE ""TRUE BLUE"" TIMBER INSECTICIDE
45408	S-ABSCISIC ACID
46041	LOGRAN 750 WG SELECTIVE HERBICIDE
46430	YATES ZERO ONCE A YEAR PATH WEED GUN
46537	PERMA4CE 500 RESIDUAL INSECTICIDE
46657	NOT AVAILABLE
46869	TITAN TEBUTHIURON AERIAL HERBICIDE
46928	NOT AVAILABLE
46929	NOT AVAILABLE
46930	NOT AVAILABLE
47480	TITAN SULFOMETURON 750 WG HERBICIDE
47481	TITAN ETHEPHON 720 GROWTH REGULATOR
47515	TURF CULTURE TURFWETT NON-IONIC SURFACTANT
45745	PAW PURE ANIMAL WELLBEING - PAWDERM GENTLE MEDICATED SHAMPOO
45920	4 FARMERS WETTER 1000
46380	RENTOKIL GASTION PHOSPHINE FUMIGATION TABLETS
47127	VETERAN PLUS SEED TREATMENT
47297	POOL PRO STABILISED CHLORINE STICKS
47587	NOT AVAILABLE
47630	NOT AVAILABLE
47674	SPA PROTECTOR BROMINE TABLETS
44469	BARRICADE TURF HERBICIDE
45728	MUNNS LAWN GRUB & LAWN BEETLE KILLER WITH LONG LIFE ORGANICALLY
45769	ADVANCED WETA-LAWN
45769	SHARP SHOOTER ROSE BLACK SPOT & PYRETHRUM CONCENTRATE
46817	SKINTRACTION
46897	NOT AVAILABLE
47018	POOL MAGIC GRANULAR POOL CHLORINE
47022	POOL MAGIC STABILISED CHLORINE
47275	NUFARM PRISTINE FUNGICIDE
47405	NOT AVAILABLE

47531	PUREPHOS PHOSPHINE FUMIGANT
47671	AW RUFFSHOD HERBICIDE
47688	CHAINDRITE CYANOFORCE 250SC TERMITICIDE
47724	AGCP TRIFLURALIN 480 SELECTIVE HERBICIDE
41964	PROCARE VITAMIN B12 INJECTION
44763	NOT AVAILABLE
46474	OSPRAY THIRAM 600 FUNGICIDE
46900	CERLONG GRANULAR SOIL FUMIGANT
47274	NOT AVAILABLE
47391	INTAKE HILOAD GOLD IN-FURROW AND FOLIAR FUNGICIDE
47562	MONUMENT LIQUID TURF HERBICIDE
47597	MERIDIAN GR TURF INSECTICIDE
47609	DUVAXYN EHV 1,4 INACTIVATED ADJUVANTED EQUINE HERPES VACCINE
47631	FLIPPER 250 CS INSECTICIDE
47637	CONTENDER 480 SELECTIVE HERBICIDE
47676	TURF CULTURE WHITE MARKING FOAM
43493	NOT AVAILABLE
43708	IMAZAPYR
45252	SIMAZINE
45944	CEFTIOFUR STERILE POWDER FOR INJECTION
46463	FUMAPHOS FUMIGATION TABLETS
46464	FUMAPHOS FUMIGATION BLANKET
46656	PROTEC PLUS SPRAY ADJUVANT
46676	NOT AVAILABLE
46805	PROPANIL
46806	GLYPHOSATE
46808	DITHIANON
46812	GLYPHOSATE
46862	AMISTAR TOP FUNGICIDE
47161	SAKURA 850 WG HERBICIDE
47261	EPOXICONAZOLE
47289	NOT AVAILABLE
47290	NOT AVAILABLE
47291	NOT AVAILABLE
47359	PYROXASULFONE
47504	HUSSAR OD SELECTIVE HERBICIDE
47540	GAUCHO 350 FLOWABLE SEED DRESSING INSECTICIDE
47560	HEXTAR HOME GARDEN 360 WEED KILLER
47613	PORCILIS PCV VACCINE
47723	AGCP GLYPHOSATE 450 HERBICIDE
47727	AGCP ATRAZINE 900 WG HERBICIDE
47731	POOL PROTECTOR POOL SHOCK 5 IN 1 GRANULES
47732	POOL PROTECTOR POOL SHOCK 5 IN 1 TABLETS
47819	NOT AVAILABLE
47823	ZOOTER SOIL GUARD INSECTICIDE

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

Application No.	Product/Active Constituent Name
47406	NOT AVAILABLE
43866	DUPONT ADVION ANT & COCKROACH BAIT ARENA
46658	NOT AVAILABLE
45609	KLEENET 300

Contact:

Application Management and Enquiries Team (AME)
Australian Pesticides and Veterinary Medicines Authority

PO Box 6182
KINGSTON ACT 2604

Ph: 6210 4701
Fax: 6210 4721

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 issued, amended or cancelled the manufacturing licences in respect 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 web site: <http://www.apvma.gov.au>.

1. NEW LICENCES:

**EQUILIBRIUM AUSTRALIA
PTY. LTD.**

ACN: 097 190 620

Unit 5, 10-12 Glasson Drive
BETHANIA QLD 4205

Product Types:*

Category 4: Supplements

Step(s) of Manufacture:

Quality assurance (QA) of raw materials, filling, packaging, labelling, storage and release for supply.

Licence No: 4086

Full licence issued 26/06/09.

**UNIVERSITY OF NEW
ENGLAND**

ABN: 75 792 454 315

Reproductive & Metabolic
Endocrinology Laboratory
School of Science & Technology
McClymont Building
University of New England
ARMIDALE NSW 2351

Product Types:*

Category 6: Single Step

Step(s) of Manufacture:

Quality assurance (QA) of raw materials, analysis and testing (physical, chemical, pharmacological test [mouse bioassay and sheep assays for oestrus synchronisation] and immunological), storage and release for supply.

Licence No: 6142

Full licence issued 13/06/09.

* *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:

BOTANICAL INGREDIENTS PTY LTD TRADING AS: BIO-TECH FREEZE DRYING

ACN: 095 816 461
26 Parkhurst Drive
KNOXFIELD VIC 3180

Product Types:*

Category 2: Liquids (Diluents Only)

Step(s) of Manufacture:

Quality assurance (QA) of raw materials, filling, packaging, labelling, microbiological reduction treatment (filtration), analysis and testing (physical and microbiological).

Licence No: 2190

Amended licence issued 19/06/09, variation to licence conditions, variation to licence scope.

CATALENT AUSTRALIA PTY LTD

ACN: 007 219 990
217-221 Governor Road
BRAESIDE VIC 3195

Product Types:*

Category 2: Tablets and capsules

Category 4: Supplements

Step(s) of Manufacture:

Quality assurance (QA) of raw materials, formulation including blending, premixing in powder or granular form, filling, packaging, labelling, strip, blister or sachet packaging, soft gelatine capsule manufacture, tableting, tablet coating, hard-shell capsule manufacture, analysis and testing (chemical), storage and release for supply.

Licence No: 2059

Amended licence issued 05/06/09, change to key personnel, change to company name and addition of steps.

C M LABORATORIES PTY LTD

ACN: 098 897 637
3-4/36 Curtis Road
MULGRAVE NSW 2756

Product Types:*

Category 2: Creams, lotions, ointments, pastes, powders, sprays 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, filling, packaging, labelling, analysis and testing (physical), storage and release for supply.

Licence No: 2150

Amended licence issued 26/6/09, addition of licence step.

EQUIVET PTY. LIMITED

ACN: 003 837 492
37 Lord Fury Court
DARLING DOWNS WA 6122

Product Types:*

Category 2: Pastes and powders

Step(s) of Manufacture:

Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, storage and release for supply.

Licence No: 2034

Amended licence issued 02/06/09, change to licence format, addition of step and change to licence condition.

* *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

FORT DODGE AUSTRALIA PTY LIMITED
ACN: 000 074 902
2152 Castlereagh Road
PENRITH NSW 2750

Product Types:*

Category 1: Immunobiologicals and sterile products

Category 2: Liquids

Step(s) of Manufacture:

Quality assurance (QA) of raw materials, bacterial fermentation, formulation including blending, filling, aseptic filling, sterilisation (heat, filtration), microbiological reduction treatment (heat, filtration, chemical), packaging, labelling, analysis and testing (physical, chemical, Limulus Amoebocyte Lysate test [LAL], microbiological, sterility test, serological, immunological), storage, and release for supply.

Licence No: 1005

Amended licence issued 17/06/09, change to licence conditions.

NATIONAL CHEMICAL PTY LTD
ACN: 077 738 740
262 Evans Road
SALISBURY QLD 4107

Product Types:*

Category 2: Creams/lotions, ointments, pastes, sprays, liquids.

Category 3: Liquids, pastes, sprays.

Step(s) of Manufacture:

Formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, analysis and testing (physical only), storage and release for supply.

Licence No: 2155

Amended licence issued 29/06/09, change to key person and change to licence conditions.

NORTHERN SERUMS PTY LTD
ACN: 003 809 318
1295 Hogarth Range Road
HOGARTH RANGE NSW 2469

Product Types:*

Category 1: Immunobiologicals (tick antiserum)

Step(s) of Manufacture:

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

Licence No: 1058

Amended licence issued 16/06/09, change to licence format, addition of steps and change to licence 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

3. LICENCE CANCELLATIONS:

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

ANADIS LIMITED

ACN: 063 114 045

4 Capital Link Drive

CAMPBELLFIELD VIC 3061

Licence No: 4075

Cancelled: 18/06/09

Reason for cancellation: s127 (1)(e)

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

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:

Michelle Elliott

GMP Section

Veterinary Medicines Program

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

Ph: (02) 6210 4745

Fax: (02) 6210 4813

Email: Michelle.Elliott@apvma.gov.au

* *Category 1:* Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: One-step manufacturer