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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

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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:	Omni Advantage Clear Pool Sanitiser
Active Constituent/s:	560g/kg chlorine present as sodium dichloroisocyanurate dihydrat
Applicant Name:	Chemtura Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of Use:	For the control of algae and bacteria in swimming pools (with stabiliser).
Date of Registration:	5 May 2011
Label Approval No:	65852/52176

Product Name:	Rainbow Mepiquat Plant Growth Regulator
Active Constituent/s:	38g/L mepiquat present as the chloride
Applicant Name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of Use:	For the management of fruiting and excessive vegetative growth in cotton.
Date of Registration:	5 May 2011
Label Approval No:	65814/52090

Product Name:	Genfarm Brom-M Herbicide
Active Constituent/s:	200g/L bromoxynil present as the n-octanoyl ester, 200g/L MCPA present as the ethyl hexyl ester
Applicant Name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of Use:	For the control of weeds in wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf.
Date of Registration:	6 May 2011
Label Approval No:	65504/51068

Product Name:	4Farmers 2, 4-D Amine 750 Selective Herbicide
Active Constituent/s:	750g/L 2,4-D present as the Dimethylamine and Diethanolamine salt.
Applicant Name:	4 Farmers Pty Ltd
Applicant ACN:	067 443 485
Summary of Use:	Registration of a 750g/L 2,4-D, present as the Diethanolamine and Dimethylamine salts (concentration) aqueous concentrate product for the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures: and in cereal crops, pastures, sugar cane, peanuts and non-agriculture areas as per the directions of use.
Date of Registration:	6 May 2011
Label Approval No:	62817/44034

Product Name:	Macphersons Paraquat 250 Herbicide
Active Constituent/s:	250g/L paraquat present as paraquat dichloride
Applicant Name:	Ronic International Pty Limited
Applicant ACN:	101 193 131
Summary of Use:	For the control of a wide range of grasses and broadleaf weeds in a range of situations.
Date of Registration:	9 May 2011
Label Approval No:	65839/52144
Product Name:	Detia Gas Ex B Fumigation Bags
Active Constituent/s:	330g/kg phosphine (ph ₃) present as aluminium phosphide
Applicant Name:	Detia Degesch GmbH
Applicant ACN:	N/A
Summary of Use:	Aluminium Phosphide product for use as a fumigant for the control of stored product pests in stored commodities and well sealed empty structures such as mills and warehouses.
Date of Registration:	9 May 2011
Label Approval No:	63588/45989
Product Name:	Freezone Shotgun Pindone Oat Rabbit Bait
Active Constituent/s:	0.5g/kg pindone as sodium salt
Applicant Name:	Freezone Public Health Pty Ltd
Applicant ACN:	132 080 098
Summary of Use:	For the control of rabbits.
Date of Registration:	9 May 2011
Label Approval No:	65834/52139
Product Name:	Pacific Glyphosate 360 SL Herbicide
Active Constituent/s:	360g/L glyphosate present as the isopropylamine salt
Applicant Name:	Pacific Agriscience Pty Ltd
Applicant ACN:	096 082 316
Summary of Use:	For the non-selective herbicide control of a broad range of annual, perennial and aquatic weeds.
Date of Registration:	9 May 2011
Label Approval No:	65314/50687
Product Name:	Rainbow Clethodim 240 Herbicide
Active Constituent/s:	240g/L clethodim
Applicant Name:	Shandong Rainbow International Co., Ltd.
Applicant ACN:	N/A
Summary of Use:	For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton faba beans, field peas, forestry, lentils, lettuce, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans.
Date of Registration:	10 May 2011
Label Approval No:	65300/52556

Product Name:	Turf Culture Azoxy 95 Fungicide
Active Constituent/s:	95g/L azoxystrobin
Applicant Name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of Use:	For the control of various diseases in turf as per the directions for use.
Date of Registration:	12 May 2011
Label Approval No:	65575/51330
Product Name:	Titan Propyzamide 500SC Herbicide
Active Constituent/s:	500g/L propyzamide
Applicant Name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of Use:	For the selective control of certain grasses and broadleaf weeds in lettuce, sports turf, home lawns, legume seed crops and pastures.
Date of Registration:	12 May 2011
Label Approval No:	66050/52596
Product Name:	Raid One Shot Crawling Insect Surface Spray Odourless
Active Constituent/s:	0.15g/kg Imiprothrin, 2.79g/kg Permethrin.
Applicant Name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of Use:	Aerosol insecticide for control of household insect pests.
Date of Registration:	12 May 2011
Label Approval No:	65864/52191
Product Name:	Chick-San Cresol
Active Constituent/s:	770g/L cresol
Applicant Name:	Sopura Australia Pty Ltd
Applicant ACN:	080 038 062
Summary of Use:	For use as a sanitiser of poultry sheds and poultry litter.
Date of Registration:	12 May 2011
Label Approval No:	65034/49936
Product Name:	Resource Gardening Glypho 360 Weedkill
Active Constituent/s:	360g/L Glyphosate present as the Isopropylamine Salt.
Applicant Name:	Kilford & Kilford Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For control of weeds and grasses in home garden situations.
Date of Registration:	13 May 2011
Label Approval No:	66070/52629
Product Name:	Amgrow Glypho 360 Non Selective Herbicide
Active Constituent/s:	360g/L glyphosate present as the isopropylamine salt
Applicant Name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For non-selective control of many annual, aquatic and perennial weeds.
Date of Registration:	13 May 2011
Label Approval No:	66136/52861

Product Name:	Apparent Diuron 500 SC Herbicide
Active Constituent/s:	500g/L diuron
Applicant Name:	Apparent Pty. Ltd.
Applicant ACN:	143 724 136
Summary of Use:	For use in certain crops to control various weeds as per the directions for use.
Date of Registration:	13 May 2011
Label Approval No:	66184/52944
Product Name:	Fosterra 2,4-D Amine 625 Selective Herbicide
Active Constituent/s:	625g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant Name:	Fosterra Pty Ltd
Applicant ACN:	132 334 920
Summary of Use:	For the control of broadleaf weeds in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas.
Date of Registration:	16 May 2011
Label Approval No:	65849/52169
Product Name:	Omni Advantage Sticks Pool Sanitiser
Active Constituent/s:	880g/kg chlorine present as trichloroisocyanuric acid
Applicant Name:	Chemtura Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of Use:	For the control of algae and bacteria.
Date of Registration:	16 May 2011
Label Approval No:	66044/52585
Product Name:	Omni Advantage Chlor Pool Sanitiser
Active Constituent/s:	94g/kg sodium tetraborate pentahydrate, 660g/kg available chlorine (Cl) present as trichloroisocyanuric acid
Applicant Name:	Chemtura Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of Use:	For the use as a swimming pool sanitiser.
Date of Registration:	16 May 2011
Label Approval No:	66031/52546
Product Name:	Brunnings Ant Kill Granular Insecticide
Active Constituent/s:	2g/kg bifenthrin
Applicant Name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of Use:	For the control of ants in the home garden.
Date of Registration:	17 May 2011
Label Approval No:	66116/52760
Product Name:	Amgrow Bin-Die Selective Lawn Weeder Ready To Use
Active Constituent/s:	12g/L Bromoxynil present as the octanoate ester, 12g/L MCPA present as the 2-ethyl hexyl ester.
Applicant Name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of Use:	For the control of a range of broadleaf weeds in home garden lawns.
Date of Registration:	17 May 2011
Label Approval No:	59176/50076

Product Name:	MaxumPRO 125 SC Insecticide
Active Constituent/s:	125g/L betacyfluthrin
Applicant Name:	Sundew Solutions Pty Ltd
Applicant ACN:	135 400 261
Summary of Use:	For control of various insect pests in various situations.
Date of Registration:	18 May 2011
Label Approval No:	64148/47682

Re-issue of 66081

Product Name:	KDPC Phos Phyt 400 Systemic Fungicide
Active Constituent/s:	400g/L phosphorus (phosphonic) acid present as mono (and) di potassium phosphite
Applicant Name:	KD Plant Care Pty Ltd
Applicant ACN:	134 592 804
Summary of Use:	For control of phytophthora diseases and downy mildew in various situations.
Date of Registration:	7 April 2011
Label Approval No:	66081/52661

2. VARIATIONS

Product Name:	Chaindrite Permforce Dust Insecticide
Applicant Name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of Variation:	To change product name from Permforce Dust Insecticide to Chaindrite Permforce Dust Insecticide, add additional pests in existing situations and add pack size range (2kg-15kg)
Date of Variation:	5 May 2011
Label Approval No:	62664/52573

Product Name:	Affinity Force Herbicide
Applicant Name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of Variation:	To extend the use pattern in wheat, barley, triticale and oats to include the control of Bifora, Cleavers, Indian hedge mustard, Paterson's curse and wild radish; replace the standard tank mix of MCPA (500g/L) amine with MCPA (750g/L) amine; add tank mixtures with dicamba, metribuzin and diuron; and add information on spray quality and nozzle selection.
Date of Variation:	06 May 2011
Label Approval No:	62003/49469

Product Name:	AW Cudgel 300 Herbicide
Applicant Name:	Agri West Pty Limited
Applicant ACN:	108 899 181
Summary of Variation:	Variation of registration and label approval to change the product name from AW CLASH 300 HERBICIDE to AW CUDGEL 300 HERBICIDE.
Date of Variation:	10 May 2011
Label Approval No:	63258/52701

Product Name:	Genfarm Panzer 450 Herbicide
Applicant Name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of Variation:	Variation to relevant label particulars to add uses for pre harvest application in pulses and wheat.
Date of Variation:	12 May 2011
Label Approval No:	58830/52147
Product Name:	Orica Industrial Chemicals Dusting Sulfur Fungicide-Miticide
Applicant Name:	Orica Australia Pty Ltd
Applicant ACN:	004 117 828
Summary of Variation:	To change product name from INCITEC INDUSTRIAL CHEMICALS DUSTING SULFUR FUNGICIDE-MITICIDE to ORICA INDUSTRIAL CHEMICALS DUSTING SULFUR FUNGICIDE-MITICIDE.
Date of Variation:	16 May 2011
Label Approval No:	50666/50689
Product Name:	Impact Topguard Fungicide
Applicant Name:	Ospray Pty Ltd
Applicant ACN:	110 199 169
Summary of Variation:	Variation of label approval to reduce the wheat grazing withholding period to 2 weeks; modify the rate of adjuvant addition, update safety directions and remove the restraint applying to open mixing and loading systems for fixed wing aircraft.
Date of Variation:	17 May 2011
Label Approval No:	63162/49431
Product Name:	Ospray Bifenthrin 100 EC Insecticide / Miticide
Applicant Name:	Ospray Pty Ltd
Applicant ACN:	110 199 169
Summary of Variation:	Variation of registration and label approval to add additional pack sizes, update storage and disposal instructions, and update safety directions.
Date of Variation:	18 May 2011
Label Approval No:	60331/52627
Product Name:	MaxumPRO 125 SC Insecticide
Applicant Name:	Sundew Solutions Pty Ltd
Applicant ACN:	135 400 261
Summary of Variation:	To extend the use to include control of litter beetle in poultry sheds.
Date of Variation:	19 May 2011
Label Approval No:	64148/50797
Product Name:	AW Flak Insecticide
Applicant Name:	Agri West Pty Limited
Applicant ACN:	108 899 181
Summary of Variation:	Variation of registration and label approval to change the product name from AW FIPRONIL 200SC INSECTICIDE to AW FLAK INSECTICIDE.
Date of Variation:	9 May 2011
Label Approval No:	65356/52702

NOTICE – NEW AGRICULTURAL ACTIVE CONSTITUENT

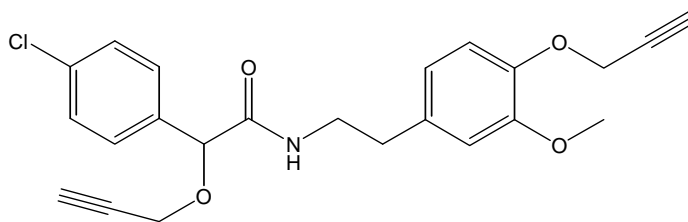
Mandipropamid

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, mandipropamid for use in grapes to control downy mildew.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	Mandipropamid
IUPAC Name:	2-(4-chlorophenyl)-N-[3-methoxy-4-(prop-2-yn-1-yloxy)phenethyl]-2-(prop-2-yn-1-yloxy)acetamide
CAS Name:	2-(4-chlorophenyl)-N-[2-[3-methoxy-4-(prop-2-yn-1-yloxy)phenyl]ethyl]-2-(prop-2-yn-1-yloxy)acetamide
CAS Registry Number:	374726-62-2
Manufacturer's Codes:	NOA 446510
Minimum Purity:	930 g/kg
Molecular Formula:	C ₂₃ H ₂₂ ClNO ₄
Molecular Weight:	411.9

Structure:



Chemical Family: Amide fungicides

SUMMARY OF THE APVMA'S EVALUATION OF MANDIPROPAMID ACTIVE CONSTITUENT

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

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

Constituent	Specification	Level
Mandipropamid	Light beige powder	Minimum 930 g/kg

Other compounds of toxicological significance are not expected to occur in mandipropamid 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 mandipropamid, and advised that there are no objections on human health grounds to the approval of mandipropamid.

An Acceptable Daily Intake (ADI) of 0.05 mg/kg bw/day has been set, based on a No-Observed Effect Level (NOEL) of 5 mg/kg bw/day in a 1-year dog study, after applying a safety factor of 100. An Acute Reference Dose (ARfD) is not necessary because mandipropamid has no significant toxicity after a single or few doses. The National Drugs and Poisons Schedule Committee (NDPSC) has considered Mandipropamid to be appropriate for inclusion in Schedule 5 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 **mandipropamid** 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.

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 mandipropamid that relate to the **grounds for approval** should be addressed in writing to:

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

Phone: (02) 6210 4936
Fax: (02) 6210 4840
Email: john.hughes@apvma.gov.au

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

NOTICE – NEW AGRICULTURAL CHEMICAL PRODUCTS

Mandipropamid in the product Revus[®] Fungicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Syngenta Crop Protection Pty Ltd for registration of a new product containing the active constituent Mandipropamid. The product is **REVUS[®] FUNGICIDE**. The product is for use on grapevines to control downy mildew.

PARTICULARS OF THE APPLICATION

Proposed Product Name(s):	REVUS[®] FUNGICIDE
Applicant Company:	Syngenta Crop Protection Pty Ltd
Name of Active Constituent:	Mandipropamid
Signal Heading:	Schedule 5
Summary of Proposed Use:	Control of downy mildew in grapevines
Pack Sizes:	1 L, 5 L 10 L
Withholding Period:	Grapes: Not required when used as directed Grazing: DO NOT graze vegetation in treated vineyards or cut for stockfood

SUMMARY OF THE APVMA'S EVALUATION OF REVUS[®] FUNGICIDE 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 **REVUS[®] FUNGICIDE** would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety and Environmental Health (OCSEH) in the Department of Health and Ageing has conducted a risk assessment on the product and concluded that it can be used safely.

A quantitative risk assessment for chronic and short-term dermal and inhalational exposure to mandipropamid is not required since no systemic effects were observed at the highest dose of 1000 mg/kg bw/d in a 28-day dermal toxicity in rats, mandipropamid has a very low vapour pressure and is unlikely to present an inhalation hazard and, also, because there are no genotoxic, carcinogenic, reproductive, developmental or neurotoxic concerns with mandipropamid. Personal and protective equipment recommendations will only need to be specified for acute risks (e.g. slight skin and eye irritation).

- (ii) The APVMA is satisfied that the proposed use of **REVUS[®] FUNGICIDE** will not be an undue hazard to the safety of people using anything containing its residues.

The product will be used as a foliar fungicide on grapes. The APVMA Pesticide Residues Section has evaluated the residues aspects of the proposed product and has recommended amendments to the APVMA MRL Standard for mandipropamid and for inclusion in the Food Standards Code. Dietary intake estimates indicate that the expected chronic and acute dietary exposures to mandipropamid are both below the relevant health standards. Recommendations in regard to the required withholding period and protection statements for livestock have been included on the label.

- (iii) The APVMA is satisfied that the proposed use of **REVUS® FUNGICIDE** containing the active constituent mandipropamid is not likely to be harmful to human beings if used according to the product label directions.

Mandipropamid is a new fungicide to the Australian market. The product, REVUS® FUNGICIDE, contains 250 g/L of mandipropamid. REVUS® FUNGICIDE is a new fungicidal product, which will be used for the control of downy mildew in grapes.

Following oral administration in rats, absorption of mandipropamid was relatively extensive at low doses suggesting saturation at the high dose level. It was poorly distributed in tissues and found mainly in the liver and kidney. The distribution of radioactivity following repeated dosing showed a similar profile to that found after a single dose indicating that mandipropamid does not accumulate in tissues. Major metabolic transformations of mandipropamid involved the loss of one or both propargyl groups followed by glucuronidation and O-demethylation. The parent compound and its major metabolites were detected primarily in rat faeces and urine. Orally administered mandipropamid was almost completely eliminated from rat within 48 hr and only trace amounts left after 7 days. Dermal absorption studies indicated that absorption of mandipropamid through the skin is limited. Mandipropamid had low acute oral, dermal and inhalational toxicity in rats. It was a slight skin and eye irritant in rabbits but not a skin sensitiser in guinea pigs. The formulated product, containing 250 g/L mandipropamid had low acute oral, dermal and inhalational toxicity in rats. It was a slight skin and eye irritant in rabbits but not a skin sensitiser in guinea pigs.

Repeat dose studies on mandipropamid indicated that the liver was the main target organ in all the species studied. There was an increase in the liver weight as well as increased activity of liver enzymes. In addition to the liver, increased kidney weights were observed in rats. Mandipropamid was neither a reproductive toxicant in rats nor a developmental toxicant in rats or rabbits. It was neither genotoxic, carcinogenic nor neurotoxic...

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of REVUS FUNGICIDE when used in accordance with the label directions.

- (iv) The APVMA is satisfied that the proposed use of **REVUS® FUNGICIDE** containing the new active constituent, mandipropamid, as a fungicide on grapes would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The Department of Sustainability, Environment, Water, Population and Communities (SEWPAC) has assessed data in support of the proposed use and has concluded that the risks to the environment from this use are acceptable.

Mandipropamid is expected to dissipate from soil and aquatic areas by microbial degradation in soil and sediment and photolysis in water and on the soil surface. It has low to medium mobility in soil and is not expected to accumulate in soil or to bioaccumulate.

DSEWPAC has considered the potential risk to organisms in the terrestrial and aquatic environment from the proposed use of mandipropamid in vineyards, based on ground application by airblast sprayers according to the draft label. The

risk assessment determined that under the proposed use pattern the chemical is unlikely to pose an environmental risk to birds from residues on exposed surfaces, to aquatic and benthic organisms from spray drift or run-off, to bees, parasitic wasps or predatory mites, to earthworms, other soil macroinvertebrates or microorganisms, or to terrestrial plants. No Downwind No-Spray Zones are required, but some minor amendments to the label should be made to meet recently altered APVMA requirements.

The APVMA has considered the findings of the Department of Sustainability, Environment, Water, Population and Communities and accepts these conclusions.

- (v) The APVMA is satisfied that the proposed use of **REVUS® FUNGICIDE** containing the new active constituent, mandipropamid would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

The APVMA is satisfied that the proposed use of Revus® Fungicide would not adversely affect trade between Australia and places outside Australia.

Export of treated produce containing finite (measurable) residues of mandipropamid may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian product are likely to exceed a residue tolerance (import tolerance) established in the importing country.

MRLs are proposed for grapes (0.3 mg/kg) and dried grapes (2 mg/kg). The grape MRL, and the corresponding maximum residues of mandipropamid expected in wine are lower than the Codex MRL, lower than the proposed MRL for the EU, and lower than existing MRLs in grapes for Austria, Korea, Slovenia, Switzerland and the USA.

No information is available on destinations of Australian exports of dried grapes. The proposed Australian MRL for mandipropamid in dried grapes is 2 mg/kg, which is lower than the current MRL in the USA and the Codex MRL.

There is a possible risk to Australian export trade of dried grapes, table grapes and wine as a result of the proposed use of mandipropamid on grapes.

The overall risk to trade in animal commodities is considered to be low, as residues of mandipropamid are not expected at the proposed GAP, and the proposed MRLs in animal commodities are recommended at the LOQ.

Comment is sought from the relevant industry groups on the perceived level of risk and whether any industry-initiated strategies are required to manage that risk. .

- (vi) 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 'Public Consultation' page, www.apvma.gov.au/consultation/public or by contacting the contact officer 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 registration of **REVUS® FUNGICIDE** 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.

When making a submission please include:

- Contact name
- Company or Group name (if relevant)
- Email or postal address
- The date you made the submission.

All personal and **confidential commercial information (CCI)**² 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:

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

Phone: (02) 6210 4700
Fax: (02) 6210 4776
Email: pesticides@apvma.gov.au

² A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

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

Nil

2. CHANGES TO EXISTING LICENCES

**AUSTRALIAN BLISTER
SEALING INCORPORATED
PTY LTD**

ACN: 001 219 003

18 Distribution Place

SEVEN HILLS NSW 2147

LICENCE NO: 6148

Product Types: *

- *Category 6: Single Step*

Step(s) of Manufacture: Packaging, labelling, strip, blister or sachet packaging and storage.

Amended Licence Issued: 05/04/2011

Variation to licence conditions and key personnel.

PLASVACC PTY LTD

ACN: 099 547 841

Rigby

6066 Cunningham Highway

KALBAR QLD 4309

LICENCE NO: 1072

Product Types: *

- *Category 1: Immunobiologicals (plasma products)*

Step(s) of Manufacture: Quality assurance (QA) of raw materials, plasma collection via plasmapheresis machine, management and immunisation of donor animals, packaging, labelling, analysis and testing (physical, sterility, serological, immunobiological and haematological), storage and release for supply.

Amended Licence Issued: 01/04/2011

Variation to conditions and steps of manufacture

* 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*

**VIRBAC (AUSTRALIA) PTY
LTD**

ACN: 003 268 871

18-22 Denison Street

CROOKWELL NSW 2583

LICENCE NO: 2188

Product Types: *

- *Category 2:* Tablets, pastes, sprays, liquids, suspensions, creams/lotions, ointments and powders
- *Category 3:* Liquids, pastes and sprays
- *Category 4:* Premixes and supplements

Step(s) of Manufacture: Formulation including blending, wet milling of powders, dry milling, filling, packaging, labelling, tableting, analysis and testing (physical) and storage.

Amended Licence Issued: 05/04/2011

Change of key personnel and steps of manufacture

**WESTERN AUSTRALIAN
AGRICULTURAL AUTHORITY**

ABN: 86 611 226 341

Animal Health Laboratories

Department of Agriculture &
Food

444 Albany Highway

ALBANY WA 6330

LICENCE NO: 1091

Product Types: *

- *Category 1:* Immunobiologicals

Step(s) of Manufacture: Quality assurance (QA) of raw materials, collection and preparation of mature nematodes, antigen extraction, formulation including blending, sterilisation (heat, filtration, chemical), microbiological reduction (filtration), aseptic filling, packaging, labelling, analysis and testing (physical, chemical, gel electrophoresis), storage and release for supply.

Amended Licence Issued: 29/04/2011

Amendment to company details

* 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*

**INTERNATIONAL ANIMAL
HEALTH PRODUCTS PTY LTD**

ACN: 003 185 699

18 Healey Circuit

HUNTINGTON NSW 2148

LICENCE NO: 2015

Product Types: *

- *Category 2:* Creams/lotions, ointments, pastes, powders, pellets, sprays, tablets and liquids
- *Category 3:* Liquids, sprays and powders
- *Category 4:* Premixes and supplements

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

Amended Licence Issued: 05/04/2011

Change of 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’].

Nil

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

* 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*

APVMA CONTACT

Cheryl Venables
GMP Officer
Manufacturing Quality and Licensing Section
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4808

Fax: (02) 6210 4741

Email: cheryl.venables@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*