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Gazette

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Published by The Australian Pesticides and Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

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

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GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, www.apvma.gov.au/publications/gazette/.

If you would like to receive email notification when a new edition is published, please subscribe on the APVMA website.

APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4870

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

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Agricultural chemical products and approved labels

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

VARIATIONS TO REGISTRATIONS AND LABEL APPROVALS

Application No:	60085
Product Name:	DuPont Altacor Insecticide
Active Constituent/s:	350 g/kg chlorantraniliprole
Applicant Name:	Du Pont (Australia) Pty Ltd
Applicant ACN:	000 716 469
Summary of Variation:	To extend the use to include the control of a range of lepidopterous pests on pulse crops and control of cluster caterpillar on cotton
Date of Variation:	30 July 2014
Product registration no.:	61824
Label Approval No:	61824/60085

Application No:	61851
Product Name:	Transit 750 Herbicide
Active Constituent/s:	750 g/kg clopyralid present as the potassium salt
Applicant Name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of Variation:	To update the label and additional use to control fleabane in forestry
Date of Variation:	31 July 2014
Product registration no.:	65239
Label Approval No:	65239/61851

Application No:	62732
Product Name:	ADAMA Captan 800 WG Fungicide
Active Constituent/s:	800 g/kg captan
Applicant Name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of Variation:	To change the product name from ‘FARMOZ CAPTAN 800 WG FUNGICIDE’ to ‘ADAMA CAPTAN 800 WG FUNGICIDE’
Date of Variation:	12 August 2014
Product registration no.:	60244
Label Approval No:	60244/62732

Application No:	62611
Product Name:	Interspeed 642 Tin Free Antifouling Topcoat
Active Constituent/s:	745 g/L copper present as copper oxides, 75 g/L diuron
Applicant Name:	Akzo Nobel Pty Limited
Applicant ACN:	000 119 424
Summary of Variation:	To change the product name from ‘INTERNATIONAL INTERSPEED 642 TIN FREE ANTIFOULING TOPCOAT’ to ‘INTERSPEED 642 TIN FREE ANTIFOULING TOPCOAT’
Date of Variation:	12 August 2014
Product registration no.:	47587
Label Approval No:	47587/62611

Application No:	62649
Product Name:	Rid Australia Medicated Rid Insect Repellent Tropical Strength + Antiseptic Pump Spray 6 Hours Mosquito Protection Neutral Scent Protection Against Mosquitoes That May Carry Ross River Virus & Dengue
Active Constituent/s:	191 g/L N,n-diethyl-m-toluamide (DEET), 40 g/L n-octyl bicycloheptene dicarboximide, 20 g/L di-n-propyl isocinchomeronate, 1 g/L triclosan
Applicant Name:	Cavalieri Investing Pty Ltd
Applicant ACN:	162 722 625
Summary of Variation:	To change product name from 'MEDICATED RID REPELLENT TROPICAL STRENGTH PUMP' to 'RID AUSTRALIA MEDICATED RID INSECT REPELLENT TROPICAL STRENGTH + ANTISEPTIC PUMP SPRAY 6 HOURS MOSQUITO PROTECTION NEUTRAL SCENT PROTECTION AGAINST MOSQUITOES THAT MAY CARRY ROSS RIVER VIRUS & DENGUE'
Date of Variation:	12 August 2014
Product registration no.:	53405
Label Approval No:	53405/62649

Application No:	60466
Product Name:	Sharpen WG Herbicide
Active Constituent/s:	700 g/kg saflufenacil
Applicant Name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of Variation:	To add the use as a stand-alone product, add additional weeds in a tank mix with glyphosate and add the use of a tank mix with paraquat
Date of Variation:	13 August 2014
Product registration no.:	62853
Label Approval No:	62853/60466

Application No:	60623
Product Name:	Movento 240 SC Insecticide
Active Constituent/s:	240 g/L siprotetramat
Applicant Name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of Variation:	Extension of use to include control and suppression of various sucking insect pests in table grapes, pome fruit and stone fruit
Date of Variation:	13 August 2014
Product registration no.:	61864
Label Approval No:	61864/60623

Application No:	62678
Product Name:	Crossbar 240 Herbicide
Active Constituent/s:	240 g/L oxyfluorfen
Applicant Name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of Variation:	To change the product name from 'PUNCHER 240 HERBICIDE' to 'CROSSBAR 240 HERBICIDE'
Date of Variation:	14 August 2014
Product registration no.:	69750
Label Approval No:	69750/62678

Application No:	62083
Product Name:	Firefighter Herbicide
Active Constituent/s:	200 g/L bromoxynil present as the n-octanoyl ester
Applicant Name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of Variation:	To change the product name from 'OSPRAY FIREFIGHTER HERBICIDE' to 'FIREFIGHTER HERBICIDE'
Date of Variation:	18 August 2014
Product registration no.:	61945
Label Approval No:	61945/62083

Application No:	62735
Product Name:	Heiniger Liquid Carbaryl Insect Spray
Active Constituent/s:	100 g/L carbaryl (an anticholinesterase compound)
Applicant Name:	Heiniger Home & Garden Care Pty Ltd
Applicant ACN:	007 910 278
Summary of Variation:	To approve label update to amend incorrect application rate for ornamentals
Date of Variation:	13 August 2014
Label Approval No:	31995/62735

Application no.:	62650
Product name:	Rid Australia Medicated Rid Insect Repellent Tropical Strength + Antiseptic Spray 6 Hours Mosquito Protection Neutral Scent Protection Against Mosquitoes that may Carry Ross River Virus & Dengue
Active constituent/s:	191 g/kg N,n-diethyl-m-toluamide (DEET), 40 g/kg N-octyl bicycloheptene dicarboximide, 20 g/kg Di-n-propyl isocinchomeronate, 1 g/kg Triclosan
Applicant name:	Cavalieri Investing Pty Ltd
Applicant ACN:	162 722 625
Summary of variation:	To change the product name from 'MEDICATED RID REPELLENT TROPICAL STRENGTH SPRAY' to 'RID AUSTRALIA MEDICATED RID INSECT REPELLENT TROPICAL STRENGTH + ANTISPETIC SPRAY 6 HOURS MOSQUITO PROTECTION NEUTRAL SCENT PROTECTION AGAINST MOSQUITOES THAT MAY CARRY ROSS RIVER VIRUS & DENGUE'
Date of variation:	15 August 2014
Label approval no:	53407/62650

Application no.:	62688
Product name:	Hymenopthor Ultra Granular Ant and Cockroach Bait
Active constituent/s:	0.1 g/kg fipronil
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of variation:	To change the product name from 'HYMENOPTHOR ULTRA GRANULAR COCKROACH BAIT' to 'HYMENOPTHOR ULTRA GRANULAR ANT AND COCKROACH BAIT', and to reinstate ants as a use
Date of variation:	18 August 2014
Label approval no:	65833/62688

Veterinary chemical products and approved labels

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

VARIATIONS OF REGISTRATION

Application No:	55916
Product Name:	Tylodox 50 G Microgranulate Feed Additive
Active Constituent/s:	50 g/kg tylosin as tylosin phosphate
Applicant Name:	Dox-Al Australia Pty Ltd
Applicant ACN:	079 454 265
Summary of Variation:	To change the product name from 'TYLODOX 50 BMP MICROGRANULATE FEED ADDITIVE' to 'TYLODOX 50 G MICROGRANULATE FEED ADDITIVE'
Date of Variation:	11 August 2014
Product registration no.:	60891
Label Approval No:	60891/55916

Cancellation of label approval at the request of the registrant

In accordance with Section 42 of the Agvet Code, if an interested or approved person in relation to an approval or registration has given to the APVMA a written notice requesting the APVMA to cancel that approval or registration, then the APVMA must give written notice of its decision on the request to the person(s) who made the request.

This gazette notice satisfies the requirement in section 45A (1) of the Agvet Code, that the APVMA must also give notice to any other person to whom, in its opinion such a notice should be given.

At the request of the registrant, following the recent approval of a new label for this product, the APVMA has cancelled the previous label approvals of the following products:

Product No.	Product Name	Registrant	Cancelled Label Approval Number	Date of Effect
50637	ACCENSI 2,4–D AMINE 500 SELECTIVE HERBICIDE	ACCENSI PTY LTD	50637/0214 50637/59865	1 August 2014
58989	DUPONT KOCIDE BLUE XTRA FUNGICIDE	DU PONT (AUSTRALIA) PTY LTD	58989/0704 58989/0705 58989/0709 58989/0806	1 August 2014

The following instructions set out how a person can deal with any product bearing a cancelled label approval.

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 1 August 2014 at wholesale and retail level, until 1 August 2015.

After 1 August 2015 it will be an offence against the Agvet Codes to have possession or custody of a product bearing a cancelled label with the intention to supply.

USE

A person may continue to use the product according to its cancelled label instructions until 1 August 2015.

Any person who possesses, has custody of, uses, or otherwise deals with the product bearing a cancelled label 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 labels have been cancelled until 1 August 2015.

The supply and use of the product bearing a cancelled label must be in accordance with the label instructions, 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
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4749
Fax: +61 2 6210 4776
Email: chemicalreview@apvma.gov.au

Cancellation of active constituent approval(s) at the request of the approval holder

In accordance with Section 42 of the Agvet Code, if an interested or approved person in relation to an approval or registration has given to the APVMA a written notice requesting the APVMA to cancel that approval or registration then the APVMA must give written notice of its decision on the request to the person(s) who made the request.

This gazette notice satisfies the requirement in section 45A (1) of the Agvet Code, that the APVMA must also give notice to any other person to whom, in its opinion such a notice should be given.

At the request of the approval holder, the APVMA has cancelled the approval(s) of the following active constituents:

Active No.	Active Name	Approval Holder	Date of Effect
62417	PERMETHRIN	JANSSEN-CILAG PTY LTD	1 August 2014
44050	AZACONAZOLE	JANSSEN-CILAG PTY LTD	1 August 2014
61540	DIETHYLTOLUAMIDE	VERTELLUS PERFORMANCE MATERIALS INC	1 August 2014
47329	GLYPHOSATE	RUNGE AGRICHEMS PTY LTD	1 August 2014
47337	MEPIQUAT CHLORIDE	RUNGE AGRICHEMS PTY LTD	1 August 2014

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

SUPPLY

A person may supply or cause to be supplied active constituents manufactured prior 1 August 2014 until 1 August 2015.

After 1 August 2015 it will be an offence against the Agvet Codes to have possession or custody of the active constituent(s) with the intention to supply the active constituent(s).

USE

Any person who possesses, has custody of, uses, or otherwise deals with the listed active constituent(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 active constituent(s) after the approval(s) have been cancelled until 1 August 2015.

The supply and use of the active constituents must be in accordance with the conditions of approval, 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 active constituent(s) 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
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4749
Fax: +61 2 6210 4776
Email: chemicalreview@apvma.gov.au

Variations to Standard 1.4.2 of the Australia New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA *MRL Standard* and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. This notice pertains to proposals (No. 6) gazetted on 3 June 2014 (No. APVMA 11).

Submissions have been sought on these proposals and the APVMA has written separately to each person or organisation that made a submission. All matters raised in the submissions have been resolved.

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Standard 1.4.2. A copy of the Amendment Instrument (No. APVMA 8, 2014) accompanies this notice. For a complete and up-to-date version of Standard 1.4.2, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislative Instrument available on the Comlaw website at www.comlaw.gov.au.

Based on dietary exposure assessments and current health standards, the APVMA and FSANZ are satisfied that these MRLs are not harmful to public health. 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 by minimising residues in foods consistent with the effective control of pests and diseases.

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) made Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) in relation to these variations and no comment was received in response to that notice.

A copy of these variations have been given to FSANZ.

The variations take effect as from the date of this notice.

This notice is published in accordance with subsection 82(7) of the *Food Standards Australia New Zealand Act 1991*.

For further information please contact:

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

Phone: +61 2 6210 4897
Fax: +61 2 6210 4840
Email: enquiries@apvma.gov.au

Australia New Zealand Food Standards Code — Standard 1.4.2–Maximum Residue Limits Amendment Instrument No. APVMA 8, 2014

I, Rajumati Bhula, Executive Director, Pesticides Program and delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Rajumati Bhula
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this fourteenth day of August 2014

Part 1 Preliminary

1 Name of Instrument

This Instrument is the *Australia New Zealand Food Standards Code — Standard 1.4.2 – Maximum Residue Limits Amendment Instrument No. APVMA 8, 2014*.

2 Commencement

Pursuant to subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this Amendment Instrument commences on the day a copy of it is published in the *Gazette*.

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia *Agricultural and Veterinary Chemicals Gazette* No. APVMA 17 of 26 August 2014.

3 Object

The object of this Instrument is for the APVMA to make variations to Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code* to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

4 Interpretation

In this Instrument: —

APVMA means the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and

Principal Instrument means Standard 1.4.2 – Maximum Residue Limits of *the Australia New Zealand Food Standard Code* as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that code. The whole of the *Australia New Zealand Food Standard Code* (including Standard 1.4.2) was further published in *Gazette* P 30 of 20 December 2000.

Part 2 Variations to Standard 1.4.2 – Maximum Residue Limits

5 Variations to Standard 1.4.2

The Schedule to this Instrument sets out the variations made to the Principal Instrument by this Amendment Instrument.

Schedule

Variations to Standard 1.4.2 – Maximum Residue Limits

1 Variations

(1) The Principal Instrument is varied by:

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

Abamectin Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Blueberries	T*0.02
Emamectin Sum of emamectin B1a and emamectin B1b	
Pulses	*0.01
Penflufen Penflufen	
Potato	T*0.01
Propyzamide Propyzamide	
Edible offal (mammalian) Meat (mammalian) Rape seed (canola)	*0.2 *0.05 0.02
Quinoxyfen Quinoxyfen	
Strawberry	T*0.01

(b) omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals –

(1) Propyzamide Propyzamide	
Cattle, edible offal of Cattle meat	*0.2 *0.05

(c) omitting from Schedule 1, under the entries for the following chemicals, the maximum residue limit for the food, substituting –

(2) Buprofezin Buprofezin	
Celery	T5
(3) Propyzamide Propyzamide	
Poppy seed	0.02

H. contortus integral membrane glycoproteins in the product: BARBERVAX Barber's Pole worm vaccine

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, ***H. contortus* integral membrane glycoproteins**. The APVMA also has before it an application from the same applicant, for the registration of a new product, **BARBERVAX Barber's Pole worm vaccine** ('the product') containing the above active constituent.

PARTICULARS OF THE ACTIVE CONSTITUENT

Applicant company:	Wormvax Australia Pty Ltd
Manufacturer:	Western Australian Agriculture Authority. Animal Health Laboratories Department of Agriculture and Food 444 Albany Highway Albany, WA 6330
Name of active constituent:	*H. contortus* integral membrane glycoproteins
Appearance and Identity:	As per Culture for larval differentiation PAM-19/PAW-7.1
Sterility:	As per US Pharmacopoeia/British Pharmacopoeia
Extraneous agents:	As per US Pharmacopoeia/British Pharmacopoeia
Mycoplasma:	As per European Pharmacopeia
Gene technology:	Not applicable
Mode of action:	Inducing immunological response

PARTICULARS OF THE PRODUCT

Proposed name:	BARBERVAX Barber's Pole worm vaccine
Active constituent	*H. contortus* integral membrane glycoproteins
Adjuvant	Saponin (Quil-A)
Name of active constituent:	*H contortus* integral membrane glycoproteins (antigen)
Pharmaceutical form:	Suspension for injection
Pack sizes:	250 doses in 250 mL pillow pack
Target species:	Sheep and lambs from 3 weeks of age
Amounts to be administered and administration route:	1 mL by subcutaneous injection into the neck

Vaccination schedule:	One injection from 3 weeks of age. Three injections 3 to 6 weeks apart are needed to induce protection. For the remainder of the Barber's Pole worm risk period, immunity can be maintained by boosters given at 6 week intervals for up to 6 months.
Indications for use:	A vaccine to reduce pasture larval contamination and disease caused by Barber's Pole worm in lambs.
Side effects:	No harmful effects are expected. Local tissue reactions in the form of swelling at the injection site may occur and last for up to 17 days. Animals may show a moderate rise of temperature for up to 3 days.
Withholding period:	Nil
Manufacturer:	Western Australia Agriculture Authority Animal Health Laboratories Department of Agriculture and Food 444 Albany Highway Albany WA 6330
Applicant name:	Wormvax Australia Pty Ltd Level 9, 575 Bourke St Melbourne, VIC 3000 AUSTRALIA

SUMMARY OF THE APVMA'S EVALUATION OF BARBERVAX BARBER'S POLE WORM VACCINE 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 the active constituent and the product, including starting materials (parasite identity, and antigen purity), vaccine production, quality control, shelf life and batch release analysis, has been assessed and found to meet APVMA registration criteria.

The APVMA is satisfied that the proposed use of *H. contortus* integral membrane glycoproteins in the product, as a vaccine to reduce pasture larval contamination and disease caused by Barber's Pole worm in lambs, would not be likely to have an effect that is harmful to human beings, environment or trade. The adjuvant and the excipients used in the product have been previously assessed and found to be safe. They are already present in vaccines registered for use in Australia.

In relation to its assessment of efficacy and safety in target animal, the APVMA is satisfied that the data supporting the efficacy and safety of the product, adequately demonstrate that this product is likely to be safe and effective under Australian conditions when used as directed according to label instructions.

SUMMARY OF THE APVMA'S EVALUATION OF *H. CONTORTUS* INTEGRAL MEMBRANE GLYCOPROTEINS ACTIVE CONSTITUENT

Constituent	Specification
H. contortus integral membrane glycoproteins	*5.0 µg/mL*

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 APVMA should approve the active constituent *H. contortus* integral membrane glycoproteins and register the product BARBERVAX Barber's Pole worm vaccine.

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 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.

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)***[1] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant approval for *H. contortus* integral membrane glycoproteins that relate to the **grounds for approval** should be addressed in writing to:

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

Phone: +61 2 6210 4700
Fax: +61 2 6210 4741
Email: enquiries@apvma.gov.au

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

Notification of label variations and cancellations for products containing the active constituent profenofos

The APVMA has varied label approvals for products containing profenofos as listed in Table 1.

In accordance with Section 41(2) the APVMA has cancelled the superseded label approvals for some products, as listed in Table 1. The label approvals were cancelled on 24 June 2014.

REASONS

Profenofos was nominated for review because of human health concerns relating to malodorous breakdown products, new evidence relating to skin sensitisation and questions about the adequacy of the existing Acceptable Daily Intake (ADI) and the lack of an Acute Reference Dose (ARfD).

The Office of Chemical Safety (OCS) within the Department of Health has completed preliminary assessments of profenofos. The OCS concluded that there may be an unacceptable exposure to workers when using profenofos products in accordance with current label instructions, and entering treated areas after the current re-entry interval of 24 hours. In addition, the current first aid instructions and safety directions were not considered adequate to address the acute hazards associated with the use of profenofos products. Inclusion of more comprehensive personal protective equipment and/or engineering controls (closed systems) may not sufficiently reduce workers' exposure to acceptable levels. To address these concerns, OCS recommended a revised re-entry interval of 34 days for workers.

In 2010, the APVMA removed profenofos from the Priority Candidate Review List, because products containing profenofos were no longer being supplied in Australia.

The APVMA wishes to ensure that if profenofos products were to return to the market that concerns already raised by OCS are addressed in the interim. In accordance with **s.34A** of the *Agricultural and Veterinary Chemicals Code Act 1994,* the APVMA has decided to reconsider the associated label approvals of products that contain profenofos.

SUMMARY OF VARIATIONS APPLIED:

Labels have been updated to:

a. include a 34 day re-entry period

b. include the first aid instruction regarding drinking water.

   i. if swallowed, do NOT induce vomiting. Give a glass of water.

c. update and correct the first aid instruction regarding atropine.

   i. If swallowed, splashed on skin or in eyes, or inhaled, contact a poisons information centre (Phone e.g. Australia 131 126; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

Table 1: Products requiring variation or cancellation of label approvals in response to OCS report

PRODUCT NUMBER	PRODUCT NAME	REGISTRANT	LABEL APPROVALS	REGULATORY ACTION
53100	Curacron 500 Pro Insecticide	SYNGENTA AUSTRALIA PTY LTD	53100/0800 53100/1001	Vary to 53100/0614 Cancel
53326	Prochem Duo 250 ULV/EC Insecticide	IMTRADE AUSTRALIA PTY LTD	53326/0900	Vary to 53326/0614
54789	Grizzly 500 Insecticide	NUFARM AUSTRALIA LIMITED	54789/0402	Vary to 54789/0614
55259	Prochem 500 Elite Insecticide	IMTRADE AUSTRALIA PTY LTD	55259/0802	Vary to 55259/0614

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH PRODUCT DISPLAYING THE CANCELLED LABEL

A person may possess, have custody of, use or otherwise deal with the product containing a cancelled label for a period of one year after the day of the cancellation.

APVMA CONTACT

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

Chemical Review and AERP/Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4749
Fax: +61 2 6210 4776
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Application Summaries

The APVMA publishes complete application summaries on the APVMA website www.apvma.gov.au/node/11061. 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. A summary will be removed from the website 28 days after the application has been finalised.

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