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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*. 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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Australian Pesticides and Veterinary Medicines Authority
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Kingston ACT 2604

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Website: www.apvma.gov.au.

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/news-and-publications/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 4988

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.

1. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	61735
Product name:	Intuity Fungicide
Active constituent/s:	250 g/L mandestrobin
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of use	For the control of blossom blight and brown rot in stone fruit
Date of registration/approval:	26 October 2016
Product registration no.:	69787
Label approval no.:	69787/61735

Application no.:	59333
Product name:	Kusabi 300 SC Fungicide
Active constituent/s:	300 g/L pyriofenone
Applicant name:	Ishihara Sangyo Kaisha Ltd
Applicant ACN:	N/A
Summary of use	For the control of powdery mildew in cucurbits and grapes
Date of registration/approval:	2 November 2016
Product registration no.:	68898
Label approval no.:	68898/59333

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	103360
Product name:	Yates Nature's Way Weed Spray
Active constituent/s:	40.4 g/L clove oil, 40.4 g/L acetic acid
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of use	For the control of a wide range of annual & perennial weeds and grasses found in home gardens
Date of registration/approval:	7 September 2016
Product registration no.:	81563
Label approval no.:	81563/103360

Application no.:	107446
Product name:	Imtarde Haloxy 900 EC Herbicide
Active constituent/s:	900 g/L haloxyfop-p present as the haloxyfop-p-methyl ester
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use	For post-emergent control of a wide range of annual and perennial grass weeds 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
Date of registration/approval:	28 September 2016
Product registration no.:	83076
Label approval no.:	83076/107446

Application no.:	60366
Product name:	GP Regain 400 Herbicide
Active constituent/s:	400 g/kg tebuthiuron
Applicant name:	Granular Products Pty Ltd
Applicant ACN:	110 555 952
Summary of use	For the control of brigalow regrowth, tea tree regrowth, mimosa pigra and certain problem woody weeds on grazing lands
Date of registration/approval:	25 October 2016
Product registration no.:	69266
Label approval no.:	69266/60366
Application no.:	105472
Product name:	Genfarm Panzer Hitech Herbicide
Active constituent/s:	500 g/L glyphosate present as the potassium salt
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For the control of a wide range of annual and perennial weeds in a range of situations
Date of registration/approval:	27 October 2016
Product registration no.:	82340
Label approval no.:	82340/105472
Application no.:	107635
Product name:	Conquest Imazamax 700 WG Herbicide
Active constituent/s:	700 g/kg imazamox
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use	For the post-emergence control of certain annual grass and broadleaf weeds in field peas, legume-based pastures, lucerne, peanuts and soybeans
Date of registration/approval:	27 October 2016
Product registration no.:	83146
Label approval no.:	83146/107635
Application no.:	107587
Product name:	Safari 750 EC Herbicide
Active constituent/s:	750 g/L triclopyr (present as the butoxyethyl ester)
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of various woody and broadleaf weeds in commercial and industrial situations, rights of way, pastures, forests, fallow, stubble and firebreaks
Date of registration/approval:	27 October 2016
Product registration no.:	83125
Label approval no.:	83125/107587
Application no.:	104549
Product name:	Roundup Ready PL Herbicide
Active constituent/s:	540 g/L glyphosate (present as the potassium salt)
Applicant name:	Monsanto Australia Ltd
Applicant ACN:	006 725 560
Summary of use	For the control of many annual and perennial weeds in roundup ready flex cotton and other situations
Date of registration/approval:	28 October 2016
Product registration no.:	81975
Label approval no.:	81975/104549

Application no.:	100550
Product name:	Winter Grass Killer for Buffalo and Couch Lawns
Active constituent/s:	100 g/kg propyzamide
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of use	For the control of winter grass (<i>poa annua</i>) in common couch and buffalo lawns
Date of registration/approval:	31 October 2016
Product registration no.:	80291
Label approval no.:	80291/100550

3. VARIATIONS OF REGISTRATION

Application no:	107987
Product name:	Huilong MSMA 720 Herbicide
Active constituent/s:	720 g/L MSMA
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY MSMA 720 HERBICIDE' to 'HUILONG MSMA 720 HERBICIDE'
Date of variation:	27 September 2016
Product registration no.:	65126
Label approval no.:	65126/107987

Application no:	107986
Product name:	Huilong Tri-Allate 500 EC Herbicide
Active constituent/s:	500 g/L triallate
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY TRI-ALLATE 500 EC HERBICIDE' to 'HUILONG TRI-ALLATE 500 EC HERBICIDE'
Date of variation:	27 September 2016
Product registration no.:	66295
Label approval no.:	66295/107986

Application no:	107988
Product name:	Huilong Iprodione 250 Fungicide
Active constituent/s:	250 g/L iprodione
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY IPRDIONE 250 FUNGICIDE' to 'HUILONG IPRDIONE 250 FUNGICIDE'
Date of variation:	27 September 2016
Product registration no.:	66255
Label approval no.:	66255/107988

Application no:	107989
Product name:	Huilong DSMA Flowable Liquid Herbicide
Active constituent/s:	526 g/L DSMA
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY DSMA FLOWABLE LIQUID HERBICIDE' to 'HUILONG DSMA FLOWABLE LIQUID HERBICIDE'
Date of variation:	27 September 2016
Product registration no.:	52263
Label approval no.:	52263/107989
Application no:	106685
Product name:	Nominee Herbicide
Active constituent/s:	100 g/L bispyribac-sodium
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of variation:	To amend claims and application rates
Date of variation:	25 October 2016
Product registration no.:	63233
Label approval no.:	63233/106685
Application no:	107590
Product name:	Brunnings Extra Strength Feed'n Weed
Active constituent/s:	2.6 g/L dicamba (present as the dimethylamine salt), 17.2 g/L MCPA (present as the dimethylamine salt)
Applicant name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of variation:	To change the product name from 'BRUNNINGS EXTRA STRENGTH FEED 'N WEED HOSE ON FOR LAWNS' to 'BRUNNINGS EXTRA STRENGTH FEED 'N WEED'
Date of variation:	26 October 2016
Product registration no.:	52012
Label approval no.:	52012/107590
Application no:	104351
Product name:	Expedite Full Insecticide
Active constituent/s:	500 g/kg sulfoxaflor
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To extend use to control a range of aphid species in pulses (adzuki bean, navy bean and mungbean), sweetcorn and tree nuts
Date of variation:	31 October 2016
Product registration no.:	65464
Label approval no.:	65464/104351
Application no:	104345
Product name:	Transform Insecticide
Active constituent/s:	240 g/L sulfoxaflor
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To extend use to control a range of aphid species in pulses (adzuki bean, navy bean and mungbean), sweetcorn and tree nuts
Date of variation:	31 October 2016
Product registration no.:	64101
Label approval no.:	64101/104345

Application no:	101896
Product name:	Success Neo Insecticide
Active constituent/s:	120 g/L spinetoram
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To extend the use to control of various pests in pistachio and macadamia
Date of variation:	4 November 2016
Product registration no.:	64109
Label approval no.:	64109/101896

Application no:	106508
Product name:	Ultraforce Termite Foam Insecticide
Active constituent/s:	0.6 g/kg fipronil
Applicant name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of variation:	To extend uses for control of ants and cockroaches
Date of variation:	4 November 2016
Product registration no.:	68977
Label approval no.:	68977/106508

4. LABEL APPROVAL

Application no:	107490
Product name:	Eliminate Dairy Equipment Sanitiser
Active constituent/s:	760 g/L phosphoric acid
Applicant name:	Dasco Proprietary Limited
Applicant ACN:	004 581 113
Summary of use:	To approve a new label for the product with the label name 'PROTOCOL DAIRY EQUIPMENT SANITISER'
Date of approval:	24 October 2016
Label approval no.:	49633/107490

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.

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	107391
Product name:	RSPCA Flea Control for Extra Large Dogs
Active constituent/s:	100 g/L fipronil
Applicant name:	Indyvet Animal Health Products Pty Ltd
Applicant ACN:	169 265 169
Summary of use	For use in dogs weighing 40–60 kg as a topical solution/suspension for the treatment and prevention of flea infestations and control of flea allergy dermatitis
Date of registration/approval:	24 October 2016
Product registration no.:	83052
Label approval no.:	83052/107391
Application no.:	107362
Product name:	RSPCA Flea Control for Small Dogs
Active constituent/s:	100 g/L fipronil
Applicant name:	Indyvet Animal Health Products Pty Ltd
Applicant ACN:	169 265 169
Summary of use	For use in dogs weighing 2–10 kg as a topical solution/suspension for the treatment and prevention of flea infestations and control of flea allergy dermatitis
Date of registration/approval:	24 October 2016
Product registration no.:	83035
Label approval no.:	83035/107362
Application no.:	107363
Product name:	RSPCA Flea Control for Medium Dogs
Active constituent/s:	100 g/L fipronil
Applicant name:	Indyvet Animal Health Products Pty Ltd
Applicant ACN:	169 265 169
Summary of use	For use in dogs weighing 10–20 kg as a topical solution/suspension for the treatment and prevention of flea infestations and control of flea allergy dermatitis
Date of registration/approval:	24 October 2016
Product registration no.:	83036
Label approval no.:	83036/107363
Application no.:	107364
Product name:	RSPCA Flea Control For Large Dogs
Active constituent/s:	100 g/L fipronil
Applicant name:	Indyvet Animal Health Products Pty Ltd
Applicant ACN:	169 265 169
Summary of use	For use in dogs weighing 20–40 kg as a topical solution/suspension for the treatment and prevention of flea infestations and control of flea allergy dermatitis
Date of registration/approval:	24 October 2016
Product registration no.:	83037
Label approval no.:	83037/107364

Application no.:	102893
Product name:	CaniPRBC - Canine Packed Red Blood Cells
Active constituent/s:	40–60 mL/100 mL Canine Erythrocytes (RBC)
Applicant name:	Plasvacc Pty Ltd
Applicant ACN:	099 547 841
Summary of use:	As an aid in the treatment of acute anaemia in dogs
Date of registration/approval:	31 October 2016
Product registration no.:	81359
Label approval no.:	81359/102893

2. VARIATIONS OF REGISTRATION

Application no.:	107805
Product name:	Aurizon Ear Drops
Active constituent/s:	Each mL contains 10 mg clotrimazole, 3 mg marbofloxacin and 1 mg dexamethasone acetate
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AURIZON EAR DROPS SUSPENSION' to 'AURIZON EAR DROPS'
Date of variation:	6 September 2016
Product registration no.:	67225
Label approval no.:	67225/107805

Approved Active Constituents

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 approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

1. ACTIVE CONSITUTENT

Application no.:	106132
Active constituent/s:	Methomyl
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	8 November 2016
Approval no.:	82585

Proposed Revision to Existing APVMA Standard for Active Constituents—Dimethoate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) invites comment on proposed changes to the current standard for the active constituent dimethoate. The purpose of the change is to update the standard in accordance with advice arising from the current reconsideration of dimethoate which is consistent with the Food and Agriculture Organisation (FAO) standard for dimethoate ¹.

DESCRIPTION OF THE PROPOSED CHANGE TO THE APVMA STANDARD FOR DIMETHOATE ACTIVE CONSTITUENT

Change to sections:

Change to Section 1. (Description) from:

- the material shall consist of dimethoate together with related manufacturing impurities and shall be in the form of white to greyish crystals, free from visible extraneous matter and added modifying agents.

To:

- the material shall consist of dimethoate together with related manufacturing impurities and shall be a white solid, having a mercaptanic odour, free from visible extraneous matter and added modifying agents.

Changes to Section 6. Composition:

6.1 Active constituent: 950 g/kg minimum—no change

6.2 Toxicological or relevant impurities:

O,O,S-Trimethyl phosphorodithioate: 5 g/kg max—no Change

ADD Omethoate (CAS No. 1113-02-6): 2 g/kg max

ADD Isodimethoate (CAS No. 3344-11-4): 3 g/kg max

ADD Water: 2 g/kg max.

The inclusion of these impurities in the standard is consistent with the FAO standard for dimethoate available from the site listed in the footnote below.

¹ www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Specs/Dimethoate2012_2.pdf available from www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/en/

PARTICULARS OF THE ACTIVE CONSTITUENT:

Common name:	Dimethoate
Chemical name IUPAC:	O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate
CAS registry number:	60-51-5
Current APVMA minimum	950 g/kg minimum
Published purity:	
Molecular formula:	C ₅ H ₁₂ NO ₃ PS ₂
Molecular weight:	229.3

THE PROPOSED REVISED STANDARD WILL BE AS FOLLOWS:

- 1. Description:** The material shall consist of dimethoate together with related manufacturing impurities and shall be a white solid, having a mercaptanic odour, free from visible extraneous matter and added modifying agents.
- 2. Common name:** Dimethoate
- 3. Chemical name (IUPAC):** O,O-dimethyl S-methylcarbamoylmethyl phosphorodithioate
- 4. CAS number:** 60-51-5
- 5. Identity test:** identity of the active constituent must be established by one or more of the following methods: spectroscopic tests (IR spectrum, NMR, mass spectra), Chromatography (HPLC or GC retention time with reference compound) or any other suitable test method.

6. Composition

6.1 Active constituent: 950 g/kg minimum

6.2 Toxicological or relevant impurities:	O,O,S-trimethyl phosphorodithioate:	5 g/kg max
	Omethoate (CAS No. 1113-02-6):	2 g/kg max
	Isodimethoate (CAS No. 3344-11-4):	3 g/kg max
	Water:	2 g/kg max

7. Analytical methods

The analytical method used for the determination of the active constituent and toxicological significant impurities must be validated in accordance with the APVMA guidelines for the validation of analytical methods.

The APVMA guidelines on validation of analytical methods state that analytical methods described in CIPAC handbooks and AOAC International Manual, and in recognized pharmacopoeias [BP, BP (Vet), Ph Eur and USP] for a particular active constituent or formulation are regarded as validated and do not require revalidation. However, the suitability of

these methods must be verified under actual conditions of use ie the selectivity and accuracy of the method should be demonstrated for the published method when applied to the relevant sample matrix and laboratory conditions.

When a CIPAC or AOAC international method is used for the assay of an active constituent in a bulk active constituent, there is no matrix. The registrants need to check the specificity of the method to ensure there is no interference from impurities or degradation products. However, determination of accuracy of the method is not required as there is no matrix effect. However, when a Collaborative International Pesticides Analytical Council (CIPAC) or AOAC international: (a non-profit scientific organisation which publishes chemical analytical methods and was formerly known as the Association of Official Analytical Chemists) method is used for the assay of an active constituent in a formulated product, determination of both specificity and accuracy is required as the matrix is relevant in formulated products (formulated products have different composition and quantities of excipients).

Refer to [Guidelines for the validation of analytical methods for active constituent, agricultural and veterinary chemical products \(PDF, 164kb\)](#).

Unless the scope of the collaborative method (CIPAC and AOAC) also includes toxicological significant impurities in the active constituent, validation data for impurities are required.

MAKING A SUBMISSION

The APVMA invites any person to submit a relevant written submission on this proposed amendment to the APVMA standard for dimethoate.

Submissions must be received by the APVMA by COB 27 January 2017 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)
- email or postal address
- the date you made the submission.

Note that all submissions received are subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code. All personal and confidential commercial information (CCI) material contained in submissions will be treated confidentially. (A full definition of 'confidential commercial information' is contained in the [Agvet Code](#)).

Written submissions on the APVMA's proposal to revise the APVMA standard for dimethoate approval can be sent by email to: chemicalreview@apvma.gov.au, or by mail to

Director Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2609

Phone: +61 2 6210 4947

Fax: +61 2 6210 4776

Email: chemicalreview@apvma.gov.au

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

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code]

PHIBRO ANIMAL HEALTH PTY LIMITED	LICENCE NO: 6209
ACN: 093 869 991	Product Types:*
1/7–10 Denoci Close	<ul style="list-style-type: none">• <i>Category 6:</i> Single step manufacture
WETHERILL PARK NSW 2164	Step(s) of Manufacture: relabelling and release for supply.
	Licence Issued: 11 October 2016

2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code]

TISMOR HEALTH & WELLNESS PTY LIMITED	LICENCE NO: 2209
ACN: 136 806 936	Product Types: *
19A Garema Circuit	<ul style="list-style-type: none">• <i>Category 2:</i> Tablets, creams/lotions, ointments, pastes, powders, liquids, suspensions and gels.
KINGSGROVE NSW 2208	Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, packaging, labelling, strip, blister or sachet packaging, tableting, tablet coating, analysis and testing (physical and chemical) storage and release for supply.
	Amended Licence Issued: 18 October 2016

ENDEAVOUR FOUNDATION	LICENCE NO: 4088
ACN: 009 670 704	Product Types: *
59–65 Kurrajong Avenue	<ul style="list-style-type: none">• <i>Category 4:</i> Therapeutic pet foods, premixes and supplements.

MOUNT DRUITT NSW 2770
Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, storage and release for supply.

Amended Licence Issued: 24 October 2016

VIRBAC (AUSTRALIA) PTY LTD

LICENCE NO: 1090

ACN: 003 268 871

Product Types: *

2152 Castlereagh Road

- *Category 1:* Immunobiologicals and sterile products
- *Category 2:* Liquids and suspensions

PENRITH NSW 2750

Step(s) of Manufacture: Quality assurance (QA) of raw materials, bacterial fermentation, formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat, filtration, chemical), microbiological reduction treatment (heat, chemical), analysis and testing (physical, chemical, microbiological, sterility testing, antibiotic assay, immunobiological, serological), storage and release for supply.

Amended Licence Issued: 25 October 2016

PIA PHARMA PTY LTD

LICENCE NO: 2232

ACN: 150 999 974

Product Types: *

Unit 3, 46 Buffalo Road

- *Category 2:* Liquids

GLADESVILLE NSW 2111

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

Amended Licence Issued: 28 October 2016

SYMBIO LABORATORIES PTY LTD

LICENCE NO: 6173

ACN: 079 645 015

Product Types:*

52 Brandl Street

- *Category 6:* Single step manufacture

EIGHT MILE PLAINS

Step(s) of Manufacture: Analysis and testing (chemical)

QLD 4113

Amended Licence Issued: 31 October 2016

3. LICENCE CANCELLATIONS

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

ULTRA MIX (AUST.) PTY. LTD. LICENCE NO: 2203
ACN: 067 526 596 **Date Cancelled:** 20 October 2016
6 McArthur Street
WEST FOOTSCRAY VIC 3012

4. LICENCE SUSPENSIONS

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

REDOX PTY LTD LICENCE NO: 6065
ACN: 000 762 345 **Date Suspended:** 21 October 2016 to 21 October 2017
26–30 Gilbertson Road
LAVERTON NORTH VIC 3026

MARKITFORCE PTY. LTD. LICENCE NO: 6194
ACN: 095 684 834 **Date Suspended:** 2 November 2016 to 1 March 2017
1/13 Childs Road
CHIPPING NORTON NSW 2170

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

Manufacturing Quality and Licensing Section
Legal and Compliance Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4899
Fax: +61 2 6210 4813
Email: mls@apvma.gov.au

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 *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012*. The *MRL Standard* lists MRLs of substances that 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, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2016 (No. 15)*.

The amendments will be incorporated into the compilation of the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012*.

The *MRL Standard* is accessible via the ComLaw website www.comlaw.gov.au or the links above.

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

Proposal to Amend Schedule 20 in the Australia New Zealand Food Standards Code

In the previous notice, the APVMA gazetted 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*, have been made.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2016 (No. 15)*) to MRLs into Schedule 20—Maximum residue limits in the *Australia New Zealand Food Standards Code*.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 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 and FSANZ are 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 Schedule 20 in the *APVMA Gazette*. The variations will take effect as from the date of that subsequent notice.

PROPOSED AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2016 (NO. 15))

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 sunseting.

To commence: on gazettal of variation

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] omitting from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Abamectin

Permitted residue: Avermectin B1a

Apple	0.01
Pear	0.01
Pome fruits [except apple; pear]	T0.01

[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Abamectin

Permitted residue: Avermectin B1a

Pome fruits	0.01
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Agvet chemical: Boscalid

*Permitted residue—commodities of plant origin:
Boscalid*

Chick-pea (dry)	T3
Lentil (dry)	T3

Agvet chemical: Cypermethrin

Permitted residue: Cypermethrin, sum of isomers

Lentil (dry)	T0.05
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Agvet chemical: Cyprodinil

Permitted residue: Cyprodinil

Broad bean (dry)	T0.2
Chick-pea (dry)	T0.2
Eggs	T*0.01
Litchi	T2
Poultry, edible offal of	T*0.01
Poultry meat	T*0.01

Agvet chemical: Dithiocarbamates

*Permitted residue: Total dithiocarbamates,
determined as carbon disulphide evolved during acid
digestion and expressed as milligrams of carbon
disulphide per kilogram of food*

Ginger, root	T3
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Agvet chemical: Fludioxonil

*Permitted residue—commodities of animal origin:
Sum of fludioxonil and oxidisable metabolites,
expressed as fludioxonil*

*Permitted residue—commodities of plant origin:
Fludioxonil*

Litchi	T2
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Invitation for Submissions

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20—Maximum residue limits in 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.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: 6 pm (AEDT) 13 December 2016

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:

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

Variations to Schedule 20 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 Schedule 20—Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. This notice pertains to proposals (No. 9) gazetted on 9 August 2016 (No. APVMA 16).

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 Schedule 20. A copy of the Amendment Instrument (No. APVMA 16, 2016) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislation available on the Legislation website at www.legislation.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 Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 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 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



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

***Australia New Zealand Food Standards
Code—Schedule 20—Maximum residue
limits Variation Instrument
No. APVMA 10, 2016***

I, Matthew O'Mullane, Executive Director, Scientific Assessment and Chemical Review 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*.

Matthew O'Mullane
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this Tenth day of November 2016

Part 1 Preliminary

1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code—Schedule 20—Maximum residue limits Variation Instrument* No. APVMA 10, 2016.

2 Commencement

In accordance with subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this instrument commences on the day 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 23 of 15 November 2016.

3 Object

The object of this instrument is for the APVMA to make variations to Schedule 20—Maximum residue limits in 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 Schedule 20—Maximum residue limits in 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. Schedule 20 was published in the *Food Standards Gazette* FSC 96 on Thursday 10 April 2015 and was registered as a legislative instrument on 1 April 2015 (F2015L00468).

Part 2 Variations to Schedule 20—Maximum Residue Limits

5 Variations to Schedule 20

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

Schedule

Variations to Schedule 20—Maximum residue limits

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] inserting in alphabetical order

Agvet chemical: Amisulbrom

Permitted residue: Amisulbrom

Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	2
Dried grapes (currants, raisins and sultanas)	1
Edible offal (mammalian)	*0.01
Eggs	*0.01
Grapes	0.5
Meat (mammalian)	*0.01
Milks	*0.01
Poultry, edible offal of	*0.01
Poultry meat	*0.01

Agvet chemical: Mandestrobin

Permitted residue: Mandestrobin

Stone fruits	3
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[1.2] omitting from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Abamectin

Permitted residue: Avermectin B1a

Potato	T0.01
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Agvet chemical: Buprofezin

Permitted residue: Buprofezin

Fruiting vegetables, other than cucurbits	T2
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Agvet chemical: Chlorothalonil

*Permitted residue—commodities of plant origin:
Chlorothalonil*

*Permitted residue—commodities of animal origin: 4-
hydroxy-2,5,6-trichloroisophthalonitrile metabolite,
expressed as chlorothalonil*

Herbs [except fennel, leaf]	T20
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[1.3] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Abamectin

Permitted residue: Avermectin B1a

Dried grapes (currants, raisins and sultanas)	T0.03
Pineapple	T*0.002

Agvet chemical: Acibenzolar-S-methyl

Permitted residue: Acibenzolar-S-methyl and all metabolites containing the benzo[1,2,3]thiadiazole-7-carboxyl moiety hydrolysed to benzo[1,2,3]thiadiazole-7-carboxylic acid, expressed as acibenzolar-S-methyl

Cucumber	T0.5
Squash, summer (including zucchini)	T0.5

Agvet chemical: Boscalid

Permitted residue—commodities of plant origin: Boscalid

Permitted residue—commodities of animal origin: Sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl) nicotinamide and the glucuronide conjugate of 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl) nicotinamide, expressed as boscalid equivalents

Onion, bulb	0.5
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Agvet chemical: Buprofezin

Permitted residue—Buprofezin

Fruiting vegetables, other than cucurbits [except tomato]	T2
Tomato	0.5

Agvet chemical: Chlorantraniliprole

Permitted residue—plant commodities and animal commodities other than milk: Chlorantraniliprole

Permitted residue—milk: Sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole

Linseed	T0.5
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Agvet chemical: Chlorothalonil

Permitted residue—commodities of plant origin:
 Chlorothalonil

Permitted residue—commodities of animal origin: 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite, expressed as chlorothalonil

Parsley	T20
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Agvet chemical: Difenoconazole

Permitted residue: Difenoconazole

Brassica leafy vegetables	T5
Mizuna	T5

Agvet chemical: Etoxazole

Permitted residue: Etoxazole

Almonds	*0.01
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Agvet chemical: Flubendiamide

Permitted residue—commodities of plant origin:
 Flubendiamide

Permitted residue—commodities of animal origin:
 Sum of flubendiamide and 3-iodo-N-(2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl)phthalimide, expressed as flubendiamide

Strawberry	0.3
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Agvet chemical: Iprodione

Permitted residue: Iprodione

Parsley	T20
Podded pea (young pods) (snow and sugar snap)	T2

[1.4] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Dithiocarbamates

Permitted residue—Total dithiocarbamates, determined as carbon disulphide evolved during acid digestion and expressed as milligrams of carbon disulphide per kilogram of food

Citrus fruits	T7
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Agvet chemical: Saflufenacil

Permitted residue—commodities of plant origin:

Sum of saflufenacil, N'-{2-chloro-4-fluoro-5-[1,2,3,6-tetrahydro-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]benzoyl-N-isopropyl sulfamide and N-[4-chloro-2-fluoro-5-({(isopropylamino)sulfonyl}amino)carbonyl]phenyl]urea, expressed as saflufenacil equivalents

Permitted residue—commodities of animal origin:

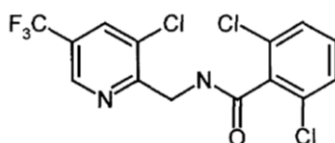
Saflufenacil

Edible offal (mammalian)	7
Pulses	0.2

New Agricultural Active Constituent Fluopicolide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, fluopicolide, for use as a fungicide in agricultural products.

Common Name	Fluopicolide
IUPAC Name:	2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide
Chemical Abstracts Name:	2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide
CAS Number:	239110-15-7
Molecular Formula:	C ₁₄ H ₈ Cl ₃ F ₃ N ₂ O
Molecular Weight:	383.6



Structure:

Chemical Family: Benzamide; pyridine

Mode of Action: Causes redistribution of spectrin-like proteins from the membrane to the cytoplasm

SUMMARY OF THE APVMA'S EVALUATION OF FLUOPICOLIDE ACTIVE CONSTITUENT

The Scientific Assessment and Chemical Review Program of the APVMA has evaluated the chemistry aspects of fluopicolide active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA active constituent standard be established for fluopicolide active constituent:

Constituent	Specification	Level
Fluopicolide	fluopicolide	970 g/kg minimum
	2,6-dichlorobenzamide	4 g/kg maximum

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

The APVMA has considered the toxicological aspects of fluopicolide, and concluded that there are no toxicological concerns regarding the approval of this active constituent. The ADI for fluopicolide was established at 0.08 mg/kg bw/day. This value is consistent with those established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and of the European Food Safety Authority (EFSA).

The ARfD for fluopicolide was established at 0.6 mg/kg bw/day. This ARfD is consistent with that of the JMPR.

Fluopicolide has been considered for scheduling and based on the data provided the Scheduling delegate concluded that fluopicolide was of low toxicity and has included fluopicolide in Appendix B of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)).

The APVMA is satisfied that the proposed importation and use of fluopicolide would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

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 fluopicolide should be granted. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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 the following information:

- contact name
- company or group name (if relevant)
- email or postal 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 should be addressed in writing to:

Director of Chemistry and Manufacture
Scientific Assessment and Chemical Review Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4701

Fax: +61 2 6210 4721

Email: enquiries@apvma.gov.au

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

Infinito SC Fungicide Containing the New Active Constituent Fluopicolide and the Existing Active Constituent Propamocarb Hydrochloride

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is Infinito SC Fungicide.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Infinito SC Fungicide
Applicant company:	Bayer CropScience Pty Ltd
Name of active constituents:	Fluopicolide and Propamocarb Hydrochloride
Signal heading:	Schedule 5
Summary of proposed use:	For the control of downy mildew in bulb vegetables, cucurbits, lettuce, and poppies and late blight in potatoes
Pack sizes:	1 L, 2.5 L, 3 L, 5 L, 7 L, 7.5 L, 10 L, 15 L, 20 L, 60 L, 110 L
Withholding period:	HARVEST: Cucumber: Do not harvest for 1 day after last application. Cucurbits (except cucumber): Do not harvest for 3 days after last application Bulb vegetables, lettuce: Do not harvest for 7 days after last application. Potatoes: Do not harvest for 14 days after last application. Poppies: Not required when used as directed.

SUMMARY OF THE APVMA'S EVALUATION OF INFINITO SC FUNGICIDE IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of Infinito SC Fungicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - (ii) The APVMA is satisfied that the proposed use of Infinito SC Fungicide will not be an undue hazard to the safety of people using anything containing its residues.
 - (iii) The APVMA is satisfied that the proposed use of Infinito SC Fungicide containing the active constituents fluopicolide and propamocarb hydrochloride is not likely to be harmful to human beings if used according to the product label directions.
 - (iv) The APVMA is satisfied that the proposed use of the new products Infinito SC Fungicide containing the active constituent fluopicolide and propamocarb hydrochloride, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (i) 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.
3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (ii) The APVMA is satisfied that the proposed use of Infinito SC Fungicide 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.

FURTHER 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/news-and-publications/public-consultations or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Infinito SC Fungicide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Phone: +61 2 6210 4701

Fax: +61 2 6210 4721

Email: enquiries@apvma.gov.au

New Chemical Products Cormoran Insecticide Containing Novaluron

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is Cormoran Insecticide.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Cormoran Insectide
Applicant company:	Adama Australia Pty Ltd
Name of active constituent:	Novaluron
Signal heading:	Schedule 6
Summary of proposed use:	For the control of apple dimpling bug, codling moth, light brown apple moth, longtailed mealybug, plague thrips and tuber mealybug in apples and pears.
Pack sizes:	1 L – 110 L
Withholding period:	Apples: Do not harvest for 70 days after application Pears: Do not harvest for 35 days after application Grazing: Do not graze any treated area or cut for stockfood.

SUMMARY OF THE APVMA'S EVALUATION OF CORMORAN INSECTICIDE IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of Cormoran Insecticide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the product and concluded that there should be no adverse effects on human health from the use of Cormoran Insecticide when used in accordance with the label directions. OCS has recommended first aid and safety directions which have been incorporated into the label particulars.

Novaluron is included in Appendix B, Part 3 of the SUSMP as an agricultural substance considered not to require control by scheduling due to its low toxicity.

Acetamiprid is in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons SUSMP except in preparations containing 1% or less of acetamiprid. Cormoran Insecticide contains 10% (w/v) novaluron and 8% (w/v) acetamiprid and is therefore included in Schedule 6.

- (ii) The APVMA is satisfied that the proposed use of Cormoran Insecticide will not be an undue hazard to the safety of people using anything containing its residues.

Novaluron has an Acceptable Daily Intake (ADI) 0.01 mg/kg bw/d, with the National Estimated Daily Intake (NEDI) equivalent to to <20 % of the ADI.

- (iii) The APVMA is satisfied that the proposed use of Cormoran Insecticide containing the active constituent novaluron is not likely to be harmful to human beings if used according to the product label directions.
- (iv) The APVMA is satisfied that the proposed use of Cormoran Insecticide is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

Studies of the environmental fate of novaluron demonstrate that it is expected to be moderately to very persistent in soil under field conditions. In natural waters novaluron is readily to moderately degradable primarily through partitioning to sediment and microbial degradation. Novaluron degrades by photochemical oxidative suggesting that the concentrations of novaluron in air are likely to be negligible in the upper atmosphere. It strongly binds to soil, which limits its potential to leach to groundwater or contaminate the aquatic environment from run-off.

Novaluron is not toxic to birds, mammals, earthworms, soil micro-organisms, or terrestrial plants and, as such, the associated risks are considered acceptable. Novaluron is not toxic to fish, algae and aquatic plants up to the limit of solubility, but has very high toxicity to aquatic invertebrates. Risks of novaluron were determined to be acceptable at the community level provided a mandatory no-spray zone of 200 metres is observed for aquatic habitat.

Novaluron is not toxic to adult worker bees; however, a field study indicates transient effects on bee brood can occur when novaluron is applied during bloom and as such, application of Cormoran Insecticide is not permitted during bloom or when bees are actively foraging. Additionally, due to toxicity to non-target arthropods, Cormoran Insecticide is not compatible with integrated pest management (IPM) strategies that utilise beneficial arthropods and a precautionary statement is required on the label to notify the user of this.

The APVMA has considered these findings and accepts these conclusions.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (v) 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 CORMORAN INSECTICIDE adequately demonstrate that if used according to the product label directions, the product is effective for its proposed use for the control apple dimpling bug, codling moth, light brown apple moth, longtailed mealybug, plague thrips and tuber mealybug in apples and pears.
3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (vi) The APVMA is satisfied that the proposed use of Cormoran Insecticide would not adversely affect trade between Australia and overseas markets.

Apples and pears are considered to be major export commodities³, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed apple pomace treated with Novaluron.

Maximum Residue Limits (MRLs) proposed for apples and pears are 0.3 mg/kg. The proposed MRL is lower than those established overseas including: European Union (2 mg/kg for apples and 3 mg/kg for pears), Japan (3 mg/kg for both apples and pears), Codex (3 mg/kg for pome fruit), USA (2 mg/kg for pome fruit), Taiwan (2.0 mg/kg for apples and pears) and Korea (1 mg/kg for apples).

Novaluron MRLs at *0.01 mg/kg are proposed for edible offal (mammalian), eggs, poultry edible offal and poultry meat [in the fat].

³ APVMA regulatory guidelines—data guidelines: agricultural—overseas trade (Part 5B)

The proposed novaluron meat (mammalian) in the fat MRL (0.1 mg/kg) is significantly lower than established MRLs in the EU, Japan and by Codex (10 mg/kg) while the USA has an MRL for cattle fat at 11 mg/kg. Similarly the proposed novaluron MRL for milk fats (0.2 mg/kg) is lower than MRLs for Codex (7 mg/kg) and the USA (20 mg/kg). Although finite MRLs have been proposed for meat (mammalian) in the fat (0.1 mg/kg) and milk fats (0.2 mg/kg), calculated maximum residue levels are in all cases much lower than the proposed MRLs. These MRLs are assumed to be conservative as the residues of novaluron observed in apples, used to calculate estimated residues in apple pomace, were based on trials in which three or four applications were made at a 14-day retreatment interval, whereas the proposed use pattern allows one application only. In addition the predicted maximum novaluron residues in animal commodities are based on animal transfer data generated by continuous feeding of novaluron to beef or dairy cattle for 28 or 42/44 days respectively, whereas in practice animals are less likely to feed continuously on apple pomace. Furthermore the calculated processing factor for novaluron in apple pomace was based on the assumption that all of the novaluron in apples was transferred into the pomace.

The following label statements have been proposed to manage the trade risks associated with the proposed use:

WITHHOLDING PERIODS:

Apples: Do not harvest for 70 days after application

Pears: Do not harvest for 35 days after application

Export of treated produce

Before using Cormoran on crops destined for export it is essential to consult your exporter or ADAMA to ensure that an appropriate MRL is in place in the importing country.

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.

FURTHER 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/news-and-publications/public-consultations or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Cormoran Insecticide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4701

Fax: +61 2 6210 4721

Email: enquiries@apvma.gov.au