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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 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.

If you would like to subscribe to receive email notification when a new edition is published, please complete a subscription form.

APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

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

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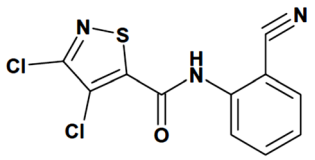
New active constituent: isotianil

The APVMA has before it an application for the approval of a new active constituent, isotianil.

Table 1: Particulars of the active constituent

Application no	Isotianil
IUPAC name	3,4-dichloro-*N*-(2-cyanophenyl)-1,2-thiazole-5-carboxamide
CAS name	3,4-dichloro-*N*-(2-cyanophenyl)-5-isothiazolecarboxamide
CAS registry number	224049-04-1
Minimum purity	970 g/kg
Molecular formula	$C_{11}H_5Cl_2N_3OS$
Molecular weight	298.15 $gmol^{-1}$
Structure	
Chemical family	Thiadiazole carboxamide
Mode of action	Isotianil is a systemic fungicide, belonging to the thiadiazole carboxamide chemical class. It induces the plant defence mechanisms against a wide range of fungal diseases. It is used for the control of rice blast, bacterial leaf blight and bacterial grain rot in seedling boxes.

Summary of the APVMA's evaluation of isotianil active constituent

The APVMA has evaluated the chemistry aspects of isotianil (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has considered the toxicological aspects of isotianil and concluded that there are no toxicological concerns regarding the approval of this active constituent. The acceptable daily intake (ADI) for isotianil was established at 0.03 mg/kg bw/day based on a NOEL of 3 mg/kg bw/d in the 2-generation study in rats. This ADI is further supported by a NOAEL of 5 mg/kg bw/d based on adverse liver effects in a one-year dog dietary toxicity study. The acute reference dose (ARfD) of 3 mg/kg bw has been set based on a NOAEL of 300 mg/kg bw in a rat and rabbit developmental study, after applying an uncertainty factor of 100.

The APVMA has recommended inclusion of isotianil in Schedule 6 (no cut-offs) of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

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

Constituent	Level
Isotianil	Minimum purity 970 g/kg

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

The APVMA accepts the findings and recommendations of its advisors on these criteria.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website or from the contact listed below.

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether isotianil should be approved. 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.

Please note: Submissions will be published on the APVMA's website unless you have asked for the submission to remain confidential (see public submission coversheet).

Please lodge your submission with a public submission coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Please send your written submission and coversheet by email or post to:

Email: enquiries@apvma.gov.au

Post:
Director Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Privacy

For information on how the APVMA manages personal information when you make a submission, see our Privacy Policy.

Routine 200 SC Fungicide containing isotianil

The APVMA has before it an application for registration of a new product, Routine 200 SC Fungicide containing a new active constituent, isotianil.

Table 2: Particulars of the application

Proposed product name	Routine 200 SC Fungicide
Applicant company	Bayer CropScience Pty Ltd
Name of active constituent	Isotianil
Signal heading	Schedule 6
Summary of proposed use	Registration of a 200 g/L isotianil suspension concentrate product for use in bananas for the control of yellow sigatoka (*Mycosphaerella musicola*) and common leaf speckle (*Mycospharella musae*)
Pack sizes	1 L to 110 L
Withholding period	Not required when used as directed

A summary of the APVMA's evaluation of Routine 200 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, proposes to determine that:

   i. The APVMA is satisfied that proposed use of Routine 200 SC Fungicide would not be an undue hazard to the safety of people exposed to it during its handling and use.

   ii. The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.

   iii. The APVMA is satisfied that the proposed use of Routine 200 SC Fungicide will not be an undue hazard to the safety of people using anything containing its residues.

   iv. The APVMA is satisfied that the proposed use of Routine 200 SC Fungicide is not likely to have an unintended effect that is harmful to animals, plants, things or the environment if used according to the product label directions.

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 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, proposes to determine that:

   i. The APVMA is satisfied that the proposed use of Routine 200 SC Fungicide would not adversely affect trade between Australia and places outside Australia as the product is not for use in major trade commodities and significant residues are not expected to arise in livestock feeds as a result of the proposed use.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website or by contacting the APVMA as 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 Routine 200 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.

Please note: Submissions will be published on the APVMA's website unless you have asked for the submission to remain confidential (see public submission coversheet).

Please lodge your submission with a public submission coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Please send your written submission and coversheet by email or post to:

Email: casemanagement@apvma.gov.au

Post:
Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

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