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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 - hydrogen cyanide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, hydrogen cyanide.

Table 1: Particulars of the active constituent - hydrogen cyanide

Common name	Hydrogen cyanide
IUPAC name	Hydrogen cyanide
CAS name	Hydrogen cyanide
CAS registry number	74-90-8
Minimum purity	976 g/kg
Molecular formula	HCN
Molecular weight	27.02 gmol ⁻¹
Structure	H—C≡N
Mode of action	Hydrogen cyanide is a respiratory poison, being the conjugate acid of cyanide. It is volatile, boiling at 26°C. It acts by inhibition of mitochondrial respiration by blocking electron transfer at the cytochrome c oxidase and the terminal oxidase enzymes, thereby reducing the availability of oxygen and causing hypoxia and cellular destruction. It is mainly absorbed through airways, digestive tract and body surface, resulting in killing pests by asphyxiation directly in tissues and also by damaging their metabolism. Hydrogen cyanide can be applied as liquid by spraying nozzles and the liquid vaporizes with air to the gaseous form of hydrogen cyanide.

Summary of the APVMA's evaluation of hydrogen cyanide active constituent

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

The proposed products containing hydrogen cyanide are not currently intended for use on food commodities. An acceptable daily intake (ADI) and acute reference dose (ARfD) have therefore not been established as part of this application. However, it is noted that Food Standards Australia New Zealand (FSANZ) has adopted a provisional maximum tolerable daily intake of 0.02 mg/kg bw/day for cyanide for assessment of foods naturally containing cyanogenic glycosides. FSANZ has also established an ARfD of 0.08 mg/kg bw for cyanide. The primary exposure to hydrogen cyanide will be to fumigators in the workplace. Safework Australia has recently reviewed the occupational exposure limits (OELs) for cyanide, with a maximum time-weighted average over an 8-hour shift of 0.9 ppm (1 mg/m³) and a peak limit over periods of 15 minutes or less of 4.7 ppm (5 mg/m³).

Hydrogen cyanide (listed under the synonym hydrocyanic acid) is included in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) except for human therapeutic use when is it is included in Schedule 4. The proposed products Bluefume Fumigant and Bluefume-D Fumigant will therefore be schedule 7 products.

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

Table 2: Proposed active constituent standard for hydrogen cyanide

Constituent	Level
Hydrogen cyanide	Minimum purity 976 g/kg

Impurities of greater or different toxicological significance from the active itself are not expected to occur in hydrogen cyanide 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 <u>APVMA website</u> 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 hydrogen cyanide 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 <u>public submission coversheet</u>).

Please lodge your submission with a <u>public submission coversheet</u>, 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:

Post:

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

Email: enquiries@apvma.gov.au

Privacy

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

Bluefume Fumigant containing hydrogen cyanide

The APVMA has before it an application for registration of a new product, Bluefume Fumigant, containing a new active constituent, hydrogen cyanide.

Table 3: Particulars of the application - Bluefume Fumigant

Proposed product name	Bluefume Fumigant
Applicant company	Draslovka Services Pty Ltd
Name of active constituent	Hydrogen cyanide
Signal heading	Schedule 7 – Dangerous Poison
Summary of proposed use	For use by professionally licensed and authorised fumigators as an indoor fumigant for empty structures against beetles, weevils, moths, mites, cockroaches, and rodents.
Pack sizes	250 g to 30 kg
Withholding period	N/A

A summary of the APVMA's evaluation of Bluefume Fumigant 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:

- 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 Agyet Code, proposes to determine that:
- i. The APVMA is satisfied that proposed use of Bluefume Fumigant would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
- ii. Bluefume Fumigant is not to be used on stored food or any agricultural food commodities. As such, Bluefume Fumigant will not be an undue hazard in relation to residues.
- iii. The APVMA is satisfied that the proposed use of Bluefume Fumigant containing the active constituent hydrogen cyanide, 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.
- 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.
- 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:
 - The APVMA is satisfied that the proposed use of Bluefume Fumigant would not adversely affect trade between Australia and places outside Australia as the product is not for use on stored food or any agricultural food commodities.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the <u>APVMA website</u> 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 Bluefume Fumigant 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 <u>public submission coversheet</u>).

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

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

Post:

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

Email: casemanagement@apvma.gov.au

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Bluefume-D Fumigant containing hydrogen cyanide

The APVMA has before it an application for registration of a new product, Bluefume-D Fumigant, containing a new active constituent, hydrogen cyanide.

Table 4: Particulars of the application - Bluefume-D Fumigant

Proposed product name	Bluefume-D Fumigant
Applicant company	Draslovka Services Pty Ltd
Name of active constituent	Hydrogen cyanide
Signal heading	Schedule 7 – Dangerous Poison
Summary of proposed use	For use by professionally licensed and authorised fumigators as an indoor fumigant for empty structures against beetles, weevils, moths, mites, cockroaches, and rodents.
Pack sizes	1.5 kg
Withholding period	N/A

A summary of the APVMA's evaluation of Bluefume-D Fumigant 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:

- 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 Agyet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Bluefume-D Fumigant would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. Bluefume-D Fumigant is not to be used on stored food or any agricultural food commodities. As such, Bluefume Fumigant will not be an undue hazard in relation to residues.
 - iii. The APVMA is satisfied that the proposed use of Bluefume-D Fumigant containing the active constituent hydrogen cyanide, 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.
- 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.
- 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:
 - The APVMA is satisfied that the proposed use of Bluefume-D Fumigant would not adversely affect trade between Australia and places outside Australia as the product is not for use on stored food or any agricultural food commodities.

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 Bluefume-D Fumigant 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.

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