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# Gazette

## Agricultural and veterinary chemicals

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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.

## Privacy

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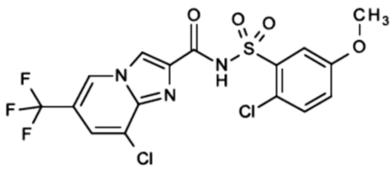
# Contents

# Fluazaindolizine

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

**Table 1: Particulars of the active constituent**

| | |
|---|---|
| **Common name** | Fluazaindolizine |
| **IUPAC name** | 8-chloro-N-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide |
| **CAS name** | 8-chloro-N-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide |
| **CAS registry number** | 1254304-22-7 |
| **Minimum purity** | 961 g/kg |
| **Molecular formula** | C16H10Cl2F3N3O4S |
| **Molecular weight** | 468.2 gmol-1 |
| **Structure** |  |
| **Chemical family** | Sulfonamide |
| **Mode of action** | Fluazaindolizine is a selective contact nematicide for the control of plant parasitic nematodes. It acts only on plant parasitic nematodes, and is not active against insect pests, plant pathogens or weeds. It exhibits the most potent toxic activity against the second-stage juveniles of root-knot nematode including Meloidogyne incognita and Tylenchulus semipenetrans in annual crops such as cucurbits, fruiting vegetables and root and tuber vegetables, and in certain perennial crops including vines, citrus, tree nuts and stone fruits. Fluazaindolizine can be applied by direct injection into drip, drench, in furrow spray with or without soil incorporation either before or at planting. |

## Summary of the APVMA's evaluation of fluazaindolizine active constituent

The APVMA has evaluated the chemistry aspects of active constituent fluazaindolizine (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 fluazaindolizine, and concluded that there are no toxicological concerns to the approval of this active constituent. The ADI for fluazaindolizine was established at 0.4 mg/kg bw/day based on a NOAEL of 36 mg/kg bw/d in 3 and 12 month dietary study in dogs, while the ARfD was established at 1.3 mg/kg bw/day based on a NOAEL of 125 mg/kg bw/d in an acute oral neurotoxicity study in rats, and using a default 100-fold uncertainty factor for extrapolation from laboratory animals to humans and to take account of differences in human responses in both cases.

The Scheduling Delegate has made a final decision to include fluazaindolizine in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) except when included in Schedule 5, for preparations containing 50% or less of fluazaindolizine, with a date of effect of 1 February 2021.

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

| Constituent | Level |
|---|---|
| Fluazaindolizine | Minimum purity 961 g/kg |

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

The APVMA considers that the toxicological aspects of fluazaindazolidine allow it to be satisfied with respect to the safety 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 fluazaindolizine 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
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## Privacy

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