



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



## TRADE ADVICE NOTICE

on mandestrobin in the product Intuity Fungicide for use on green beans

APVMA Product Number 69787

JANUARY 2019

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This publication is available from the APVMA website: [www.apvma.gov.au](http://www.apvma.gov.au).

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## CONTENTS

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|   |           |
|---|-----------|
| PREFACE   | IV        |
| <b>About this document</b>                                | <b>iv</b> |
| <b>Making a submission</b>                                | <b>iv</b> |
| <b>Further information</b>                                | <b>v</b>  |
| <hr/>   |           |
| 1 INTRODUCTION  | 6         |
| 2 TRADE CONSIDERATIONS                                    | 6         |
| 2.1 Commodities exported                                  | 6         |
| 2.2 Destination and value of exports                      | 6         |
| 2.3 Proposed Australian use-pattern                       | 6         |
| 2.4 Results from residues trials presented to the APVMA   | 7         |
| 2.5 Codex alimentarius commission and overseas MRLs       | 8         |
| 2.6 Current and proposed Australian MRLs for mandestrobin | 8         |
| 2.7 Potential risk to trade                               | 9         |
| <hr/>   |           |
| 3 CONCLUSIONS   | 10        |

## PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

## About this document

This is a trade advice notice.

It indicates that the APVMA is considering an application to vary the use of an existing registered agricultural or veterinary chemical. It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

## Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of Intuity Fungicide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 8 February 2019 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 to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- postal address
- email address (if available)
- the date you made the submission.

All personal and confidential commercial information (CCI)<sup>1</sup> material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Residues and Trade

Scientific Assessment and Chemical Review

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

Kingston ACT 2604

**Phone:** +61 2 6210 4701

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

## Further information

Further information can be obtained via the contact details provided above.

Further information on public release summaries can be found on the APVMA website: [apvma.gov.au](http://apvma.gov.au)

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<sup>1</sup> A full definition of 'confidential commercial information' is contained in the Agvet Code.

## 1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Sumitomo Chemical Australia Pty Limited, to vary the registration of Intuity Fungicide to add new uses on green beans and lettuce.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Green beans and lettuce are not considered to be major export commodities<sup>2</sup>. However, commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock on fed treated bean vines, are major export commodities. Residues in animal commodities resulting from the use of *Intuity Fungicide* on green beans may have the potential to unduly prejudice trade.

### 2.2 Destination and value of exports

The significant export markets for Australian beef, sheep, pig meat and offals are listed in the APVMA Regulatory Guidelines—Data Guidelines: Agricultural—overseas trade (Part 5B).

### 2.3 Proposed Australian use-pattern

Intuity Fungicide (250 g/L Mandestrobin)

| CROP        | DISEASE  | RATE                      | CRITICAL COMMENTS   |
|-------------|--|---------------------------|---|
| Green beans | White mould<br>( <i>Sclerotinia sclerotiorum</i> ) | 1.2 L/ha<br>(300 g ai/ha) | <p>Apply at 20% flowering then again at full flowering when pods are starting to form. This is generally 7 to 10 days apart.</p> <p>Good coverage is important to get good control. Generally water rates of 400-500L/ha should be used.</p> <p>DO NOT apply more than twice per crop. Under conditions of high pressure a third application may be required about 7 days later, but this should be a chemical from a different mode of action group.</p> <p>Concentrate spraying is not recommended.</p> |

Withholding periods:

Green beans: harvest: do not harvest for 7 days after application.

<sup>2</sup> APVMA regulatory guidelines—data guidelines: agricultural—overseas trade (Part 5B)

Grazing: do not graze or cut treated areas for stock food for 7 days after application.

#### LIVESTOCK DESTINED FOR EXPORT MARKETS

Grazing withholding periods apply to stock slaughtered for domestic market. Some export markets apply different standards. To meet these standards, ensure that the Export Slaughter Interval (ESI) is observed before stock are sold or slaughtered.

#### EXPORT SLAUGHTER INTERVAL (ESI)

Livestock that have been grazing on or fed treated material from treated areas should be placed on clean feed for 7 DAYS prior to export slaughter.

## 2.4 Results from residues trials presented to the APVMA

Residues of mandestrobin in green bean trash at 7 days after the last of 2 applications at approximately 300 g ai/ha (1x) were 5.20, 10.0, 10.2, 17.1, 24.2 and 33.3 mg/kg on a dry weight basis (STMR = 13.65 mg/kg, n = 6). MRLs of 70 mg/kg are recommended for mandestrobin on AL 0061 Bean fodder and AL 1030 Bean forage (green) in conjunction with a 7 day grazing withholding period.

Bean vines can form 60% of the diet for beef cattle in Australia and 70% for dairy cattle. Based on a HR in bean trash of 33 mg/kg the maximum livestock dietary burden is 20 ppm for beef cattle and 23 ppm for dairy cattle.

A mandestrobin animal transfer study for beef and dairy cattle is available. Estimated residues in tissues and milk as a result of feeding livestock on bean vines are calculated below along with the required animal commodity MRLs:

#### Cattle

| FEEDING LEVEL (PPM)          | MILK                         | MUSCLE            | LIVER        | KIDNEY | FAT   |
|------------------------------|------------------------------|-------------------|--------------|--------|-------|
|                              | MANDESTROBIN RESIDUE (mg/kg) |                   |              |        |       |
| 25                           | <0.005                       | <0.005            | 0.018        | <0.005 | 0.007 |
| 20–beef, estimated burden    | -                            | <0.005            | 0.014        | <0.005 | 0.006 |
| 23.3–dairy, estimated burden | <0.005                       | -                 | -            | -      | -     |
| Established MRLs             | -                            | -                 | -            | -      | -     |
| Recommended MRLs             | *0.02                        | 0.02 (in the fat) | 0.02 (offal) |        | 0.02  |

LOD = 0.005 mg/kg, LOQ = 0.02 mg/kg for mandestrobin in tissues and milk.

In the animal transfer study there were no detectable residues in tissues after animals were placed on clean feed for 7 days following initial dosing at 150 ppm.

## 2.5 Codex alimentarius commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Mandestrobin has not been considered by Codex. The following relevant overseas MRLs have been established for mandestrobin.

Table 1: Proposed Australian and overseas MRLs/tolerances for mandestrobin

| COMMODITY                    | TOLERANCE FOR RESIDUES ARISING FROM THE USE OF MANDESTROBIN (mg/kg) |                                 |                                |       |        |              |
|------------------------------|---|---------------------------------|--------------------------------|-------|--------|--------------|
|                              | AUSTRALIA   | EU                              | JAPAN                          | KOREA | TAIWAN | USA          |
| Residue Definition           | Mandestrobin  | Mandestrobin                    | The sum of (R) and (S) isomers | -     | -      | Mandestrobin |
| Edible offal (mammalian)     | 0.02 (proposed)   | *0.01 (bovine liver and kidney) | -                              | -     | -      | -            |
| Meat [mammalian][in the fat] | 0.02 (proposed)   | *0.01 (bovine muscle and fat)   | -                              | -     | -      | -            |
| Milks                        | *0.02 (proposed)  | *0.01                           | -                              | -     | -      | -            |

## 2.6 Current and proposed Australian MRLs for mandestrobin

Table 2: Current MRL Standard – Table1

| COMPOUND     | FOOD         | MRL (mg/kg) |
|--------------|--------------|-------------|
| Mandestrobin |              |             |
| FS 0012      | Stone fruits | 3           |

Table 3: Proposed MRL Standard – Table1

| COMPOUND     | FOOD                                   | MRL (mg/kg) |
|--------------|--|-------------|
| Mandestrobin |  |             |
| ADD:         |  |             |
| VP 0061      | Beans, except broad bean and soya bean | 0.7         |
| MO 0105      | Edible offal (Mammalian)               | 0.02        |
| VL 0482      | Lettuce, Head                          | 0.7         |
| VL 0483      | Lettuce, Leaf                          | 7           |
| MM 0095      | Meat [mammalian] [in the fat]          | 0.02        |
| ML 0106      | Milks                                  | *0.02       |

Table 4: Proposed MRL Standard – Table4

| COMPOUND     | ANIMAL FEED COMMODITY | MRL (mg/kg) |
|--------------|-----------------------|-------------|
| ADD:         |                       |             |
| Mandestrobin |                       |             |
| AL 0061      | Bean fodder           | 70          |
| AL 1030      | Bean forage (green)   | 70          |

## 2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of mandestrobin may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Residues below 0.02 mg/kg may be expected in liver and fat from the proposed uses and MRLs are not established any of the markets for Australian animal commodities, except the EU where the MRLs are established at \*0.01 mg/kg.

However the proposed 7 day ESI will ensure there are no detectable residues in animal commodities for export. The risk to trade is considered to be low.

### 3 CONCLUSIONS

Sumitomo Chemical Australia Pty Limited have applied to vary the registration of Intuity Fungicide, to add uses on green beans and lettuce. As bean vines may be fed to livestock this requires the establishment of animal commodity MRLs for mandestrobin.

Comment is sought on the potential for Intuity Fungicide to prejudice Australian trade in animal commodities when used on green beans according to the proposed label directions.