



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



TRADE ADVICE NOTICE

on Azoxystrobin in the Product Amistar 250 SC Fungicide

APVMA Product Number P58340

JANUARY 2013

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator 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 proposed extensions of use for existing chemicals where there may be trade implications, as defined in *Ag MORAG: Manual of Requirements and Guidelines* Part 5B.

About this document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (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 **Amistar 250 SC Fungicide** containing the existing active constituent azoxystrobin 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. In relation to this document, these grounds relate to the **trade implications** of the extended use of the product. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on **28 February 2013** 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)**¹ 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:

Contact Officer, Pesticides
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Phone: 02 6210 4748
Fax: 02 6210 4776
Email: pesticides@apvma.gov.au

Further information

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

Further information on trade advice notices can be found on the APVMA website: www.apvma.gov.au

¹ 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 Syngenta Crop Protection Pty Limited to vary the registration of the product, Amistar 250 SC Fungicide, containing 250 g/L azoxystrobin, to include new uses on almonds, green beans, citrus fruits and green peas. The proposed extensions of use require the establishment of relevant MRLs for azoxystrobin.

Citrus fruits are a significant export commodity², along with meat and dairy products from animals that have been fed feeds containing residues arising from the proposed use. Hence, only the residues in citrus fruit, animal feeds and animal commodities and their potential to unduly prejudice trade is discussed below. As existing MRLs associated with the use on peas, beans and almonds do not change the risk to trade, no further discussion of these uses is included below.

² Appendix 1 of Part 5B of the Agricultural Manual of Requirements and Guidelines (Ag MORAG).

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus fruits 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 feeding on commodities derived from treated crops. Residues in these commodities resulting from the use of Amistar 250 SC Fungicide have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Australia exported \$171 million worth of citrus fruits such as oranges, mandarins, lemon, limes and grapefruit in the 2007-2008 financial year. Major Australian export markets include the US, Hong Kong and Japan.

The significant export markets for Australian beef, sheep and pig meat and offals are listed in Appendix 3 of Part 5B of Ag MORAG. Australia exports significant quantities of dairy products (~\$2275m in 2010-11),⁴ with the main markets being Japan and other countries in Asia.

³ Appendix 1 of Part 5B of the Agricultural Manual of Requirements and Guidelines (Ag MORAG).

⁴ adl.brs.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022011/ACS_2011_1.0.3.pdf

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for Amistar 250 SC Fungicide (250 g/kg azoxystrobin) in citrus fruit, almonds and legume vegetables is summarised below.

Table 1: Proposed use pattern

Amistar 250 SC Fungicide (250 g/L azoxystrobin)

| TREE AND VINE CROPS | | | | |
|--|---|---|---------|---|
| Rate | | | | Critical Comments |
| In the following table Tree and Vine Crops, all rates given are for dilute spraying. For concentrate spraying, refer to the Application section. | | | | For all uses in the table Tree and Vine Crops: Apply by dilute or concentrate spraying equipment. Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. When applying AMISTAR 250 SC through low volume application equipment, DO NOT use a concentrate factor greater than 4X. In these cases adequate coverage of all plant surfaces is still required to achieve control of diseases. |
| Crop | Disease | Rate | WHP | |
| Almonds | Anthraco-nose (<i>Colletotrichum acutatum</i>) | 1.1 L/ha | 4 weeks | Apply using orchard airblast/mister sprayer applying sufficient water to obtain uniform coverage. May be applied as a Dilute or Concentrate spray. Alternate with sprays of other chemical groups. Dilute application: Water volumes typically range from 1800 to 20000 L/ha. Concentrate application: Apply in 800 to 1000 L/ha. Apply as part of an anthracnose disease management program. DO NOT apply more than 3 applications per season |
| Citrus | Brown Spot (<i>Alternaria sp.</i>), Black Spot (<i>Guignardia citricarpa</i>) | 40 mL/100 L | - | For best results apply 1 to 2 applications of AMISTAR 250 SC after copper fungicides, at no less than 14 day intervals. Follow with applications of an approved fungicide from a different chemical group. Ensure thorough spray coverage. DO NOT use AMISTAR 250 SC curatively. DO NOT apply more than 2 application of AMISTAR 250 SC per season. DO NOT start the disease control program with AMISTAR 250 SC. |
| OTHER CROPS | | | | |
| Crop | Disease | Rate | WHP | Critical Comments |
| Beans | Suppression of: Sclerotinia Rot (<i>Sclerotinia spp.</i>) | 500 to 600 mL/ha or 50 to 60 mL/100 L | - | Apply in sufficient volume of water to achieve thorough coverage of all foliage. Use the higher rates when climatic conditions are humid and mild which favours disease infection. Spray Interval: Apply a maximum of 2 consecutive applications at 7 to 14 day intervals commencing soon after planting and continuing up to crop maturity. Use the recommended shorter interval under humid weather conditions that are favourable for disease infection or where there is rapid vegetative growth during the early part of the crop cycle. DO NOT apply more than 3 applications per crop See Resistance Management |
| Snow Peas, Sugar Snap Peas, Garden Peas | Suppression of: <i>Stemphyllium spp.</i> Suppression of: Botrytis grey mould (<i>Botrytis cinerea</i>) | 600 mL/ha or 60 mL/100 L | - | Apply in sufficient volume of water to achieve thorough coverage of all foliage. Sprays should be applied at 7 to 14 day intervals commencing soon after transplanting and continuing up to maturity. Use the shorter interval under humid conditions that are favourable for disease infection or when there is rapid vegetative growth during the early part of the crop cycle. DO NOT apply more than 3 applications per crop DO NOT graze or cut treated crops for stockfeed See Resistance Management |

WITHHOLDING PERIODS

Beans, Citrus, Peas:
Almonds:

NOT REQUIRED WHEN USED AS DIRECTED
DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION

2.4 Results from residues trials presented to the APVMA

Citrus Fruit

The proposed use of azoxystrobin on citrus involves up to two applications made at 14 day intervals at a spray concentration of 10 g ai/100 L with a withholding period not required when used as directed.

The Australian and overseas citrus data show that following 2-6 treatments of azoxystrobin at 7.5-10 g ai/100 L, residues in citrus 0 days after treatment were 0.12, 0.19, 0.20, 0.23 (x2), 0.25, 0.26, 0.27, 0.28, 0.30, 0.31 (x2), 0.32, 0.41 (x2), 0.42 (x2), 0.52, 0.53, 1.0, 1.4, 1.6 and 1.8 mg/kg. An MRL of 3 mg/kg for azoxystrobin on citrus fruits is appropriate for the proposed use.

Livestock Feeds

Citrus Pulp

Processing studies indicate that residues do not concentrate into juice. Residues concentrate into dry pulp, with a processing factor of 1.25x. An MRL of 5 mg/kg is appropriate for citrus pulp, dry.

Almond Hulls

The proposed use of azoxystrobin on almonds involves up to three applications at a rate of 275 g ai/ha with a 4 week withholding period.

Almonds were treated six times with azoxystrobin at a rate of 280 g ai/ha (1x the maximum rate). Azoxystrobin residues in almond hulls 28 days after treatment were 1.1 (x2), 1.3, 1.5, 1.9, 2.3, 2.5, 3.1, 3.5 and 3.9 mg/kg. An MRL of 7 mg/kg is appropriate for almond hulls.

Legume Animal Feeds

The proposed use of azoxystrobin on legume vegetables involves up to three applications made at 7 day intervals at a rate of 150 g ai/ha. A withholding period is not required when used as directed.

Australian trials show that following 3 treatments of azoxystrobin at 150 g ai/ha (1x the maximum rate), residues in green bean foliage on a dry weight basis (assuming 35% dry material) 1 day after treatment were 4.9, 8.6, 10.3 and 13.4 mg/kg.

Trials from Europe show that azoxystrobin residues on dry pea and bean plant material following two applications at a rate of 250 g ai/ha (1.7x the maximum rate), 0 days after treatment were 28, 30, 32 (x2), 36 (x2), 42 and 49 mg/kg on a dry weight basis. Scaled to the maximum rate of 150 g ai/ha, residues of azoxystrobin are 17, 18, 19 (x2), 22 (x2), 25 and 29 mg/kg. An MRL of 50 mg/kg is appropriate for legume animal feeds.

Animal Commodities

Based on the proposed uses of *Amistar 250 SC Fungicide*, the maximum livestock burden is based on the consumption of legume animal feeds. The potential azoxystrobin residues in animal commodities derived from livestock fed on these treated commodities (29 mg/kg azoxystrobin for beef cattle and 21 mg/kg for dairy cattle) are summarised below. It is proposed to increase the MRLs for mammalian edible offal and mammalian meat (in the fat) from *0.01 mg/kg to 0.03 and 0.02 mg/kg, respectively. Commodities treated under the proposed use are not considered to be significant poultry feeds.

Table 2: Beef cattle feed exposure - 500 kg bw, 20 kg DM/day

| COMMODITY | % IN DIET | FEED INTAKE (kg) | RESIDUE (mg/kg) | % DM | LIVESTOCK BURDEN | | |
|---------------------|-----------|------------------|-----------------|------|------------------|-----------------|----------|
| | | | | | mg/animal | ppm in the feed | mg/kg bw |
| Legume animal feeds | 100 | 20 | 29 (HR) | 100 | 580 | 29 | 1.16 |

Table 3: Dairy cattle feed exposure - 500 kg bw, 20 kg DM/day

| COMMODITY | % IN DIET | FEED INTAKE (kg) | RESIDUE (mg/kg) | % DM | LIVESTOCK BURDEN | | |
|---------------------|-----------|------------------|-----------------|------|------------------|-----------------|----------|
| | | | | | mg/animal | ppm in the feed | mg/kg bw |
| Legume animal feeds | 70 | 14 | 29 (HR) | 100 | 406 | 20.3 | 0.812 |
| Almond hulls | 10 | 2 | 2.1 (STMR) | 100 | 4.2 | 0.21 | 0.008 |
| Total | 80 | 16 | | | 410 | 20.5 | 0.820 |

Table 4: Potential residues of azoxystrobin (mg/kg) for animal commodities from feeding of treated feeds and current and proposed Australian MRLs

| SAMPLE | MILK | MEAT | LIVER | KIDNEY | FAT |
|--|-------|-------|-------|--------|-------|
| Potential azoxystrobin residue (mg/kg) | 0.004 | <0.01 | 0.019 | <0.01 | 0.012 |
| Current MRL | 0.005 | *0.01 | *0.01 | | - |
| Proposed MRL | 0.005 | - | 0.03 | | 0.02 |

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. Azoxystrobin has been considered by Codex. Changes are also proposed to Australian animal commodity MRLs (which are previously established at the LOQ). The following relevant overseas residue MRLs/ tolerances have been established for azoxystrobin:

Table 5: Codex CXLs and other MRLs/tolerances for azoxystrobin

| COUNTRY/STATUS | COMMODITY | TOLERANCE (mg/kg) |
|----------------|-------------------------|-------------------|
| Australia | Citrus fruits | 3 (proposed) |
| CODEX | Citrus fruits | 15 |
| EU | Grapefruit | 15 |
| | Oranges | 15 |
| | Lemons | 15 |
| | Limes | 15 |
| | Mandarins | 15 |
| | Other Citrus fruit | 15 |
| Japan | Lemon | 2 |
| | Orange | 2 |
| | Grapefruit | 2 |
| | Lime | 2 |
| | Citrus fruits | 2 |
| USA | Fruit, Citrus, Group 10 | 10 |
| | Citrus, dried pulp | 20 |

Table 6: Codex CXLs and other MRLs/tolerances for azoxystrobin in animal commodities

| Commodity | Tolerance for residues arising from the use of azoxystrobin (mg/kg) | | | | |
|---|---|------------------------------|--|------------------------------|------------------------------|
| | Australia | EU | USA | Japan | CODEX |
| Animal Commodities | | | | | |
| Residue Definition | Azoxystrobin Azoxystrobin | Azoxystrobin Azoxystrobin | Azoxystrobin sum of azoxystrobin and the Z-isomer of azoxystrobin | Azoxystrobin Azoxystrobin | Azoxystrobin Azoxystrobin |
| Edible offal (mammalian) | 0.03 (proposed) | | | | 0.07 |
| Cattle kidney | | 0.07 | | 0.07 | |
| Sheep kidney | | 0.07 | | | |
| Cattle liver | | 0.07 | | 0.07 | |
| Sheep liver | | 0.07 | | | |
| Cattle meat by-products | | | 0.07 | | |
| Sheep meat by-products | | | 0.07 | | |
| Sheep, Edible offal | | 0.07 | | | |
| Cattle, edible offal | | 0.07 | | 0.07 | |
| Other terrestrial mammals, muscle | | | | 0.01 | |
| Other terrestrial mammals, fat | | | | 0.05 | |
| Other terrestrial mammals, liver | | | | 0.07 | |
| Other terrestrial mammals, kidney | | | | 0.07 | |
| Other terrestrial mammals, edible offal | | | | 0.07 | |
| Cattle fat | | *0.05 | 0.03 | 0.05 | |
| Sheep fat | | *0.05 | 0.03 | | |
| Cattle, muscle | | | | 0.01 | |
| Cattle, meat | 0.02 (mammalian, fat) (proposed) | *0.05 | 0.01 | | 0.05 (mammalian, fat) |
| Sheep meat | | *0.05 | 0.01 | | |
| Milks | 0.005 | *0.01 | 0.006 | 0.01 | 0.01 |
| Milk fats | | | | | 0.03 |

Note: Standards are not known to be established in Russia, China or Taiwan.

2.6 Current and proposed Australian MRLs for azoxystrobin

Current relevant MRLs and the residue definition for azoxystrobin are presented below. A full listing of MRLs can be found at www.apvma.gov.au/residues/standard.php.

Table 7: Current relevant entries in the MRL Standard - Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

| COMPOUND | FOOD | MRL (mg/kg) |
|--------------|--------------------------|-------------|
| AZOXYSTROBIN | | |
| FC 0001 | Citrus fruits | T2 |
| MO 0105 | Edible offal (mammalian) | *0.01 |
| MM 0095 | Meat (mammalian) | *0.01 |
| ML 0106 | Milks | 0.005 |

MRL Standard: TABLE 3

| COMPOUND | RESIDUE |
|--------------|--------------|
| AZOXYSTROBIN | Azoxystrobin |

MRL STANDARD: TABLE 4

| COMPOUND | ANIMAL FEED COMMODITY | MRL (mg/kg) |
|--------------|-----------------------------|-------------|
| AZOXYSTROBIN | | |
| | Almond hulls | 5 |
| AL 0061 | Bean fodder | T10 |
| AL 1030 | Bean forage (green) | T10 |
| AL 0524 | Chick-pea fodder | T2 |
| | Chick-pea forage (green) | T20 |
| AB 0001 | Citrus pulp, dry | T10 |
| | Lentil forage (green) | T20 |
| | Lentil fodder | T2 |
| AL 0072 | Pea hay or Pea fodder (dry) | T10 |
| AL 0697 | Peanut fodder | 25 |
| | Peanut hulls | 1 |
| AL 0528 | Pea vines (green) | T10 |

The following changes are proposed to Australian azoxystrobin MRLs:

Table 8: Proposed changes to the MRL Standard - Table1, Table 4

MRL STANDARD: TABLE 1

| COMPOUND | FOOD | MRL (mg/kg) |
|--------------|-------------------------------|-------------|
| AZOXYSTROBIN | | |
| DELETE: | | |
| FC 0001 | Citrus fruits | T2 |
| MO 0105 | Edible offal (mammalian) | *0.01 |
| MM 0095 | Meat (mammalian) | *0.01 |
| ADD: | | |
| FC 0001 | Citrus fruits | 3 |
| MO 0105 | Edible offal (mammalian) | 0.03 |
| MM 0095 | Meat (mammalian) [in the fat] | 0.02 |

MRL STANDARD: TABLE 4

| COMPOUND | FOOD | MRL (mg/kg) |
|--------------|-----------------------------|-------------|
| AZOXYSTROBIN | | |
| DELETE: | | |
| | Almond hulls | 5 |
| AL 0061 | Bean fodder | T10 |
| AL 1030 | Bean forage (green) | T10 |
| AL 0524 | Chick-pea fodder | T2 |
| | Chick-pea forage (green) | T20 |
| AB 0001 | Citrus pulp, dry | T10 |
| | Lentil forage (green) | T20 |
| | Lentil fodder | T2 |
| AL 0072 | Pea hay or Pea fodder (dry) | T10 |
| AL 0697 | Peanut fodder | 25 |
| | Peanut hulls | 1 |
| AL 0528 | Pea vines (green) | T10 |
| ADD: | | |
| | Almond hulls | 7 |
| AB 0001 | Citrus pulp, dry | 5 |
| AL 0157 | Legume animal feeds | 50 |

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of azoxystrobin 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.

While several overseas countries have established azoxystrobin MRLs in citrus fruit, some key Australian export markets have not. As detectable residues are expected to occur if the product is used as directed this creates a potential risk to trade. In Japan the MRL is 2 mg/kg, below the Australian MRL of 3 mg/kg. From residue trials approximating the proposed use it is noted that the highest residue in citrus fruits was 1.8 mg/kg, and the supervised trial median residue was 0.31 mg/kg. The applicant is proposing to mitigate this risk to trade through the inclusion of the following statement on the label:

EXPORT TRADE ADVICE – TREATED CITRUS: *Treated crop commodities destined for export may require extra time being allowed between application and harvest, to be accepted in some export markets. Before you use this product, you are advised to contact Syngenta Crop Protection and/or your industry body about any potential trade issues and their management.*

Based on the proposed uses of *Amistar 250 SC Fungicide*, the maximum livestock burden is based on the consumption of legume animal feeds for beef cattle or from the consumption of legume vegetables and almond hulls for dairy cattle. It is proposed to increase the MRLs for mammalian edible offal and mammalian meat (in the fat) from *0.01 mg/kg to 0.03 and 0.02 mg/kg, respectively. Residues are expected to be below the MRLs of major markets where they are established. It is also noted that declaration of feeding of by-product stockfeeds within 60 days of sale is required on NVDs.

3 CONCLUSIONS

It is proposed to vary the MRLs for azoxystrobin in citrus fruit and mammalian meat and offal. Comment is sought on the potential for azoxystrobin in *Amistar 250 SC Fungicide* to prejudice Australian trade when it is used on citrus fruit for the control of brown spot and black spot and when treated legume crops are fed to animals. Comment is also sought on the practicality of managing risks to trade in citrus fruit and animal commodities from an industry perspective.