



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



TRADE ADVICE NOTICE

on Azoxystrobin and Tebuconazole in the Product Custodia Fungicide

APVMA Product Number P66541

SEPTEMBER 2013

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), and State Departments of Primary Industry.

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 the APVMA's publication *Ag MORAG: Manual of Requirements and Guidelines*.

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 **Custodia Fungicide** containing the existing active constituents azoxystrobin and tebuconazole 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 **2 October 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
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Phone: +612 6210 4748

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Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained via the contact details provided above.

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 Sumitomo Chemical Australia Pty Limited to vary the registration of the product, *Custodia Fungicide*, containing 200 g/L tebuconazole and 120 g/L azoxystrobin, to increase the application rate and reduce the withholding period for grapevines. The proposed variation requires an increase in the MRL for tebuconazole in grapes and dried grapes. No changes to the current azoxystrobin MRLs are required at this time and no further consideration of azoxystrobin MRLs will be made here.

The potential for tebuconazole residues to unduly prejudice trade in grapes, arising from the proposed use, is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Grapes are considered to be a major export commodity.² No changes have been recommended to azoxystrobin grape MRLs, therefore only the potential for tebuconazole residues in grapes to prejudice trade will be discussed below.

2.2 Destination and value of exports

Table grape exports in 2010/2011 were worth A\$79.5 million, with significant markets including Hong Kong (\$27.1 million), Indonesia (\$12.6 million), Thailand (\$9.87 million), Vietnam (\$7.12 million), Singapore (\$6.05 million), Russia (\$1.78 million), and Taiwan (\$1.24 million).

Australian exports of wine were worth A\$1,957 million during 2010–2011, with significant markets including the United States (\$477.8 million), the United Kingdom (\$451.6 million), Canada (\$198.3 million), China (\$181.4 million), New Zealand (\$56 million), Germany (\$51.9 million) and Hong Kong (\$51.4 million).

² http://www.apvma.gov.au/morag_ag/vol_3/part_05b_trade.php

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Custodia Fungicide* (200 g/L tebuconazole, 120 g/L azoxystrobin) in grapes is summarised below.

Table 1: Proposed use pattern of *Custodia Fungicide* (200 g/L tebuconazole, 120 g/L azoxystrobin) on grapevines

DISEASE	RATE	WHP	CRITICAL COMMENTS
Downy Mildew (<i>Plasmopara viticola</i>)	<p>Dilute spraying: 100 mL/100 L (20 g tebuconazole/100 L, 12 g azoxystrobin/100 L)</p> <p>Concentrate spraying: 1 L/ha</p>	H: 4 weeks	Apply CUSTODIA as part of a seasonal preventative spray program commencing when shoots are approximately 20 cm long. Use CUSTODIA in rotation with other mode of action fungicides on a 7-21 day spray interval. Under conditions of high disease pressure and/or at critical timings i.e. during flowering; ensure that CUSTODIA is applied in rotation with fungicides from a different mode of action group such as AXIOM PLUS.
Botrytis Bunch Rot (<i>Botrytis cinerea</i>)	(200 g tebuconazole/ha, 120 g azoxystrobin/ha)		<p>When CUSTODIA is used in a seasonal spray programme it will provide control of Botrytis additional to that of specific botryticides.</p> <p>Under conditions of high disease pressure, Custodia should not be used for Botrytis control particularly at critical timings such as 80 to 100% capfall and pre-harvest.</p> <p>This use is subject to a CropLife Fungicide Resistance Management Strategy:</p> <p>Apply CUSTODIA preventatively.</p> <p>DO NOT apply more than two sprays per season of CUSTODIA or any other Group 11 fungicide.</p> <p>If three or fewer Botrytis sprays are applied in a season, use no more than one spray of CUSTODIA during the season.</p> <p>If four or more Botrytis sprays are to be applied in a season, up to two CUSTODIA sprays can be applied per season.</p>

WITHHOLDING PERIODS

GRAPEVINES:

DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION

DIRECTION FOR USE

Restraints: **DO NOT** apply more than two sprays of CUSTODIA per season.

Except when applying with orchard airblast equipment, **DO NOT** apply with spray droplets smaller than a MEDIUM spray droplet size category according to nozzle manufacturer specifications that refer to the ASAE S572 Standard or the BCPC Guideline.

2.4 Results from residues trials presented to the APVMA

The proposed use of tebuconazole on grapevines involves up to two applications at a concentration of 20 g ai/100 L. The applicant has proposed a 4 week harvest withholding period.

In support of the proposed use the applicant submitted three Australian GLP trials on grapes and grape products as well as two GLP trials from Italy on grapes.

Australian trials involved two applications of tebuconazole at a concentration of 20 g ai/100 L (1x the proposed concentration). Residues in grapes at 4 weeks after the last application were 0.11, 0.15 and 0.33 mg/kg.

Trials from Italy involved two applications of tebuconazole at a concentration of 20 g ai/100 L (1x the proposed concentration). Residues in grapes at 4 weeks after the last application were 0.13 and 0.14 mg/kg.

Data previously submitted involved application of tebuconazole to grapes at a rate of 15 g ai/100 L (0.75x the proposed concentration). Residues in grapes were 0.25, 0.33, 0.45, 0.62, 0.70, 1.09, 1.33 and 2.65 mg/kg at 28 days after application.

Considering the available data, the current MRL for grapes of 2 mg/kg will be increased to 5 mg/kg. The current tebuconazole MRL of 5 mg/kg for dried grapes will also be increased to 7 mg/kg.

From the processing of Australian grapes, tebuconazole was not found to concentrate in juice or wine. The processing factor from fresh grapes to wine is approximately 0.1x. Applying this processing factor to the grape residue data, the highest residue (HR-P) expected for wine is 0.27 mg/kg (STMR-P = 0.03 mg/kg).

A tebuconazole MRL of 50 mg/kg has been established for primary animal feeds, however, a Table 4 entry has not previously been established for dried grape pomace. The processing factor from fresh grapes to dried pomace is approximately 3.5x. The highest residue expected in dried grape pomace is 9 mg/kg (STMR-P = 1.2 mg/kg). An MRL of 15 mg/kg for tebuconazole in dried grape pomace is recommended. This does not change the estimates of livestock burden and no changes to animal commodity MRLs are required.

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. Tebuconazole has been considered by Codex. The following relevant international MRLs have been established for tebuconazole:

Table 2: Comparison of tebuconazole MRLs (mg/kg) for grapes

COUNTRY	COMMODITY	TEBUCONAZOLE TOLERANCE (mg/kg)
Australia	Grapes	5 (proposed)
	Dried grapes	7 (proposed)
CODEX	Grapes	6
	Dried grapes	7
EU	Grapes	2
Japan	Grapes	10
Russia	Grapes	1
US	Grapes	5

2.6 Current and proposed Australian MRLs for tebuconazole

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

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

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
TEBUCONAZOLE		
DF 0269	Dried grapes	5
FB 0269	Grapes	2

MRL Standard: TABLE 3

COMPOUND	RESIDUE
TEBUCONAZOLE	Tebuconazole

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
TEBUCONAZOLE		
	Primary feed commodities	50

The following changes are proposed to Australian tebuconazole MRLs:

Table 4: Proposed changes to the MRL Standard - Table 1

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
TEBUCONAZOLE		
DELETE:		
DF 0269	Dried grapes	5
FB 0269	Grapes	2
ADD:		
DF 0269	Dried grapes	7
FB 0269	Grapes	5

Table 5: Proposed changes to the MRL Standard - Table4

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
TEBUCONAZOLE		
ADD:		
AB 0269	Grape pomace, dry	15

2.7 Potential risk to trade

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

No changes have been recommended to the existing azoxystrobin grape or animal commodity MRLs. Therefore the risk to Australian trade associated with azoxystrobin residues arising from the proposed use is not significantly changed.

Russia and the EU have established MRLs for tebuconazole in grapes of 1 and 2 mg/kg, respectively, below the proposed Australian MRL of 5 mg/kg. However, it is noted that the highest tebuconazole residue observed in grapes following application approximating the proposed use was 2.65 mg/kg, and the supervised trial median residue was 0.33 mg/kg.

It is noted that the Australian Wine Research Institute (AWRI) publishes a guide for grape growers and winemakers exporting wine entitled "Agrochemicals registered for use in Australian viticulture". In this publication it is stated that *Custodia* should not be used later than 80% capfall.

3 CONCLUSIONS

It is proposed to increase the MRL for tebuconazole in grapes and dried grapes. Comment is sought on the potential for tebuconazole residues resulting from the proposed use of *Custodia Fungicide* on grapes to unduly prejudice Australian trade, and the ability of industry systems to manage any identified risk.