



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



TRADE ADVICE NOTICE

on Etoxazole in the Product Paramite Selective Miticide

APVMA Product Number 56791

JUNE 2010

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CONTENTS

PREFACE	IV
About this document	iv
Making a submission	iv
Further information	v
1 INTRODUCTION	1
2 TRADE CONSIDERATIONS	2
2.1 Commodities exported	2
2.2 Destination and value of exports	2
2.3 Proposed Australian use-pattern	5
2.4 Results from residues trials presented to the APVMA	6
2.5 Codex alimentarius commission and overseas MRLs	6
2.6 Current and proposed Australian MRLs for etoxazole	8
2.7 Potential risk to trade	10
3 CONCLUSIONS	11

List of tables

Table 1: Largest Export markets by value for citrus in 2007-2008 financial year	2
Table 2: Largest Export markets by value for fresh grapes in 2007-2008 financial year	3
Table 3: Largest Export markets by value for dried grapes and raisins in 2007-2008 financial year	3
Table 4: Largest Export markets by value for wine in 2007-2008 financial year	4
Table 5: Proposed use pattern	5
Table 6: Codex CXLs and overseas residue MRLs/tolerances for etoxazole	7
Table 7: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4	8
Table 8: Proposed changes to the MRL Standard – Table1 and Table 4	9

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 **PARAMITE SELECTIVE MITICIDE** containing the existing active constituent etoxazole 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 **10th August 2010** 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 Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: (02) 6210 4748

Fax: (02) 6210 4776

Email: AgProductscoordinator@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: <http://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 Sumitomo Chemical Australia Pty Limited to vary the registration of the product, Paramite Selective Miticide, containing 110 g/L etoxazole, to add use on citrus, wine grapes, tomatoes and capsicums for control of various pests. The proposed extensions of use require an increase in the MRL for etoxazole in grapes and the establishment of permanent MRLs for citrus and fruiting vegetables, other than cucurbits. As tomatoes and capsicums are not major export commodities they will not be discussed further in this note.

The potential for etoxazole residues in citrus and grapes to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus fruit, grapes and wine are considered to be major export commodities thus the presence of detectable residues has the potential to prejudice trade.

2.2 Destination and value of exports

Citrus

Australia exported \$172 million worth of citrus fruits such as oranges, mandarins, lemon, limes, grapefruit and other citrus in the 2007-2008 financial year. The major export markets and value of citrus exported to each country in the 2007-2008 financial year are shown below.

Table 1: Largest Export markets by value for citrus in 2007-2008 financial year

DESTINATION	VALUE, \$ MILLION
United States	52.2
Hong Kong	30.5
Japan	20.1
Malaysia	9.2
United Arab Emirates	8.4
New Zealand	7.9
Singapore	6.6
Indonesia	5.9
United Kingdom	4.5
Canada	4.2
Other	22.1
TOTAL	171.4

Source of data: Australian Bureau of Statistics

Grapes

In the 2007/2008 financial year Australia exported approximately \$100.5 million of table grapes, a total of \$12.67 million of dried grapes, raisins and an estimated \$876.5 million in wine exports. The top ten export markets for these commodities are summarized below.

Table 2: Largest Export markets by value for fresh grapes in 2007-2008 financial year

DESTINATION	VALUE, \$ MILLION
Hong Kong	29.34
Indonesia	16.78
Thailand	12.59
Singapore	7.99
Malaysia	7.21
Vietnam	5.32
New Zealand	4.54
United Arab Emirates	3.67
Taiwan	3.33
Bangladesh	2.04
TOTAL	100.51

Source of data: Australian Bureau of Statistics

Table 3: Largest Export markets by value for dried grapes and raisins in 2007-2008 financial year

DESTINATION	VALUE, \$ MILLION
Germany	4.96
United Kingdom	2.52
New Zealand	1.63
Netherlands	1.02
Italy	0.73

Japan	0.63
Malaysia	0.28
Belgium	0.27
Canada	0.18
Fiji	0.15
TOTAL	12.67

Source of data: Australian Bureau of Statistics

Table 4: Largest Export markets by value for wine in 2007-2008 financial year

DESTINATION	VALUE, \$ MILLION
United Kingdom	876.5
United States	741
Canada	258.9
New Zealand	83.9
Netherlands	70.6
Ireland	69.2
China	60.5
Germany	49.2
Japan	48
Singapore	45.3
TOTAL	2656.8

Source of data: Australian Commodity Statistics, ABARE

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for Paramite Selective Miticide (110 g/kg etoxazole) in citrus and grapes is summarised below.

Table 5: Proposed use pattern

Paramite Selective Miticide (110 g/L, Etoxazole)

Crop	Pest	Rate/100L	Critical Comments
Wine grapes	Two-spotted mite	35 mL/100	<p>Paramite is a mite growth regulator that causes adults to lay sterile eggs and stops existing eggs and nymphs developing. Control of these stages is generally achieved within 7 days. Paramite also has translaminar and residual activity which means control of the population may last for four to five weeks. It does not, however, control adult mites who will die naturally – normally over a two week period.</p> <p>To give effective long term population control Paramite should therefore be applied at the first signs of mite crawlers. Once large numbers of adults are present it may be necessary to also apply a miticide from a different group to control the adults immediately and reduce potential damage.</p> <p>As a guide, if there are 2 or more adults per leaf, and 15% or more of leaves are infested, a knockdown of adults with a different miticide may be required.</p> <p>Paramite can be applied as dilute or concentrated sprays on apples, stone fruit and table grapes but good coverage is important so the volume should be no less than 750 L/ha. DO NOT apply in greater than 2000L/ha.</p> <p>On Citrus, water rates of 2000-3000 L/ha are generally used and concentrate spraying is not recommended, DO NOT use a water volume of more than 3000 L/ha.</p> <p>If re-treatment is required, use an approved miticide from a different chemical group.</p>
Citrus	Oriental Spider Mite <i>(Eutetranychus orientalis)</i>	L (3.85 g ai/100L)	

WITHHOLDING PERIOD

Citrus: Do not harvest for 28 days after application.

Grapes: Do not harvest for 21 days after application.

2.4 Results from residues trials presented to the APVMA

Citrus

The applicant has requested an application rate of 3.85 g ai/ha on citrus with a 28 day WHP. At an application rate of 3.85-5.5 g ai/100L (1-1.43x) following a 28-29 day WHP etoxazole residues were <LOD, <LOD, 0.01, 0.01, 0.03, 0.03, 0.04, 0.05, 0.07, 0.07 mg/kg. A citrus fruits MRL of 0.2 mg/kg is recommended. Maximum expected residues in citrus pulp, dry are calculated to be 0.5 mg/kg. Therefore a citrus pulp, dry MRL of 1 mg/kg is recommended.

Grapes

Grape trials treated at 3.85-4 g ai/100L (1-1.03x) after a 21 day WHP resulted in residues in rank order of <0.01, <0.01, 0.01, 0.01, 0.01, 0.01, 0.03, 0.04, 0.04, 0.08, 0.14 mg/kg. An increase in the current grape MRL to 0.2 mg/kg is recommended. As residues did not concentrate in wine (and were all below the LOQ, n = 6) a separate MRL for wine is not required. Processing factors for grapes to pomace and grapes to dried fruit were calculated to be 5.89 and 2.67 respectively. Based on these processing factors highest expected residues in grape pomace and dried grape are 0.825 mg/kg and 0.37 mg/kg respectively. Increases to the grape pomace MRL to 2 mg/kg and the dried grapes MRL to 0.7 mg/kg are recommended.

Animal Commodities

Based on the predicted maximum dietary burden in cattle residues in tissues and milk are not expected to exceed current animal commodity MRLs. Existing MRLs for etoxazole in animal commodities remain appropriate (The PRS for etoxazole published in May 2004 provides justification for current animal commodity MRLs²).

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. Etoxazole has not been considered by Codex. No changes are proposed to Australian animal commodity MRLs (which are established at the LOQ) and they will not be considered further. The following relevant overseas residue MRLs/ tolerances have been established for etoxazole:

² <http://www.apvma.gov.au/registration/assessment/public/index.php>

Table 6: Codex CXLs and overseas residue MRLs/tolerances for etoxazole

COUNTRY/STATUS	COMMODITY	TOLERANCE, mg/kg
Australia	Citrus Dried grapes Edible offal (mammalian) Fruiting vegetables, other than Cucurbits Grapes Meat [mammalian] [in the fat] Milks	#0.2 #0.7 *0.01 #0.05 #0.2 *0.02 *0.01
USA ³	Cattle, fat Cattle, liver Grape Grape, raisin Milk, fat Tangerine	0.02 0.01 0.05 1.5 0.01 0.1
EU ⁴	Citrus fruit Table grapes Wine grapes Currants (red, black and white) Tomatoes (Cherry tomatoes) Peppers (chilli peppers)	0.1 *0.02 *0.02 *0.02 0.1 *0.02
Japan ⁵	Lemon Orange (including navel orange) Grapefruit Lime Other citrus fruits Cattle, muscle Cattle, fat Cattle, liver Cattle, kidney Milk	0.7 0.7 0.7 0.7 0.7 0.05 0.05 0.05 0.05 0.01

proposed MRL

Canada and Taiwan have no relevant MRLs established for etoxazole.

³ http://edocket.access.gpo.gov/cfr_2007/julqtr/pdf/40cfr180.593.pdf

⁴ http://ec.europa.eu/food/plant/protection/pesticides/database_pesticide_en.htm

⁵ <http://www.m5.ws001.squarestart.ne.jp/foundation/agrlist.php>

2.6 Current and proposed Australian MRLs for etoxazole

Current relevant MRLs and the residue definition for etoxazole are presented below. A full listing of MRLs can be found at <http://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)
Etoxazole		
FC 0001	Citrus fruit	T0.1
MO 0105	Edible offal (mammalian)	*0.01
VO 0050	Fruiting vegetables, other than Cucurbits	T0.1
DF 0269	Dried grapes	0.2
FB 0269	Grapes	0.1
MM 0095	Meat [mammalian][in the fat]	*0.02
ML 0106	Milks	*0.01

MRL Standard: TABLE 3

COMPOUND	RESIDUE
ETOXAZOLE	Etoxazole.

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Etoxazole		
AB 0269	Grape pomace, dry	1

The following changes are proposed to Australian etoxazole MRLs:

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

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
ETOXAZOLE		
DELETE:		
FC 0001	Citrus fruits	T0.1
DF 0269	Dried grapes	0.2
VO 0050	Fruiting vegetables, other than cucurbits	T0.1
FB 0269	Grapes	0.1
ADD:		
FC 0001	Citrus fruits	0.2
DF 0269	Dried grapes	0.7
VO 0050	Fruiting vegetables, other than Cucurbits	0.05
FB 0269	Grapes	0.2

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
ETOXAZOLE		
DELETE:		
AB 0269	Grape pomace, dry	1
ADD		
AB 0001	Citrus pulp, dry	1
AB 0269	Grape pomace, dry	2
	Tomato pomace, dry	0.5

2.7 Potential risk to trade

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

Citrus

Of the key export markets for citrus the EU and Japan have MRLs established. The Australian proposed MRL of 0.2 mg/kg is higher than the MRL currently established for citrus in the EU (0.1 mg/kg) however the Australian MRL is based on the HR of 0.07 mg/kg. The MRL established in Japan (0.7 mg/kg) is also higher than the proposed Australian MRL so should result in no trade implications. Australia's largest export destination of citrus, the United States has no relevant MRL established. Codex also has not established an MRL for citrus, so etoxazole residues in citrus may be a trade issue in the following countries; China (Hong Kong), Malaysia, the United Arab Emirates, Singapore, and Indonesia. The relevant industry groups are asked to comment on the perceived level of risk and whether any industry-initiated strategies are required to manage the risk associated with exporting citrus to countries without MRLs in place.

Grapes/wine

The US and EU have MRLs for grapes at 0.05 and 0.02* mg/kg respectively. These are the only countries with MRLs established for grapes. The proposed Australian MRL of 0.2 mg/kg was based on the HR of 0.14 mg/kg observed in a trial on wine grapes. The following statement was recommended to be placed on the product label and is relevant for use on grape vines also:

“Treated fruit for export to particular destinations outside Australia may require a longer interval before harvest to comply with residues standards of importing countries. Please contact your industry body or exporter before using Paramite Selective Miticide.”

As quantifiable residues of etoxazole are not expected to occur in wine, the risk to exports of Australian wine is low.

3 CONCLUSIONS

It is proposed to increase the MRL for etoxazole on grapes and establish a permanent MRL for etoxazole on citrus. Comment is sought on the potential for etoxazole in Paramite Selective Miticide to prejudice Australian trade when it is used on wine grapes and citrus for the control of two spotted mites and oriental spider mites.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at (02) 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street

Symonston ACT, 2609 Office hours: 9.00 - 5.00 (EST) Monday to Friday