



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



## TRADE ADVICE NOTICE

on Etoxazole in the Product Paramite Selective Miticide

APVMA Product Number P56791

**JULY 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 **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 **2 September 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)***<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:

Contact Officer  
Pesticides Program  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Symonston ACT 2609

**Phone:** +612 6210 4748

**Fax:** +612 6210 4776

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

## Further information

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

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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 the product, *Paramite Selective Miticide*, containing 110 g/L etoxazole, to reduce the withholding periods for citrus fruits. The proposed variation of use requires an increase in the MRL for etoxazole in citrus.

The potential for etoxazole residues to unduly prejudice trade in citrus fruit and in animal commodities, arising from the proposed use, is discussed below.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Citrus fruits are considered to be a major export commodity,<sup>2</sup> as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feed containing residues arising from the proposed use.

### 2.2 Destination and value of exports

Major export markets for Australian citrus fruit from the 2010/2011 financial year are presented below.

Table 1: Major destinations for Australian citrus exports

COMMODITY	MAJOR DESTINATIONS
Citrus	Japan, Hong Kong, Indonesia, New Zealand, Singapore, UAE, Canada, Thailand, Malaysia

The significant export markets for animal commodities are defined in Part 5B of Ag MoRaG.

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<sup>2</sup> [http://www.apvma.gov.au/morag\\_ag/vol\\_3/part\\_05b\\_trade.php](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 *Paramite Selective Miticide* (110 g/L etoxazole) in citrus fruit is summarised below.

**Table 2: Proposed use pattern of *Paramite Selective Miticide* (110 g/L etoxazole)**

SITUATION	PEST	RATE / 100 L	CRITICAL COMMENTS
Citrus	Oriental Spider Mite ( <i>Eutetranychus orientalis</i> )	35 mL (3.85 g ai)	<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. However, it does not control adult mites, which normally live for up to two weeks.</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>On <b>Citrus</b>, water rates of 2000-3000 L/ha are generally used and concentrate spraying is not recommended. <b>DO NOT use a water volume of more than 3000 L/ha.</b></p> <p>If re-treatment is required, use an approved miticide from a different chemical group.</p>

### WITHHOLDING PERIODS

CITRUS: DO NOT HARVEST FOR 7 DAYS AFTER APPLICATION

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 SUMITOMO CHEMICAL AUSTRALIA PTY LTD OR YOUR INDUSTRY BODY OR EXPORTER BEFORE USING PARAMITE SELECTIVE MITICIDE.

## 2.4 Results from residues trials presented to the APVMA

The proposed use of etoxazole on citrus fruit involves a single application of etoxazole made at a concentration of 3.85 g ai/100 L. The applicant has proposed a 7 day harvest withholding period.

### *Citrus*

The applicant has previously submitted Australian trials on citrus (56797/48336). In these trials citrus fruit were treated with 2 foliar applications of etoxazole, at a 14 day retreatment interval, at 4 g ai/100 L (1× the proposed concentration). Residues in citrus fruit (oranges, mandarins and lemons) 7 days after the final application were 0.04, 0.05, 0.06, 0.07, 0.07, 0.08, 0.09, 0.09, 0.12, 0.13 and 0.24 mg/kg.

On the basis of the available data it is recommended that the current group MRL for citrus fruit is increased to 0.5 mg/kg to cover the proposed use of etoxazole on citrus fruit in conjunction with a 7 day withholding period. An MRL of 3 mg/kg for dry citrus pulp is also recommended.

### *Animal Commodities*

The maximum livestock dietary burden for cattle will be as a result of the consumption of treated citrus pulp and cotton seed with an estimated dietary burden of 0.23 ppm in the feed. Based on the predicted maximum residues in tissues and milk for an etoxazole dietary intake of 0.23 ppm, the current animal commodity MRLs set at LOQ remain appropriate.

## 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 been considered by Codex. The following relevant international MRLs /tolerances have been established for etoxazole:

Table 3: Comparison of etoxazole MRLs (mg/kg) for citrus

COUNTRY	COMMODITY	TOLERANCE (mg/kg)
<b>Australia</b> (proposed)	Citrus fruits	0.5
<b>CODEX</b>	Citrus fruits	0.1
<b>EU</b>	Citrus fruits	0.1
<b>Japan</b>	Unshu orange, pulp	0.5
	Citrus natsudaikai, whole	0.7
	Lemon	0.7
	Orange (including navel orange)	0.7
	Grapefruit	0.7
	Lime	0.7
	Other citrus fruits	0.7
<b>US</b>	Tangerine	0.10 <sup>a</sup>

<sup>a</sup> there are no US registrations for use of etoxazole on tangerines as of September 26, 2003

## 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 [www.apvma.gov.au/residues/standard.php](http://www.apvma.gov.au/residues/standard.php).

Table 4: 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 fruits	0.2
SO 0691	Cotton seed	0.2
MO 0105	Edible offal (Mammalian)	*0.01
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 0001	Citrus pulp, dry	1

The following changes are proposed to Australian etoxazole MRLs:

Table 5: 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	0.2
ADD:		
FC 0001	Citrus fruits	0.5

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
ETOXAZOLE		
DELETE:		
AB 0001	Citrus pulp, dry	1
ADD:		
AB 0001	Citrus pulp, dry	3

## 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.

While several overseas countries have established etoxazole MRLs in citrus fruits, some key Australian export markets for these commodities have not. As detectable residues are expected to occur when the product is used as directed this creates a potential risk to trade.

Codex and the EU have established MRLs for etoxazole in citrus fruits of 0.1 mg/kg, below the proposed Australian MRL of 0.5 mg/kg. However, it is noted that the residue considered as the highest residue in citrus fruits was 0.24 mg/kg, and the supervised trial median was 0.08 mg/kg.

The applicant is proposing to mitigate the risk to trade through the inclusion of the following statement on the label:

*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 Sumitomo Chemical Australia Pty Ltd or your industry body or exporter before using Paramite Selective Miticide.*

The relevant industry groups should be given the opportunity to comment on the perceived level of risk and whether any industry-initiated strategies are required to manage the risk.

### 3 CONCLUSIONS

It is proposed to increase the MRL for etoxazole on citrus fruit. Comment is sought on the potential for etoxazole residues resulting from the proposed use of *Paramite Selective Miticide* on citrus to prejudice Australian trade.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at +612 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