

Trade Advice Notice

on

Thiamethoxam

in the product

Actara Insecticide

Product No. 56499

June 9, 2009

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The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Australia

1. PREFACE

1.1 About this Document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an 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 notice.

The APVMA will only consider comment on submissions that relate to the **trade implications** of the extended use of the product. Comments received outside these grounds will not be considered by the APVMA. Comments made on appropriate grounds will be considered with details posted on the APVMA website noting what action has/will be taken in regard to concerns.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found at:

http://www.apvma.gov.au/registration/data_requirements_subpage.shtml

1.2 Prior to Submission

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent (you) unless a request for anonymity accompanies your submission. If no request for anonymity is made, you will be taken to have consented to the disclosure of your identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988*.

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and you have provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

1.3 About this consultation

The APVMA invites comment on this Trade Advice Notice until the 7th July, 2009
Submissions should be addressed to:

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2. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Syngenta Crop Protection Pty Ltd to amend the label of Actara Insecticide (APVMA No. 56499, containing 250 g thiamethoxam/kg) to include the use on tomatoes grown in greenhouse / glasshouse situations.

Thiamethoxam is currently registered as a planting-hole application for tomatoes at the time of transplant. For indoor grown tomatoes application will be to the potting media at 10 g ai/1000 plants to the base of seedlings not later than BBCH 51 [First inflorescence visible (first bud erect)]. The current and proposed use patterns for tomatoes are summarized below:

Actara Insecticide (250 g/kg Thiamethoxam)

Crop	Pest	Rate	Critical Comments
Tomatoes	Silverleaf Whitefly (<i>Bemisia tabaci</i>), Greenhouse Whitefly	40 g/1000 plants (equivalent to 10 g ai/1000 plants)	Apply to the soil as a planting-hole application at the time of transplant. Apply in 50-100 mL of water per plant.
Tomatoes Grown in greenhouse / glasshouse	(<i>Trialeurodes vaporariorum</i>), Green PeachAphid (<i>Myzus persicae</i>)		Apply to seedlings directly to the potting media at the base of the plant. DO NOT apply Actara later than GS 51 – bud emergence.

Withholding periods:

Tomatoes: Do not harvest for 6 weeks after application.

EXPORT TRADE ADVICE – TREATED CROPS: *Treated tomatoes grown in a protected cropping situation that are destined for export may require a longer withholding period than specified above, to be accepted in some export markets. Before using this product, you are advised to contact Syngenta and/or your industry body about any potential trade issues and their management.*

3. TRADE CONSIDERATIONS

3.1 Commodities Exported

Tomatoes and animal commodities derived from livestock fed on tomato pomace from treated crops, are the commodities exported. Detectable residues are not expected to occur in animal commodities as a result of the proposed use.

3.2 Destination and Value of Exports

Tomatoes are not considered to be a major export commodity.¹ In the 2002/03 season Australia exported 3,199 tonnes of tomatoes valued at \$7.5 million.² The main export markets were New Zealand (2,491 t), Singapore (311 t) and Hong Kong (220 t). Other export markets each accounted for less than 50 t. More recent industry data show that in 2007/08 Australian exports of fresh tomatoes were worth \$13.7 million. Again the main market was New Zealand (\$11.7 million). Other markets accounted for significantly less, including Singapore (\$0.41 million), Indonesia (\$0.25 million) and Hong Kong (\$0.20 million).

3.3 Results from residues trials presented to the APVMA

Previously assessed data, including one glass house trial which is representative of the proposed use pattern, were provided with the application. Six new trials on indoor grown tomatoes have also been provided. In these trials thiamethoxam was applied by drip irrigation at later growth stages than proposed (BBCH 71 – 83).

In the greenhouse trial representative of the use pattern, residues of thiamethoxam were below the LOQ (0.02 mg/kg) by harvest (90 Days after treatment, DAT). Residues at the LOQ were detected in this trial at 69 and 77 DAT.

With the indoor trials involving drip application at generally higher rates (0.7 - 2× when calculated in terms of g ai/plant) residues in fruit were below the LOQ with one exception: a residue of 0.02 mg/kg was detected in a trial 21 days after the last of 2 applications at 0.7× the proposed rate.

An increase in the current tomato thiamethoxam MRL from *0.02 mg/kg to 0.05 mg/kg is recommended. Although the timing of application in greenhouse situations is limited to no later than growth stage BBCH 51, the 6 week withholding period should remain in place to cover the currently registered use on field grown tomatoes.

¹ Part 5B of the Vet Requirements Series and Ag Requirements Series, Overseas Trade Aspects of Residues in Food Commodities, August 2004.

² The Australian Horticulture Statistics Handbook 2004

In a tomato processing study residues in paste were at similar levels to those in fruit. Data were not available for tomato pomace, which may be used as a livestock feed in Australia. As a worst case it can be assumed that tomatoes contain 10% dry matter and that all the residue remains in the pomace. The highest residue of 0.02 mg/kg in tomato fruit would then give a maximum predicted residue of 0.2 mg/kg in tomato pomace (dry weight). It is therefore appropriate to establish a Table 4 entry of 0.2 mg/kg for tomato pomace, dry. Residues in tomato pomace resulting from this use do not require changes in animal commodity MRLs which are set at the limit of quantitation.

3.4 Overseas registration and approved label instructions

The applicant has indicated that this formulation of thiamethoxam is registered throughout the world for a number of different crops and use patterns. Countries with thiamethoxam registrations include Brazil, Italy, Mexico, Portugal, Russia and Spain. For tomatoes, thiamethoxam is registered as either a foliar or soil applied formulation.

3.5 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.

Thiamethoxam has not been considered by Codex. JMPR consideration of thiamethoxam and its use on tomatoes is scheduled for 2010. Overseas MRLs have not been established for thiamethoxam in tomatoes in markets relevant to Australia.

3.6 Current and proposed Australian MRLs for thiamethoxam

The following amendments are recommended to the MRL Standard:

Table 1

Compound	Food		MRL (mg/kg)
Thiamethoxam: DELETE:	VO 0448	Tomato	*0.02
ADD:	VO 0448	Tomato	0.05

Table 4

Compound	Animal feed commodity	MRL (mg/kg)
Thiamethoxam		
ADD:	Tomato pomace, dry	0.2

3.7 Potential Risk to Trade

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

The risk to trade in tomatoes is considered to be low as residues are unlikely to occur in harvested tomato fruit at levels above the LOQ when the product is used as directed. The main market for Australian tomatoes is New Zealand which will accept Australian MRLs under the Trans-Tasman Mutual Recognition Agreement. As detectable residues may be present it is proposed that the following Trade Advice Statement is included on the label with respect to export of treated tomatoes:

EXPORT TRADE ADVICE – TREATED CROPS: *Treated tomatoes grown in a protected cropping situation that are destined for export may require a longer withholding period than specified above, to be accepted in some export markets. Before using this product, you are advised to contact Syngenta and/or your industry body about any potential trade issues and their management.*

The overall risk to the export trade in animal commodities resulting from the proposed use is considered to be low as no increase to the currently established MRLs for thiamethoxam in animal commodities is required.

Stakeholders are requested to provide comment on the potential risks to trade in tomatoes grown in protected cropping situations and the inclusion of the above statement on the product label.

4 CONCLUSION

Syngenta Crop Protection Pty Ltd has applied to amend the label of Actara Insecticide (APVMA No. 56499, containing 250 g thiamethoxam/kg) to include the use on tomatoes grown in greenhouse / glasshouse situations. Available residue data suggest the possibility of residues in fruit at or about the LOQ (0.02 mg/kg) if tomatoes are treated as proposed. It is recommended that the current MRL of *0.02 mg/kg for thiamethoxam on tomatoes be increased to 0.05 mg/kg. At the same time it is proposed to establish an MRL of 0.2 mg/kg for tomato pomace (dry weight), which may be used as an animal feed in Australia. No changes are required to the current animal commodity MRLs which are set at the LOQ for each substrate and remain acceptable for the proposed use on greenhouse tomatoes.

While detectable residues may be present in tomatoes the risk to trade is considered to be low as the main export market is New Zealand which will recognize the proposed Australian MRL. In addition it is proposed that a trade advice statement be included on the label to advise growers to seek information on the potential trade implications of using thiamethoxam on greenhouse grown tomatoes.

The APVMA is seeking advice on the potential for the proposed use of Actara Insecticide on indoor grown tomatoes to unduly prejudice Australian export trade.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA or alternatively, the reports can be viewed at the APVMA Library which is located at:

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Office hours: 9.00 - 5.00 (EST) Monday to Friday