



Australian Government
Australian Pesticides and
Veterinary Medicines Authority



TRADE ADVICE NOTICE

on Acetamiprid and Pyriproxyfen in the Product *Trivor Insecticide*

APVMA Product Number 80807/101694

DECEMBER 2015

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This publication is available from the APVMA website: www.apvma.gov.au.

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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 Aging, 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 regulatory guidance published on the APVMA website.

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.

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 on the APVMA website: www.apvma.gov.au

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of TRIVOR INSECTICIDE should 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. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on Friday, 5 February 2016 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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:

Scientific Assessment and Chemical Review
Residues and Trade
Australian Pesticides and Veterinary Medicines Authority
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Email: enquiries@apvma.gov.au

Further information

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

Further information on public release summaries 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 ADAMA Australia Pty Ltd to register a new combination product, *Trivor Insecticide* (containing 186 g/L acetamiprid and 124 g/L pyriproxyfen), for use on citrus for the control of various insects.

Citrus fruits, as well as meat and dairy products from animals that have been fed feeds containing residues arising from the use of *Trivor Insecticide* may be exported. In this Trade Advice Notice the potential for residues arising from the proposed use on citrus to unduly prejudice trade is discussed. No amendments to the current pyriproxyfen MRLs established for citrus are recommended thus trade aspects of pyriproxyfen use in citrus remains unchanged and are not discussed here.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus fruits are considered to be major export commodities, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds such as pulp produced from treated citrus fruits. .

2.2 Destination and value of exports

In 2013–14, Australia exported 108 kt of Navel oranges, (\$122m), 15 kt of Valencia oranges (\$14m), 36 kt of mandarins (\$57m), 1.4 kt of lemons and limes (\$3m) and 0.2 kt of grapefruit (\$0.3m) (Australian Commodity Statistics 2014). Details of export destinations for 2013–14 are not available however in 2010–2011 the major export destinations of Australian citrus were Japan, Hong Kong, Indonesia, New Zealand, Singapore, UAE, Canada, Thailand and Malaysia.

The significant export markets for Australian beef, sheep, pig meat and offals are listed in the APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B).

2.3 Proposed Australian use-pattern

RESTRAINTS

DO NOT apply by air.

DO NOT apply if rainfall that is likely to produce runoff is forecast within 48 hours.

DO NOT apply TRIVOR during flowering.

DO NOT apply TRIVOR more than twice per growing season.

TRIVOR INSECTICIDE (CONTAINING 186 g/l ACETAMIPRID AND 124 g/l PYRIPROXYFEN)

CROP	PEST	RATE	CRITICAL COMMENTS
Citrus	Red scale (<i>Aonidiella aurantii</i>)	40 mL/100 L (7.44g ai/100L acetamiprid and 4.96g ai/100L pyriproxyfen)	Apply TRIVOR post-flowering when crop monitoring indicates the onset of crawler release. Do not target TRIVOR applications on populations that are well- established where mature adult insects dominate the population.
	Pink wax scale (<i>Ceroplastes rubens</i>)	or	
	Black scale (<i>Saissetia oleae</i>)	1.6 L/ha	After application, continue monitoring crops and if required apply a second application after a minimum interval of 21 days. If monitoring indicates additional applications are required, rotate to an insecticide from a different mode of action group.
	Citrus mealybug (<i>Planococcus citri</i>)	(298g ai/ha acetamiprid and 198g ai/ha pyriproxyfen)	

CROP	PEST	RATE	CRITICAL COMMENTS
			<p>Application</p> <p>Apply TRIVOR as a dilute (high volume) spray to the point of runoff, ensuring thorough coverage. Select the TRIVOR application rate based on the spray volume, as follows:</p> <ul style="list-style-type: none"> • Spray volumes up to 4000 L/ha water apply TRIVOR at 40 mL/100 L • Spray volumes >4000 L/ha water apply TRIVOR at 1.6 L/ha <p>Do not exceed 1.6 L of TRIVOR per hectare in a single application.</p>
	Citrus leafminer (Phyllocnistis citrella)		<p>Monitor crops and apply TRIVOR as part of a spray program for citrus leafminer. Apply in late spring after the main flowering has finished and prior to the summer or autumn flush. Apply prior to pest establishment or at the first signs of infestation. Continue to monitor crops after applying TRIVOR and if additional sprays are required apply an insecticide from a different mode of action group before applying a second TRIVOR application. Do not apply consecutive applications of TRIVOR for control of citrus leafminer.</p> <p>Application</p> <p>Apply TRIVOR as a dilute (high volume) spray to the point of runoff, ensuring thorough coverage. Select the TRIVOR application rate based on the spray volume, as follows:</p> <ul style="list-style-type: none"> • Spray volumes up to 4000 L/ha water apply TRIVOR at 40 mL/100 L • Spray volumes >4000 L/ha water apply TRIVOR at 1.6 L/ha <p>Do not exceed 1.6 L of TRIVOR per hectare in a single application.</p>
	Kelly's citrus thrips (Pezothrips kellyanus)		<p>Carefully monitor crops from flowering for the presence of Kelly's citrus thrips. After flowering has finished, apply TRIVOR when local pest thresholds are reached, typically just prior to calyx closure. Do not target TRIVOR applications on populations that are well-established where mature adult insects dominate the population.</p> <p>A single application of TRIVOR may be sufficient under low pest pressure. Continue to monitor crops and if thrip pressure persists/moderate to high numbers are present, apply a second application after a minimum spray interval of 14 days. If</p>

CROP	PEST	RATE	CRITICAL COMMENTS
			<p>monitoring indicates additional applications are required, rotate to an insecticide from a different mode of action group.</p> <p>Application</p> <p>Apply TRIVOR as a dilute (high volume) spray to the point of runoff, ensuring thorough coverage. Select the TRIVOR application rate based on the spray volume, as follows:</p> <ul style="list-style-type: none"> • Spray volumes up to 4000 L/ha water apply TRIVOR at 40 mL/100 L • Spray volumes >4000 L/ha water apply TRIVOR at 1.6 L/ha <p>Do not exceed 1.6 L of TRIVOR per hectare in a single application</p>

Withholding periods:

Harvest: Do not harvest for 14 days after application.

Grazing: Do not graze or cut treated area for stockfood.

2.4 Results from residues trials presented to the APVMA

Full details of 14 Australian GLP decline residues trials conducted on oranges (6), mandarins (4), lemons (2) and limes (2) were provided. These trials involved two foliar applications of acetamiprid and pyriproxyfen at approximately 1x the proposed spray concentration. In two of these trials, acetamiprid and pyriproxyfen residues were analysed in processed fractions such as juice, pulp and peel.

Full details from a further 8 GLP decline trials conducted in Southern Europe were provided. These trials involved two foliar applications of acetamiprid at approximately 1.6x the proposed spray concentration. Acetamiprid residues data in processed fractions (dry pomace, juice, marmalade, jam, jelly, canned orange, essential oil, dried slices) following a single application of acetamiprid at 4x the proposed label rate (1200 g ai/ha acetamiprid) were also provided.

Citrus data set

At PHIs of 13–14 days after 2 sprays at 1–1.6x proposed concentration, residues of acetamiprid in citrus fruits were in rank order 0.04, 0.05, 0.06, 0.06, 0.06, 0.06, 0.06, 0.06, 0.07, 0.07, 0.07, 0.07, 0.08, 0.09, 0.11, 0.16, 0.16, 0.20, 0.30, 0.49, 0.53 and 0.62 mg/kg. (STMR = 0.07 mg/kg).

Based on the available residues data, an acetamiprid MRL of 1 mg/kg for citrus fruits (FC 0001) is considered appropriate for the proposed use pattern in conjunction with a harvest WHP of 14 days.

Processing data

Dry pomace: The mean processing factor for dry pomace is estimated to be approximately 4.95 from processing studies. A permanent acetamiprid MRL of 5 mg/kg for Citrus pulp, dry (AB 0001) (HR of 0.62 mg/kg x mean P_f of 4.95 = 3.1 mg/kg estimated HR in pomace) is considered appropriate for the proposed use pattern.

Animal commodities

The livestock burden for dairy and beef cattle resulting from this use is estimated to be 0.10 ppm based on citrus dried pulp consumption at 30% of the diet containing acetamiprid residues of 0.35 mg/kg (STMR: 0.07 x P_f: 4.95). The Kow Log P for acetamiprid is 0.8 so the potential for bio-accumulation is low. No changes are required to established acetamiprid animal commodity MRLs and there is no change to the risk to trade in animal commodities associated with the proposed use. Residues in animal commodities will not be discussed further.

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. Acetamiprid has been considered by Codex. The following relevant international MRLs have been established for acetamiprid.

TABLE 1: COMPARISON OF ACETAMIPRID MRLS (mg/kg) FOR CITRUS.

COUNTRY	RESIDUE DEFINITION	CITRUS MRLS (mg/kg)
Australia	Acetamiprid	1 (Proposed)
Codex	Acetamiprid	1
EU	Acetamiprid	0.9
Japan	Acetamiprid	2
USA	Acetamiprid	1
China	Acetamiprid	2
Hong Kong	Acetamiprid	0.5
Korea	-	0.5 (mandarins)

2.6 Current and proposed Australian MRLs for acetamiprid

TABLE 2: CURRENT MRL STANDARD

COMPOUND	FOOD	MRL (mg/kg)
Acetamiprid		
MO 0105	Edible offal (Mammalian)	*0.05
MM 0095	Meat [mammalian]	*0.01
ML 0106	Milks	*0.01

TABLE 3: PROPOSED MRL STANDARD—TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
Acetamiprid		
ADD:		
FC 0001	Citrus fruits	1

TABLE 4: PROPOSED MRL STANDARD—TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
ADD:		
Acetamiprid		
AB 0001	Citrus pulp, dry	5

2.7 Potential risk to trade

An acetamiprid MRL of 1 mg/kg for citrus fruits is recommended for the proposed use, which is lower than the Japanese and Chinese MRL of 2 mg/kg and in line with the Codex and the US MRL. The recommended MRL is slightly higher than EU MRL of 0.9 mg/kg, however the highest residue observation of acetamiprid in citrus is lower than the EU MRL.

Hong Kong and Korea have established MRLs of 0.5 mg/kg for citrus fruits and mandarins respectively, lower than that currently proposed. The highest acetamiprid residue observed in the available trials was 0.62 mg/kg, detected in mandarins at a spray concentration of 1.6x. The scaled residues at 1x the proposed spray concentration is estimated to be 0.38 mg/kg, lower than Hong-Kong and Korean MRLs. Based on citrus fruits STMR of 0.07 mg/kg and a scaled residue observation of 0.38 mg/kg, the risk to trade in these countries is considered to be low.

The applicant has proposed the following statement to mitigate risk for produce destined for export 'Before using TRIVOR on crops destined for export it is essential to consult your exporter or ADAMA to ensure that an appropriate MRL is in place in the importing country'.

3 CONCLUSIONS

Comments are sought on the potential for Trivor Insecticide to unduly prejudice Australian export trade in citrus fruits following the proposed use.