

Trade Advice Notice

on

Spirotetramat

in the product

Movento 240 SC Insecticide

[APVMA Product Number 61864]

October 2009

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

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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 proposed use of the product. Comments received on matters other than trade implications will not be considered by the APVMA. Comments received 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 2 December 2009. Submissions should be addressed to:

Annelies McGaw
Pesticides Division
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4753
Fax: (02) 6210 4776
Email: annelies.mcgaw@apvma.gov.au

2. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd to register the foliar insecticide Movento 240 SC Insecticide (240 g/L spirotetramat) for the control of silverleaf whitefly and cotton aphid in cotton. The potential for spirotetramat residues resulting from the proposed use of Movento 240 SC Insecticide on cotton to unduly prejudice Australian trade is discussed below.

2.1 Proposed Use

The proposed use pattern for Movento 240 SC Insecticide is presented below:

Movento 240 SC Insecticide (240 g/L spirotetramat)

Crop	Pest	Rate	WHP	Critical Comments
Cotton	Silverleaf whitefly (<i>bemisia tabaci</i>)	300-400 ml/ha (72-96 g ai/ha) + adjuvant*	Harvest- 21 days Grazing- Refer to grazing statement below	Monitor crops and commence applications once local thresholds are reached. Use the higher rate when periods of high pest pressure or rapid crop growth are evident, when longer residual control is desired or when crops are well advanced. Continue to monitor crops and make a subsequent application as necessary. Do not re-apply within 14 days of a previous Movento spray. Do Not apply more than 2 applications per crop. Ensure thorough coverage of the target crop - refer "Application" section in the GENERAL INSTRUCTIONS. *Always add a specified spray adjuvant - Refer "Adjuvant" section in the GENERAL INSTRUCTIONS.
	Cotton aphid (<i>Aphis gossypi</i>)	300-400 ml/ha (72-96 g ai/ha) + adjuvant*		

Withholding periods:

Harvest: DO NOT HARVEST FOR 21 DAYS AFTER APPLICATION
Grazing: DO NOT FEED COTTON FODDER, STUBBLE OR TRASH TO LIVESTOCK

Export of treated produce

Growers should note that suitable MRLs or import tolerances do not exist in all markets for produce treated with Movento 240 SC. In some situations export requirements may be met by limiting application number and/or imposing a longer withholding period than specified above. If you are growing produce for export, please check with Bayer CropScience Pty Ltd or your industry body for the latest information on any potential trade issues and their management before using Movento 240 SC.

2.2 Current and Proposed Australian MRLs for Spirotetramat

Current MRLs and residue definition for spirotetramat are presented below.

Table 1

Compound	Food	MRL (mg/kg)	
Spirotetramat	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead Brassicas [except Brussels sprouts]	7
	VB 0402	Brussels sprouts	1
	FC 0001	Citrus fruits	T1
	SO 0691	Cotton seed	T1
	MO 0105	Edible offal (mammalian)	0.05
	FI 0345	Mango	T0.3
	VC 0045	Fruiting vegetables, Cucurbits	T2
	VL 0482	Lettuce, Head	T5
	VL 0483	Lettuce, Leaf	T10
	MM 0095	Meat (mammalian)	*0.01
	ML 0106	Milks	*0.005
	VA 0385	Onion, Bulb	T0.5
	VO 0445	Peppers, Sweet [capsicums]	T5
	VO 0448	Tomato	T7

Table 3

Compound	Residue
Spirotetramat	<p>For compliance for commodities of plant and animal origin: Sum of spirotetramat, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.</p> <p>Commodities of plant origin for dietary risk assessment: Sum of spirotetramat, cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, cis-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one and the glucoside of cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.</p> <p>Commodities of animal origin for dietary risk assessment: Sum of spirotetramat, cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one and the glucuronic acid conjugate of cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.</p>

The following amendments to the MRL Standard are proposed. MRLs in Table 1 will be recommended for inclusion in the Australia New Zealand Food Standards Code:

Table 1

Compound	Food		MRL mg/kg)
DELETE:			
Spirotetramat	SO 0691	Cotton seed	T1
ADD:			
Spirotetramat	SO 0691	Cotton seed	0.7

Table 4

Compound	Animal feed commodity	MRL (mg/kg)
ADD:		
Spirotetramat	Cotton seed meal and hulls	1

3. TRADE CONSIDERATIONS

3.1 Commodities Exported

Cotton seed, including cotton seed meal and oil as well as animal commodities which may be derived from animals fed on treated cotton seed commodities are exported, and are considered to be major export commodities in Appendix 1 of Part 5B of Ag MoRaG. Residues in these commodities resulting from the use of Movento have the potential to unduly prejudice trade.

No changes are proposed to animal commodity MRLs and residues arising in animal commodities will not be considered further.

3.2 Destinations and Value of Exports

Australia exported 17.36 kt of cotton seed in the 2007-2008 financial year, with Japan being the major export destination. Australia also exported 5.62 kt of cotton seed oil and 9.15 kt of cotton and sunflower seed meal in the 2007-2008 financial year¹. It is noted that exports of cotton seed in recent years are considerably lower than historical levels.

The volume and major destinations of Australian commodity from 2000-01 to 2007-08 are presented table 1 below.

¹ Reference: Australian commodity statistics, 2008; http://www.abareconomics.com/publications_html/acs/acs_08/acs_08.pdf

Table 1: Volume of Australian cotton seed exports from 2000 – 2008.

Destination	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08
Volume of cotton seed exported (kt)								
Chinese Taipei	2.45	1.47	0.57	0.42	0.61	0.87	0.49	0.00
Japan	152.57	164.48	133.41	134.12	144.67	162.72	86.39	17.36
Korea, Rep. of	99.44	88.47	22.72	28.42	56.04	39.64	16.21	0.00
Saudi Arabia	17.00	8.50	0.00	0.00	10.58	0.00	0.00	0.00
United States	386.54	327.68	98.81	1.34	1.00	0.00	0.00	0.00
Other	4.64	3.05	3.05	2.26	1.47	1.20	1.00	0.49
Total	662.63	593.65	258.57	166.57	214.35	204.44	104.08	17.84

Source: Reference: Australian commodity statistics, 2008; http://www.abareconomics.com/publications_html/acs/acs_08/acs_08.pdf

No figures for the value of cotton seed, oil and meal exports are available. Total exports of all oilseeds and vegetable oils in 2007/08 were 547.77 and 93.37 kilotonnes respectively, worth \$337.89 million and \$163.42 million. Exports of oilseed meals were 19.7 kt in 2006/07, worth \$26.02 million. Cotton seed exports and cotton seed oil exports were only a small fraction (around 3% and 6% respectively) of the total exports of oilseeds and vegetable oils.

3.3 Results from Residues Trials Presented to the APVMA

Details of 8 Australian and 12 US cotton trails as well as a cotton processing study were provided.

In each trial, residues of spirotetramat, as well as its metabolites spirotetramat-enol, spirotetramat-keto-hydroxy, spirotetramat-mono-hydroxy and spirotetramat-enol-glucoside were determined. Results are expressed below in accordance with the Australian residue definition for dietary risk assessment ('Total' residues; sum of spirotetramat and spirotetramat-enol, spirotetramat-keto-hydroxy, spirotetramat-mono-hydroxy and spirotetramat-enol-glucoside expressed as spirotetramat) and compliance (sum of spirotetramat and spirotetramat-enol). A number of markets utilise a residue definition for compliance purposes that is equivalent to the Australian definition for dietary risk assessment.

The proposed use of Movento 240 SC Insecticide on cotton involves a maximum of 2 spirotetramat applications at the rate of 96 g ai/ha, with a minimal re-application interval of 14 days and a 21-day withholding period. The highest residues that resulted in cotton seed, at or beyond 21 DALA from each Australian or US residue trial are provided in table 2 below.

Table 2: Summary of Australian and US cotton seed residue data.

COMMODITY	Proposed Max. Rate (applications)	Proposed WHP (days)	Proposed MRL (mg/kg)	Trial Rate (applications)	Residues (Total) (mg/kg)	Residues (BYI 08330 + BYI 08330-enol) (mg/kg)
Cotton seed (Australian data)	96 g ai/ha (2)	21	0.7	144 g ai/ha (2) (1.5x proposed)	0.11, 0.11, 0.12, 0.13, 0.15, 0.23, 0.38, 0.41	0.04, 0.04, 0.06, 0.07, 0.09, 0.17, 0.31, 0.34
Cotton seed (US data)				88 ± 4 g ai/ha (2) (0.92x proposed)	0.018, 0.029, 0.033, 0.034, 0.039, 0.042, 0.064, 0.075, 0.102, 0.104, 0.109, 0.124, 0.133, 0.242, 0.273	0.009, 0.011, 0.012, 0.012, 0.012, 0.021, 0.027, 0.030, 0.031, 0.058, 0.059, 0.096, 0.105, 0.231, 0.256

According to the residue definition for compliance, the HR and STMR in cotton seed following application according to the Australian use pattern were 0.26 and 0.04 mg/kg respectively. A spirotetramat MRL of 0.7 mg/kg is recommended for SO 0691 Cotton seed.

According to the residue definition for dietary risk assessment, which is used in some export markets for compliance purposes; the HR and STMR in cotton seed following application according to the Australian use pattern were 0.27 and 0.09 mg/kg respectively.

Processing

The results of the processing study demonstrate that residue levels in refined oil were 0.02x that of the cotton seed, in terms of total spirotetramat residue. In terms of the residue definition for compliance, residues in refined oil were 0.03x that of the cotton seed.

The results of the processing study also found that the total spirotetramat residues concentrate by 1.2x in cotton seed meal and by 1.5x in cotton seed hulls. In terms of the residue definition for compliance, residues concentrated by 2.4x and 2.2x in cotton seed meal and hulls respectively.

When these processing factors are applied to the HR (compliance residue definition) of 0.26 mg/kg, it is estimated that the proposed GAP would result in 0.62 mg/kg in meal and 0.57 mg/kg in hulls. It is therefore recommended that a MRL at 1 mg/kg for Cotton seed meal and hulls be established in Table 4 of the MRL standard.

3.4 Overseas registration and approved label instructions

The applicant indicated that spirotetramat products are registered for use on various crops in several overseas countries, with several more registrations likely in the next 12 months. A summary of overseas spirotetramat registrations, as provided by the applicant, is provided below.

Country	Product Name	Formulation	Crops
Austria	Movento 150 OD	150 g/L spirotetramat	Numerous vegetable crops
Canada	Movento 240 SC	240 g/L spirotetramat	Numerous crops including potato, sweet potato, eggplant, capsicum, chilli and tomato
Colombia	Movento 150 OD	150 g/L spirotetramat	Onion, tomato
New Zealand	Movento 240 SC	240 g/L spirotetramat	Kiwi fruit
Togo	Tihan 175 O-Teq	100 g/L flubendiamide 75 g/L spirotetramat	Cotton
Tunisia	Movento 150 OD	150 g/L spirotetramat	Citrus
Turkey	Movento 240 SC	240 g/L spirotetramat	Alfalfa, citrus, pears
United States	Movento 240 SC Movento 150 OD	240 g/L spirotetramat 150 g/L spirotetramat	Numerous crops including potato, sweet potato, eggplant, capsicum, chilli and tomato

The applicant has stated that Togo is the only country that has a registration in cotton although an application for the registration of Movento in cotton was submitted in the US in early 2009. The spirotetramat use pattern that is registered for use on cotton in Togo is described below.

Country	Trade name	Crop	PHI (days)	No. of applications	Product rate
Togo	Tihan 175 O-Teq (100 g/L flubendiamide 75 g/L spirotetramat)	Cotton	21	Max. 2 (at 14 day intervals)	400 ml/ha (30 g spirotetramat / ha)

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. Spirotetramat was considered by JMPR in 2008 and CXLs were adopted at the Codex Alimentarius Commission meeting in June/July 2009. The Codex Alimentarius Commission has not considered the use of spirotetramat on cotton and therefore CXLs have not been adopted for cotton seed.

The following overseas residue MRLs/ tolerances have been recommended or established:

Country (Status)	Residue Definition (for Compliance)	Commodity	Tolerance (mg/kg)
Australia	Sum of spirotetramat & its enol metabolite	Cotton seed	0.7
EU ²	Sum of spirotetramat & its 4 metabolites (enol, keto-hydroxy, mono-hydroxy & enol-glucoside)	Cotton seed	*0.1

² European Union – Regulation (EC) No. 396/2005 (updated 17 April 2009)
http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm

3.6 Potential Risk to Trade

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

Japan, which has been the major export destination of cotton seed since 2003, does not currently have MRLs established for spirotetramat. The only international jurisdiction to have a spirotetramat MRL established for cotton seed is the EU (*0.1 mg/kg), which is not a major export destination of Australian cotton seed.

In order to mitigate the risk in trade of cotton seed with countries where a lower MRL has been established, or to countries where a MRL has not yet been established, the applicant has proposed the following trade advice statement for inclusion on the label:

'Growers should note that suitable MRLs or import tolerances do not exist in all markets for produce treated with Movento 240 SC. In some situations export requirements may be met by limiting application number and/or imposing a longer withholding period than specified above. If you are growing produce for export, please check with Bayer CropScience Pty Ltd or your industry body for the latest information on any potential trade issues and their management before using Movento 240 SC'

4. CONCLUSION

Comment is sought on the potential for the proposed uses of Movento 240 SC Insecticide to prejudice Australian trade in cotton seed.

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