Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Spirotetramat in the Product Movento 240 SC Insecticide

APVMA Product Number 61864

FEBRUARY 2011

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

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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 register **Movento 240 SC Insecticide** containing the existing active constituents spirotetramat 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 **17 March 2011** 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:

Pesticides 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: Pesticides@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 Bayer Cropscience Pty Limited to extend the use of Movento 240 SC Insecticide, containing 240 g/L spirotetramat, to green beans and peas, and add additional pests (at a higher rate) for Brassica leafy vegetables. The proposed use requires the establishment of MRLs for Legume vegetables, Brassica leafy vegetables and Legume animal feeds. Increases are also proposed to the current mammalian offal and meat MRLs.

The potential for use of spirotetramat on green beans, green peas and Brassica leafy vegetables to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Green beans, green peas and Brassica leafy vegetables are not considered major export commodities[2] and the overall risk to export trade in these commodities is considered to be small. Animal commodities derived from livestock that have been fed treated legume animal feeds are considered to be major export commodities and the risk to trade is considered below.

2.2 Destination and value of exports

The significant export markets for Australian meat, kidney and liver are listed in Appendix 3 of Part 5B of Ag MORAG.

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for Movento 240 SC Insecticide in green beans, green peas and Brassica leafy vegetables is summarised below.

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

Table 1: Proposed use pattern -Movento 240 SC Insecticide (240 g/L spirotetramat)

CROP	PEST	RATE	WHP	CRITICAL COMMENTS
Beans, peas (green) including snow peas and sugar snap peas	Green peach aphid (*Myzus persicae*)	200 mL/ha + adjuvant* (48 g ai/ha)	7 days (3 days snow and sugar snap peas)	Monitor crops and commence applications once local thresholds are reached. Where applicable, use the higher rate when periods of high pest pressure or rapid crop growth are evident or when longer residual control is desired or when crops are advanced. Continue to monitor crops and make subsequent applications as necessary. Do not re-apply within 7 days of a previous Movento spray. **Do not apply more than a total of 2 applications per crop.** Ensure thorough coverage of the target crop – refer "Application" section in GENERAL INSTRUCTIONS. ***Always add a specified spray adjuvant – refer "Adjuvant" section in GENERAL INSTRUCTIONS.**
	Silverleaf whitefly (*Bemisia tabaci* Biotype B)	300 – 400 mL/ha + adjuvant* (72 – 96 g ai/ha)		
Beans (green)	Western flower thrips (*Frankliniella occidentalis*), tomato thrips (*Frankliniella schultzei*)	300 – 400 mL/ha + adjuvant* (72 – 96 g ai/ha)		Commence applications at the flower budding growth stage. Use the higher rate when periods of high pest pressure or rapid crop growth are evident or when longer residual control is desired. Continue to monitor crops and make subsequent applications as necessary. Do not re-apply within 7 days of a previous Movento spray. **Do not apply more than a total of 2 applications per crop.** Ensure thorough coverage of the target crop – refer "Application" section in GENERAL INSTRUCTIONS. ***Always add a specified spray adjuvant – refer "Adjuvant" section in GENERAL INSTRUCTIONS.**

CROP	PEST	RATE	WHP	CRITICAL COMMENTS
Brassica leafy vegetables including Bok choy, Chinese broccoli (Gai lum/Gai lan/Kai lan), Chinese cabbage (Pet sai/Wombok/ Haksukai), Choy sum, Gai choy/Am soy, Kai choy, Kale, Mibuna, Mustard (leafy) including Indian mustard and Mustard spinach (Komatsuma), Pak choy, Tat soy	Green peach aphid (*Myzus persicae*)	200 mL/ha + adjuvant* (48 g ai/ha)	3 days	Monitor crops and commence applications once local thresholds are reached. Where applicable, 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 dense or large. Continue to monitor crops and make subsequent applications as necessary. Do not re-apply within 7 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 GENERAL INSTRUCTIONS. ***Always add a specified spray adjuvant – refer "Adjuvant" section in GENERAL INSTRUCTIONS.**
	Grey cabbage aphid (*Brevicoryne brassicae*)	200 – 300 mL/ha + adjuvant* (48 – 72 g ai/ha)		
	Silverleaf whitefly (*Bemisia tabaci* Biotype B)	300 – 400 mL/ha + adjuvant* (72 – 96 g ai/ha)		

WITHHOLDING PERIOD
Harvest:
Beans, Peas (other than snow peas and sugar snap peas): Do not harvest for 7 days after application.
Snow and sugar snap peas: Do not harvest for 3 days after application.
Brassica leafy vegetables: Do not harvest for 3 days after application.
Grazing:
Beans, Peas: Do not graze or cut for stock food for 7 days after application.
Brassica vegetables (including Brassica leafy vegetables): Do not graze treated Brassica crops.

Livestock Destined For Export Markets
The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the Export Slaughter Interval is observed before stock are sold or slaughtered.

Export Slaughter Interval (ESI) – 3 Days
Livestock that has been grazed on or fed treated crops should be placed on clean feed for 3 days prior to slaughter.

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

2.4 Results from residues trials presented to the APVMA

Australian residue data for green beans and green peas have been provided. Overseas data for Brassica leafy vegetables is supported by Australian data for leafy lettuce.

Green beans and green peas
Residues of spirotetramat plus its enol metabolite (enforcement definition) in green bean pods and green pea pods at 7 days after the last of 2 applications at 96 g ai/ha were 0.06, 0.07 (2), 0.08, 0.28, 0.38, 0.47 and 0.69 mg/kg (The highest total residue for risk assessment was 0.90 mg/kg). It is proposed that the current temporary MRL of T2 mg/kg for spirotetramat on VP 0060 Legume vegetables be made permanent.

Residues of spirotetramat plus its enol metabolite in green bean and pea plant material at harvest after removal of the pods (7 day PHI, 2 applications at 96 g ai/ha) were 0.33, 0.46, 0.48, 0.87, 1.14, 1.21, 2.11, 6.32 (2), 10.53 and 15.54 mg/kg (dry weight). Residues of spirotetramat plus its enol metabolite in green bean forage 7 days after 1 – 2 early season applications at 96 g ai/ha were 0.74, 5.25, 10.25 and 13.69 mg/kg (dry weight). An MRL of 20 mg/kg is therefore proposed for spirotetramat on AL 0157 Legume animal feeds in conjunction with a 7 day grazing withholding period. The highest total spirotetramat residue in green bean and pea plant material for risk assessment was 19.21 mg/kg (dry weight).

A 3 day withholding period has been proposed for snow peas and sugar snap peas. Residues of spirotetramat plus its enol metabolite in green pea pods at 2-4 days after the last application at 96 g ai/ha were <0.04, 0.11, 0.12 and 0.13 mg/kg. Residues of spirotetramat plus its enol metabolite in green bean pods at 2-3 days after the last application at 96 g ai/ha were 0.08, 0.16, 0.18 and 0.54 mg/kg.

Residues of spirotetramat plus its enol metabolite in green pea plant material at 3 days after the last of 2 applications at 96 g ai/ha were 0.33, 1.62, 1.81 and 4.37 mg/kg (dry weight). The highest total residue for risk assessment was 6.32 mg/kg (dry weight). It is noted that residues in green pea plant material were significantly lower than those observed in green beans and can be considered different populations. If the green pea data is taken as an indication of the likely residues in snow and sugar snap pea plant material, it is proposed that a 3 day grazing withholding period for snow and sugar snap peas will be covered by the proposed legume animal feeds MRL at 20 mg/kg.

Brassica leafy vegetables
In US trials, residues of spirotetramat plus its enol metabolite in mustard greens at 3 days after the last of 2 applications at 88 g ai/ha (0.92× proposed rate) were 0.42, 0.48, 0.58, 0.70, 2.05, 2.06, 2.16, 2.64, 3.57 and 5.36 mg/kg. In European trials, residues of spirotetramat plus its enol metabolite at 3 days after the last of 3 applications at 72 g ai/ha (0.75× proposed rate) were 0.20, 0.46, 0.49 and 0.62 mg/kg. In Australian trials, residues of spirotetramat plus its enol metabolite in leafy lettuce at 3 days after the last of 1 – 3 applications at 96 g ai/ha were 0.28, 0.51, 1.19, 1.51, 3.37, 3.72 and 5.60 mg/kg. An MRL of 10 mg/kg is recommended for spirotetramat on VL 0054 Brassica leafy vegetables in conjunction with a 3 day withholding period. The highest total spirotetramat residue for risk assessment was 5.86 mg/kg in an Australian leafy lettuce trial.

Animal Commodities

OECD guidelines indicate bean forage can form up to 70% of the diet for dairy cattle and 60% for beef cattle. Part 5B of the AgMORAG indicates that the forage and fodder of legumes can form 100% of the diet for cattle. The estimated maximum livestock dietary exposure for beef cattle is calculated below and is based on legume animal feeds forming 95% of the diet, with Brassica leafy vegetables making up the remaining 5%.

BEEF CATTLE- 500 KG BW, 20 KG DM/DAY

FEED GROUP	COMMODITY	% IN DIET	FEED INTAKE	RESIDUE, MG/KG	% DM	LIVESTOCK DIETARY EXPOSURE		
						MG/ANIMAL	PPM	MG/KG BW
Legume animal feeds	Bean forage	95	19	19.21	100	364.99	18.25	0.730
Vegetables, vegetable waste	Brassica leafy vegetables	5	1	5.86	5	117.2	5.86	0.234

The estimated livestock dietary exposure for dairy cattle is calculated below assuming bean forage forms up to 70% of the diet as in the OECD guidelines.

DAIRY CATTLE- 500 KG BW, 20 KG DM/DAY

FEED GROUP	COMMODITY	% IN DIET	FEED INTAKE	RESIDUE, MG/KG	% DM	LIVESTOCK DIETARY EXPOSURE		
						MG/ANIMAL	PPM	MG/KG BW
Legume animal feeds	Bean forage	70	14	19.21	100	268.94	13.447	0.538

The maximum intake of spirotetramat is estimated at 24.11 ppm for beef cattle and 13.45 ppm for dairy cattle. Predicted residues in tissues and milk are summarised below, based on a lactating cattle animal transfer study. Predicted residues are based on interpolation between the highest residues observed at 3 ppm, 9 ppm and 30 ppm dose levels in the animal transfer study:

SUBSTRATE	PREDICTED TOTAL HIGHEST RESIDUE AFTER DOSING AT 24.11 PPM (13.45 PPM FOR DAIRY)	PREDICTED HIGHEST RESIDUE (SPIROTETRAMAT + BYI 08330 – ENOL) AFTER DOSING AT 24.11 PPM (13.45 PPM FOR DAIRY)
Fat	0.032	0.030
Kidney	0.344	0.322
Liver	0.046	0.033
Muscle	0.015	0.013
Milk	<0.005	<0.005

Based on these results the following changes are recommended to the current mammalian commodity MRLs:

MO 0105	Edible offal (Mammalian)	Increase from 0.05 mg/kg to 0.5 mg/kg
MM 0095	Meat (mammalian)	Increase from *0.01 mg/kg to 0.02 mg/kg
ML 0106	Milks	*0.005 mg/kg (no change)

A beef cattle transfer study has also been provided in which animals were dosed with spirotetramat for 28 days at 60 ppm in the diet. Residues in tissues were shown to fall below detectable levels after 3 days on clean feed. The proposed 3 day ESI will therefore ensure that residues in tissues of animal commodities for export will be below detectable levels and will not present a risk to trade.

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. Spirotetramat has been considered by Codex. The following relevant overseas residue MRLs/ tolerances have been established for spirotetramat:

Table 2: Codex CXLs and overseas residue MRLs/tolerances for spiroteramat

COUNTRY/STATUS	COMMODITY	TOLERANCE, MG/KG	RESIDUE DEFINITION
Australia	MO 0105 Edible offal (mammalian)	0.5 (proposed)	Spirotetramat + BYI 08330-enol (for enforcement)
	MM 0095 Meat (mammalian)	0.02 (proposed)	
	ML 0106 Milks	*0.005 (established)	
Codex	Edible offal (mammalian)	0.03	Spirotetramat + BYI 08330-enol
	Meat (from mammals other than marine mammals)	0.01	
	Milks	0.005	
USA	Cattle, goat, horse, sheep fat	0.02	Spirotetramat + BYI 08330-enol
	Cattle, goat, horse, sheep meat	0.02	
	Cattle, goat, horse, sheep meat byproducts	0.02	
	Milks	0.01	
EU	Bovine, sheep, goat, horse meat	*0.01	Spiroteramat + BYI 08330-enol
	Bovine, sheep, goat, horse fat	*0.01	
	Bovine, sheep, goat, horse liver	0.03	
	Bovine, sheep, goat, horse kidney	0.03	
	Bovine, sheep, goat, horse edible offal	0.03	
	Milk	*0.005	
Japan	Cattle, pig, other terrestrial mammals, muscle	0.02	Spirotetramat + BYI 08330-enol
	Cattle, pig, other terrestrial mammals, fat	0.02	
	Cattle, pig, other terrestrial mammals, liver	0.02	
	Cattle, pig, other terrestrial mammals, kidney	0.02	
	Cattle, pig, other terrestrial mammals, edible offal	0.02	

Note: MRLs for spirotetramat in animal commodities have not been set by Korea, Taiwan or Russia.

2.6 Current and proposed Australian MRLs for spirotetramat

Current relevant MRLs and the residue definition for spirotetramat are presented below. A full listing of MRLs can be found at http://www.apvma.gov.au/residues/standard.php.

Table 3: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
Spirotetramat		
MO 0105	Edible offal (Mammalian)	0.05
VL 0053	Leafy vegetables [except Lettuce, Head]	5
VP 0060	Legume vegetables	T2
MM 0095	Meat (mammalian)	*0.01
ML 0106	Milks	*0.005

MRL STANDARD: TABLE 3

COMPOUND	RESIDUE
Spirotetramat	For enforcement 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. Commodities of plant origin for dietary exposure 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. Commodities of animal origin for dietary exposure 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.

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Spirotetramat		
AB 0001	Citrus pulp, dry	2
	Cotton seed meals and hulls	1
	Tomato pomace, dry	20

The following changes are proposed to Australian spirotetramat MRLs:

Table 4: Proposed changes to the MRL Standard – Table1 and Table 4

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (MG/KG)
SPIROTETRAMAT			
DELETE:			
MO	0105	Edible offal (Mammalian)	0.05
VL	0053	Leafy vegetables [except Lettuce, Head]	5
VP	0060	Legume vegetables	T2
MM	0095	Meat (mammalian)	*0.01
ADD:			
VL	0054	Brassica leafy vegetables	10
MO	0105	Edible offal (Mammalian)	0.5
VL	0053	Leafy vegetables [except Lettuce, Head; Brassica leafy vegetables]	5
VP	0060	Legume vegetables	2
MM	0095	Meat [Mammalian]	0.02

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (MG/KG)
SPIROTETRAMAT			
ADD:			
AL	0157	Legume animal feeds	20

2.7 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.

Only the USA and Japan have established meat MRLs in line with that proposed for Australia. The proposed Australian offal MRL is also higher than the established standards and not all markets for Australian animal commodities have established relevant MRLs. However, the proposed 3 day ESI will ensure that residues in animal commodities for export will be below detectable limits and the risk to trade will be negligible.

3 CONCLUSIONS

It is proposed to establish permanent MRLs for spirotetramat on legume vegetables, legume animal feeds and Brassica leafy vegetables. At the same time it is proposed to increase the current mammalian offal and meat MRLs for spirotetramat. Comment is sought on the potential for spirotetramat in Movento 240 SC Insecticide to prejudice Australian trade when it is used to control various pests on green beans, green peas and Brassica leafy vegetables.

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