Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Milbemectin in the Product Milbeknock Miticide

APVMA Product Number 61269

NOV 2010

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CONTENTS

List of tables

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 grant the registration of **MILBEKNOCK MITICIDE** containing the existing active constituent milbemectin 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 **4 January 2010** 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:

Kim Garsia
Evaluator, Pesticides
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: (02) 6210 4858
Fax: (02) 6210 4776
Email: kim.garcia@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 Sipcam Pacific Australia Pty Ltd to extend the use of the product, MILBEKNOCK MITICIDE, containing 9.3 g/L milbemectin, to stone fruit for the control of two-spotted mite (*Tetranychus urticae*).

The potential for milbemectin residues in stone fruit to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Stone fruit are considered to be a major export commodity[2].

2.2 Destination and value of exports

The total combined exports of Australian apricots, cherries, peaches and plums were approximately $30.62 million in the 2007-2008 financial year. The 10 largest export markets for various Australian stone fruit commodities by value are shown in the following table.

Table 1: Australian Stone Fruit Exports in 2007/08 (Australian Bureau of Statistics)

APRICOTS		CHERRIES		PEACHES		PLUMS	
DESTINATION	$ MILL.	DESTINATION	$ MILL.	DESTINATION	$ MILL.	DESTINATION	$ MILL.
Netherlands	0.31	Taiwan	4.41	UAE	0.86	Hong Kong	4.30
UAE	0.17	Hong Kong	3.23	Singapore	0.82	UK	2.12
Hong Kong	0.14	Singapore	1.71	Hong Kong	0.29	Singapore	1.65
France	0.11	Thailand	1.64	Saudi Arabia	0.27	Malaysia	0.69
Belgium	0.06	Netherlands	1.13	Malaysia	0.16	UAE	0.45
Singapore	0.03	UAE	0.56	France	0.16	Thailand	0.25
Saudi Arabia	0.03	USA	0.43	Kuwait	0.14	Kuwait	0.25
Canada	0.03	Malaysia	0.42	UK	0.13	India	0.19
Russia	0.03	Japan	0.22	Jordan	0.09	Vietnam	0.17
Qatar	0.02	Russia	0.21	Qatar	0.08	New Caledonia	0.15
Total Exports	**1.05**	**-**	**15.24**	**-**	**3.46**	**-**	**10.87**

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

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for MILBEKNOCK MITICIDE (9.3 g/L milbemectin) is summarised below.

Table 2: Proposed use pattern for MILBEKNOCK MITICIDE (9.3 g/L milbemectin)

CROP	PEST	RATE	CRITICAL COMMENTS
Stone Fruit	Two-Spotted Mite (*Tetranychus urticae*)	**Dilute Spraying** 100-150 mL/100L plus Agral® 600 at 25 mL/100 L (0.9-1.4 g ai/100 L) **Concentrate Spraying** Refer to the Mixing/Application section	Spray to wet foliage to near the point of run-off. Thorough coverage and penetration into the plant canopy is essential. Use the higher rate on larger mature trees with dense foliage or when a longer period of residual control is required. The lower rate should be used on smaller trees where good coverage is more easily achieved and when predators are present and Integrated Mite Control (IMC) is being practiced. Total volume of application should be 1000-200 L/ha. For best results, apply the product using dilute spraying equipment. MILBEKNOCK will control moderate to high mite populations, but in the absence of predatory mites, re-treatment with another miticide may be necessary. If re-treatment is required, use an approved miticide from a different chemical group.

Restraints:

DO NOT apply if rainfall or irrigation is expected before the MILBEKNOCK spray has time to dry on the leaves.

DO NOT use by aerial application.

Withholding periods:

Stone Fruit: DO NOT harvest for 14 DAYS after application.

Stone fruit: DO NOT allow livestock to graze treated area.

Export Trade Advice:

Treated crop commodities destined for export may require extra time being allowed between application and harvest, as some export markets have either no Maximum Residue Limit (MRL) or different MRL to those of Australia. Details of overseas standards and export interval can be obtained by contacting Sipcam before using this product.

Spray drift

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour at the application site.

DO NOT apply if there are livestock, pasture or any land that is producing feed for livestock downwind from the application area and within the mandatory no-spray zone shown in the table below.

FOR GROUND APPLICATION: AIRBLAST APPLICATION	
Wind Speed Range at Time of Application	Downwind Mandatory No-Spray Zone
from 3 to 20 kilometres per hour	80 m

2.4 Results from residues trials presented to the APVMA

The applicant has proposed that a maximum concentration of 9.3 g ai/100L be allowed on stone fruit. In support of this application, the Applicant has submitted Australian residue data from 3 peach, 2 nectarine and 2 cherry trials. Overseas residue data for stone fruit was submitted from 10 US trials and 1 New Zealand trial.

At the proposed withholding period of 14 days, residues in peaches taken from the Australian trials were at the LOQ for total milbemectin of <0.02 mg/kg (n=3), in nectarines were <0.02 and 0.02 mg/kg and in cherries were also <0.02 and 0.02 mg/kg. Residues in peaches taken from the US trials, 14 days after the last application were 0.02 (n=2), and <0.04 mg/kg, in cherries were <0.02 and 0.02 mg/kg, and in plums were <0.02 (n=4) and 0.03 mg/kg. Residues in peaches taken from the NZ trial, 14 days after the last application were <0.004 mg/kg. Residues in prunes taken and processed 14 days after the last application were 0.03 mg/kg.

Residue data support the establishment of a MRL of 0.1 mg/kg for stone fruit, accompanied by a WHP of 14 days. A grazing restriction of ‘DO NOT allow livestock to graze treated area’ should also be included on the label’.

Spray drift modelling, using APVMA spray drift standard application scenarios, shows that with respect to no-spray zones for a ‘sparse orchard’ airblast application a downwind buffer of 68 m is required and for a ‘dense orchard’ a buffer of 78 m is required to ensure residues are below 0.001 mg/kg for animal commodities.

Animal Commodities

Stone fruit are not considered to be stockfeed. Vegetable by-products and waste fruit are assumed to be fed at proportions not exceeding 5% of the animal diet on a dry matter basis. The maximum dietary intake for beef cattle based on the highest residue of 0.03 mg/kg observed in plums with a dry matter content of 12%[3] is calculated below:

Cattle- 500 kg bw, 20 kg DM/day

COMMODITY	% IN DIET	FEED INTAKE	RESIDUE, mg/kg	% DM	LIVESTOCK DIETARY EXPOSURE		
					mg/ANIMAL	ppm	mg/kg BW
Plums	5	20	0.03	12	0.25	0.01	0.0005

The Applicant had proposed a grazing withholding period to reflect the harvest withholding period; however, as no residue data for pasture or animal feed commodities or an animal transfer study have been provided a 'DO NOT allow livestock to graze treated area' statement should be included on the label.

Based on a lactating goat metabolism study, residues resulting from feeding at 0.01 ppm are expected to be two orders of magnitude below analytical method LOQs for this class of compounds. However, as animal transfer studies are currently not available, animal commodity MRLs will not be established at this time.

2.5 Overseas registration and approved label instructions

The applicant indicated that milbemectin products are registered for use on unspecified commodities in the USA, EU, Japan, Taiwan, Korea, India, Thailand, Kenya, South Africa, Colombia, Ecuador, Peru, Chile, Brazil, Syria, Egypt, UAE, Israel, Mexico, New Zealand, Jordan, Turkey, Qatar, Morocco and Cyprus.

2.6 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. Milbemectin has been considered by Codex. Animal commodity MRLs are not currently established and are not required at this time. The following relevant Codex CXLs and overseas residue MRLs/ tolerances have been established for milbemectin in plant commodities:

[3] Department of Community Services and Health 1991, Nutritional Values of Australian Foods, Canberra

Table 3: Overseas tolerances for milbemectin in relevant commodities

COUNTRY	PLANT COMMODITY	TOLERANCE (MG/KG)	RESIDUE DEFINITION
Australia[#]	Stone fruit	0.1	Sum of milbemycin MA3 and milbemycin MA4 and their photoisomers, milbemycin (Z) 8,9-MA3 and (Z) 8,9Z-MA4
Canada[4]	Stone fruit	None Est.	-
CODEX[5]	Stone fruit	None Est.	-
EU[6]	Stone fruit	*0.05	Monitoring: Milbemectin (sum of MA4 +8,9Z-MA4, expressed as milbemectin) Risk Assessment: (MA3 + 8,9Z-MA3) + (MA4 + 8,9Z-MA4), expressed as milbemectin or Monitoring RD × Conversion Factor (1.5), accounting for MA3: MA4 ratio of 3:7.
Japan[7]	Peach, Nectarine	0.2	Sum of residues of milbemectin A3 and milbemectin A4
	Apricot, Japanese plum (inc. prune), Mume plum, cherry	0.5	
Korea[8]	Stone fruit	None Est.	-
Malaysia	Stone fruit	0.01[+]	-
New Zealand[9]	Stone fruit	*0.02	Sum of milbemycin A3, milbemycin A4, (Z)-8,9 milbemycin A3, (Z)-8,9 milbemycin A4, expressed as Milbemectin
Taiwan[10]	Stone fruit	None Est.	-
US[11]	Stone fruit	None Est.	-

[4] Health Canada – List of Maximum Residue Limits Regulated Under the Pest Control Products Act (current 26 July 2010) http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/food-nourriture/mrl-lmr-eng.php

[5] CODEX alimentarius – Pesticide Residues in Food (updated 30 March 2009) http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp

[6] EU Pesticides Database – Regulation (EC) N°149/2008 (updated 5 August 2010) http://ec.europa.eu/sanco_pesticides/public/index.cfm

[7] The Japan Food Chemical Research Foundation – Compositional Specification for Foods (updated 29 January 2010) http://www.m5.ws001.squarestart.ne.jp/foundation/search.html

[8] Korean Food and Drug Administration – MRLs for Pesticides in Foods (updated September 2009) http://eng.kfda.go.kr/file/PesiticideMRLs.pdf

[9] New Zealand Food Safety Authority – New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2010 (current 8 April 2010) http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm#mrl

[10] Department of Health – Standards for Pesticide Residue Limits in Foods (updated 7 October 2009) http://food.doh.gov.tw/english/Acts_Regulations/Foodsafety.asp

2.7 Current and proposed Australian MRLs for milbemectin

Current relevant MRLs and the residue definition for milbemectin are presented below. A full listing of MRLs can be found at 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)
MILBEMECTIN		
FB 0275	Strawberry	0.2

MRL Standard: TABLE 3

COMPOUND	RESIDUE
MILBEMECTIN	Sum of milbemycin MA_3 and milbemycin MA_4 and their photoisomers, milbemycin (Z) 8,9-MA_3 and (Z) 8,9Z-MA_4

The following changes are proposed to Australian milbemectin MRLs:

Table 5: Proposed changes to the MRL Standard

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
MILBEMECTIN		
ADD:		
FS 0012	Stone fruits	0.1

[11] United States Food and Drug Administration – Code of Federal Regulations, Part 180 – Tolerances and Exemptions for Pesticide Chemical Residues in Food (current 2 September 2010) http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=5d35d354cc838eb105a733f5dff13ab8&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of milbemectin 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 proposed MRL of 0.1 mg/kg is higher than the tolerances currently establish in the EU and NZ for stone fruit of *0.05 and *0.02 mg/kg, respectively; however is lower than those established in Japan for various stone fruit commodities (0.2 and 0.5 mg/kg). The key export markets of UAE, Hong Kong, Singapore, Taiwan and Thailand do not currently have established export tolerances.

In order to mitigate the risk to trade 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 product label:

> ‘Treated crop commodities destined for export many require extra time being allowed between application and harvest, as some export markets have either no Maximum Residue Limit (MRL) or different MRL to those of Australia. Details of overseas standards and export interval can be obtained by contacting Sipcam before using this product.’

Comment is sought on the likelihood of the changes in use for MILBEKNOCK MITICIDE to cause undue prejudice to Australian trade in stone fruit commodities.

3 CONCLUSIONS

It is proposed to establish MRLs for Apricots, Citrus fruits, Kiwifruits, Peaches, Pome fruit and Stone fruit [except apricots and peaches]. Comment is sought on the potential for milbemectin in MILBEKNOCK MITICIDE to prejudice Australian trade when it is used on stone fruit for the control of two spotted mite.

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