Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on milbemectin in the product Milbeknock Miticide

APVMA Product Number 61269

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Comments and enquiries regarding copyright:

Director Public Affairs and Communication
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@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 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 vary the registration of Milbeknock Miticide 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 Wednesday 6 April 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.

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:

Residues and Trade
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4701
Fax: +61 2 6210 4776
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 Sipcam Pacific Australia Pty Ltd, to vary the registration of Milbeknock Miticide on pome and stone fruit. Milbeknock Miticide contains milbemectin as its active ingredient.

Specifically Sipcam propose to:

- Increase the maximum rate in pome fruit from 75 mL/100 L to a rate range of 100–125 mL/100 L (0.93–1.16 g ai/100 L). At the same time the applicant is proposing to increase the withholding period for pome fruit from 7 to 14 days.
- Change the current rate in stone fruit of 100 mL/100 L to a rate range of 100–125 mL/100 L (0.931.16 g ai/100 L), retaining the currently approved withholding period of 14 days.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Pome and stone fruit are considered to be major export commodities[2], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated apple pomace. Residues in these commodities resulting from the use of *Milbeknock Miticide* may have the potential to unduly prejudice trade. However, no changes are required to the current stone fruit or animal commodity MRLs for milbemectin. Only pome fruit requires further consideration with respect to trade.

2.2 Destination and value of exports

Values of recent exports of Australian pome fruit are not readily available. Major markets for Australian apples by volume in 2010–2011 were Papua New Guinea, Indonesia, the United Kingdom, Sri Lanka and Thailand (Australian Bureau of Statistics). Leading markets for Australian pears in 2013 were New Zealand, Indonesia and Canada.[3]

2.3 Proposed Australian use-pattern

Milbeknock Miticide (9.3 g/L milbemectin)

CROP	PEST	RATE	CRITICAL COMMENTS
Pome fruit	European Red Mite	Dilute spraying	DO NOT apply more than one application

[2] APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

[3] apal.org.au/supply-chain/trade/export-markets/

CROP	PEST	RATE	CRITICAL COMMENTS
	(Panonychus ulmi) Two-spotted Mite (Tetranychus urticae)	100–125 mL/100 L (0.93–1.16 g ai/100 L) plus 25 mL/100 L of a 60% non-ionic surfactant	per season. Use the higher rate on larger, mature trees with dense foliage or when there is a high population of mites. Application should be made soon after mite numbers have reached the threshold for your area. For European red mite, apply from 2 weeks after petal fall if monitoring shows high numbers of over-wintering European red mite eggs. MILBEKNOCK takes 7–14 days to reach maximum mite control. In the absence of predatory mites, re-treatment with another miticide may be necessary. Dilute Spraying: Spray to wet foliage to near the point of run-off. Thorough coverage and penetration into plant canopy is essential. Concentrate spraying: Refer to the Mixing/Application section.
Stone fruit	Two-spotted Mite (Tetranychus urticae)	Dilute spraying 100–125 mL/100 L (0.93–1.16 g ai/100 L) plus 25 mL/100 L of a 60% non-ionic surfactant	Use the higher rate on larger, mature trees with dense foliage or when there is a high population of mites. Application should be made soon after mite numbers have reached the threshold for your area. MILBEKNOCK takes 7–14 days to reach maximum mite control. In the absence of predatory mites, re-treatment with another miticide may be necessary. A second application of MILBEKNOCK may be applied per season. DO NOT apply the second application of MILBEKNOCK within 7 days of the first and do not apply 2 consecutive sprays within or between seasons or crops without an unrelated chemical being used in between. Dilute Spraying: Spray to wet foliage to near the point of run-off. Thorough coverage and penetration into plant canopy is essential. Concentrate spraying: Refer to the Mixing/Application section.

Withholding periods (pome fruit, stone fruit):

Harvest: DO NOT harvest for 14 days after application.

Grazing: DO NOT allow livestock to graze in treated areas.

2.4 Results from residues trials presented to the APVMA

Pome fruit

In trials conducted in Australia and New Zealand, residues of milbemectin in apples and pears at 14 days after treatment at 0.93–1.50 g ai/100 L (0.80–1.3× proposed) were <0.001, <0.001, <0.002, 0.003, <0.005, 0.005, 0.006, 0.011 and 0.015 mg/kg. It is recommended that the current MRL of 0.02 mg/kg for milbemectin on FP 009 Pome fruits be increased to 0.03 mg/kg to cover residues arising from the new use pattern.

The processing factors for juice and wet pomace were <1 and 6.4, respectively. The HR in pome fruit from the available trials matching GAP was 0.015 mg/kg. The estimated HR in wet pomace is therefore 0.096 mg/kg (0.015 × 6.4). When correcting for a 40 per cent dry matter content the HR in pomace is 0.24 mg/kg on a dry weight basis. It is recommended that the current MRL of 0.1 mg/kg for milbemectin on AB 0226 Apple pomace, dry be increased to 0.3 mg/kg to cover the amended use pattern for pome fruit.

It is noted that the STMR-P for apple pomace for estimating livestock dietary burden is unchanged from that considered for the previous use pattern at 0.08 mg/kg (0.005 × 6.4 ÷ 0.40). No changes are required to the current animal commodity MRLs for milbemectin to cover residues in livestock through consumption of apple pomace as the livestock dietary burden is the same as previously estimated.

Stone fruit

In Australian stone fruit trials, milbemectin was applied once at an application rate of 1.4 g ai/100 L, with spray volumes of 990 to 2073 L/ha. 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 <0.02 and 0.02 mg/kg. In a New Zealand trial, milbemectin was applied once at rate of 0.7 or 1.4 g ai/100 L in a spray volume of 1500 L/ha and this resulted in a residue level <0.004 mg/kg 14 days after application.

In US trials, milbemectin was applied to trees twice at a nominal rate of 26.9 g ai/ha per application, 21 and 14 days prior to normal harvest. All applications were made with spray volumes ranging from 1337 to 3115 L/ha which resulted in a rate of 0.86–1.95 g ai/100L. 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.

The Australian trials were at a higher concentration than proposed (1.2×), but only involved one application per crop when up to 2 are allowed. However, the US trials involving two applications at 0.74–1.7× the proposed concentration showed similar residues, all of which were within the current stone fruits MRL. No changes are required to the MRL of 0.1 mg/kg for milbemectin on FS 0012 Stone fruits to cover the amended use pattern.

2.5 Overseas registration and approved label instructions

The applicant has not provided any details of overseas registrations or label instructions of products containing milbemectin.

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 not been considered by Codex. The following relevant overseas MRLs have been established for milbemectin.

Table 1: Overseas MRLs

COUNTRY	COMMODITY	TOLERANCE (mg/kg)	RESIDUE DEFINITION
Australia	Pome fruits	0.02 (proposed 0.03)	Sum of milbemycin MA3 and milbemycin MA4 and their photoisomers, milbemycin (Z) 8,9-MA3 and (Z) 8,9Z-MA4
EU	Pome fruits	0.02*	Sum of milbemycin A4 and milbemycin A3, expressed as milbemectin
Japan	Apple	0.2	Sum of milbemectin A3 and milbemectin A4
	Japanese pear	0.2	
	Pear	0.2	
Korea	Apple	0.1	
	Pear	0.1	
Taiwan	Pome	0.2	

2.7 Current and proposed Australian MRLs for milbemectin

Table 2: Current MRL Standard

COMPOUND		FOOD	MRL (mg/kg)
	Milbemectin		
MO	0105	Edible offal (mammalian)	*0.002
MM	0095	Meat [mammalian][in the fat]	*0.002
FM	0183	Milk fats	*0.0005
ML	0106	Milks	*0.0005
FP	0009	Pome fruits	0.02
FS	0012	Stone fruits	0.1

Table 3: Proposed changes to MRL Standard

COMPOUND		FOOD	MRL (mg/kg)
	Milbemectin		
FP	0009	Pome fruits	0.02
ADD:			
FP	0009	Pome fruits	0.03

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.

MRLs established overseas for pome fruit are generally higher than that proposed for Australia with the exception of the EU. The following trade advice statement appears on the current Milbeknock label:

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 intervals can be obtained by contacting Sipcam before using this product.

3 CONCLUSIONS

Sipcam Pacific Australia Pty Ltd have applied to vary the registration of Milbeknock Miticide on pome and stone fruit. The APVMA proposes to be satisfied that the risk to trade associated with the product is manageable under established industry systems. Comment is sought on the potential for Milbeknock Miticide to prejudice Australian trade when used on pome and stone fruit.