



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



# TRADE ADVICE NOTICE

on Milbemectin in the Product Milbeknock Miticide

APVMA Product Number P61269

**JANUARY 2014**

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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 Ageing, 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 the APVMA's publication *Ag MORAG: Manual of Requirements and Guidelines*.

## 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 vary 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 **26 February 2014** 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)**<sup>1</sup> 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:

Contact Officer  
Pesticides Program  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Symonston ACT 2609

**Phone:** +61 2 6210 4748

**Fax:** +61 2 6210 4776

**Email:** [pesticides@apvma.gov.au](mailto:pesticides@apvma.gov.au)

## Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained via the contact details provided above.

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<sup>1</sup> 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 the product, *Milbeknock Miticide*, containing 9.3 g/L milbemectin, to include the use on pome fruit. The proposed variation requires the establishment of a milbemectin MRL for pome fruit as well as mammalian animal commodity MRLs as pome fruit pomace may be fed to livestock.

The potential for milbemectin residues to unduly prejudice trade in pome fruit or animal commodities, arising from the proposed use, is discussed below.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Pome fruit, cattle, cattle dairy products and sheep are considered to be major export commodities.<sup>2</sup>

### 2.2 Destination and value of exports

The significant export markets for animal commodities are defined in Part 5B of AgMORAG.

Pome fruit, principally apples and pears are exported from Australia. The volume of Australian apples that were exported and the major export destinations for Australian apples from 2007–2008 to 2010–2011 are shown below.

**Table 1: Largest Export markets by volume for apples from 2007-2008 to 2010-2011 financial years**

DESTINATION	2007-2008	2008-2009	2009-2010	2011-2012
Papua New Guinea	546.0	742.2	758.8	79.6
Indonesia	662.9	567.3	569.7	766.6
United Kingdom	620.9	572.5	261.5	373.5
Sri Lanka	441.2	431.0	271.4	179.7
Thailand	5.6	2.1	139.0	130.2
Other	1,300.7	2,008.4	2,674.8	289.1
Total	3,577.3	4,323.7	4,675.1	2508.5

<sup>2</sup> [www.apvma.gov.au/morag\\_ag/vol\\_3/part\\_05b\\_trade.php](http://www.apvma.gov.au/morag_ag/vol_3/part_05b_trade.php)

The value of apples and pears exported to each major export destination in the 2007–2008 financial year are shown below.

Table 2: Largest Export markets by value for apples and pears in 2007-2008 financial year

APPLES		PEARS	
DESTINATION	VALUE, \$'000	DESTINATION	VALUE, \$'000
United Kingdom	2123.5	Canada	2,411.3
Indonesia	1549.9	New Zealand	1,545.5
Papua New Guinea	925.8	New Caledonia	560.5
Taiwan	754.0	Netherlands	329.8
Sri Lanka	486.7	Indonesia	284.4
Malaysia	318.0	Papua New Guinea	272.3
India	227.9	Fiji	252.9
Singapore	151.3	Singapore	190.5
Hong Kong	110.7	Hong Kong	121.6
New Caledonia	97.1	Malaysia	103.4
Other	382.4	Other	569.2
<b>TOTAL</b>	<b>7,127.4</b>	<b>TOTAL</b>	<b>6,641.4</b>

## 2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Milbeknock Miticide* (9.3 g/L milbemectin) in pome fruit is summarised below.

**Table 3: Proposed use pattern of *Milbeknock Miticide* (9.3 g/L milbemectin) on pome fruit**

DISEASE	RATE	WHP	CRITICAL COMMENTS
European Red Mite ( <i>Panonychus ulmi</i> )	75 ml/100L <b>(0.7 g ai/100L)</b>	H: 7 days	Spray to wet foliage to near the point of run-off. Thorough coverage and penetration into plants is essential. <b>Dilute spraying:</b> Total spray volume 2000 L/ha. <b>Concentrate spraying:</b> Refer to the Mixing / Application section.
Two-spotted Mite ( <i>Tetranychus urticae</i> )	Plus 25ml/100L of a 60% non-ionic surfactant eg AGRAL 600		<b>Apple or Pear trees with mite eggs</b> – apply MILBEKNOCK from 2 weeks after petal fall if monitoring shows high numbers of over-wintering European Red Mite eggs are present. <b>Apple or pear trees with mobile mites</b> – MILBEKNOCK application against motile mite stages of both species should be made soon after mite numbers have reached the threshold for your area. MILBEKNOCK takes 7-14 days to reach maximum mite control. 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. Do not apply more than one application per season

### WITHHOLDING PERIODS

**Pome Fruit: Do Not harvest for 7 days after application**  
**Do Not allow livestock to graze in treated areas**

## 2.4 Results from residues trials presented to the APVMA

The proposed use of milbemectin on pome fruit involves application at 75 ml/100L (0.7 g ai/100L). The proposed harvest withholding period for pome fruit is 7 days.

Data from available pome fruit trials resulted in residue levels of <0.002, <0.002, 0.002, 0.003 <0.005, <0.005, <0.005, <0.005, <0.005 and <0.005 mg/kg in apple and pear samples collected at or after the proposed withholding period of 7 days following application at 1x rate. The establishment of a milbemectin MRL of 0.02 mg/kg for FP 0009 Pome fruit is proposed.

In an apple processing study, milbemectin residues concentrated 6.39 times in the wet pomace compared to the residues in whole fruit. The corresponding STMR-P for wet pomace is  $PF \times STMR = 6.39 \times <0.005 = <0.032$  mg/kg. When corrected for a 40% dry matter content, the corresponding residue is <0.08 mg/kg on a dry weight basis. The establishment of a milbemectin MRL of 0.1 mg/kg for AB 0226 Apple pomace, dry is proposed.

The potential exposure of livestock to milbemectin is estimated as 0.016 mg/kg in the feed. In the lactating dairy cattle study, feeding at a level of 0.03 mg/kg in the feed did not result in milbemectin residues above LOQ (0.0005 mg/kg) in milk, skim milk or cream. In the beef cattle study at a feeding level of 0.02 mg/kg in the feed, did not milbemectin residues above LOQ (0.002 mg/kg) in kidney, liver, mesentery fat, muscle, peri-renal fat and subcutaneous fat were not found. The animal transfer studies therefore indicate that the proposed use of milbemectin on pome fruit should not result in quantifiable levels of milbemectin residues in animal commodities.

Based on the available information, it is recommended that milbemectin MRLs be established for MO 0105 Edible offal (Mammalian) at \*0.002 mg/kg, MM 0095 Meat [mammalian] [in the fat] at \*0.002 mg/kg, ML 0106 Milks at \*0.0005 mg/kg and FM 0183 Milk fats at \*0.0005 mg/kg.

## 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. Milbemectin has not been considered by Codex, Canada or the United States. The following relevant international MRLs have been established for milbemectin:

Table 4: Comparison of milbemectin MRLs (mg/kg) for pome fruit and animal commodities

COUNTRY	COMMODITY	MILBEMECTIN TOLERANCE (mg/kg)
<b>Australia</b>	Edible offal (Mammalian)	*0.002 (proposed)
	Meat [mammalian] [in the fat]	*0.002 (proposed)
	Milks	*0.0005 (proposed)
	Milk fats	*0.0005 (proposed)
	Pome fruit	0.02 (proposed)
<b>EU</b>	Pome fruit	*0.05
	Terrestrial animal tissue	*0.02 (pending, in force 06/07/2014)
	Milk	*0.02 (pending, in force 06/07/2014)
<b>Japan</b>	Apple	0.2
	Japanese pear	0.2
	Pear	0.2
<b>Korea</b>	Apple	0.1
	Pear	0.1
<b>New Zealand</b>	Pome fruit	0.02
<b>Taiwan</b>	Pome fruit	0.2

## 2.6 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 [www.apvma.gov.au/residues/standard.php](http://www.apvma.gov.au/residues/standard.php).

Table 5: Current entries in the MRL Standard

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
MILBEMECTIN			
VO	0445	Peppers, Sweet [capsicum]	0.02
FS	0012	Stone fruits	0.1
FB	0275	Strawberry	0.2

MRL Standard: TABLE 3

COMPOUND	RESIDUE
MILBEMECTIN	Sum of milbemycin MA3 and milbemycin MA4 and their photoisomers, milbemycin (Z) 8,9-MA3 and (Z) 8,9Z-MA4

The following changes are proposed to Australian milbemectin MRLs:

Table 6: Proposed changes to the MRL Standard - Table1

MRL STANDARD: TABLE 1

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

Table 7: Proposed changes to the MRL Standard - Table4

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
MILBEMECTIN		
ADD:		
AB 0226	Apple pomace, dry	0.1

## 2.7 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.

It is proposed to establish a milbemectin MRL for FP 0009 Pome fruit of 0.02 mg/kg. This MRL is equivalent to that established in New Zealand and lower than that established in the EU (\*0.05 mg/kg), Japan (0.2 mg/kg), Korea (0.1 mg/kg) and Taiwan (0.2 mg/kg). There is considered to be minimal trade risk associated with these countries that have MRLs established at or below the proposed MRL for pome fruit.

To help mitigate potential trade risk associated with the proposed use on pome fruit the applicant has proposed the following trade advice statement for inclusion on the product label:

“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 Limits (MRLs) or different MRLs to those of Australia. Details of overseas standards and export interval can be obtained by contacting Sipcam before using the product.”

The overall risk to export trade in pome fruit is considered to be low.

Apple pomace which may be derived from apples treated with milbemectin may be fed to animals. Animal commodity MRLs need to be established to account for this potential exposure. It is proposed that milbemectin MRLs are established for MO 0105 Edible offal (Mammalian) at \*0.002 mg/kg, MM 0095 Meat [mammalian] [in the fat] at \*0.002 mg/kg, ML 0106 Milks at \*0.0005 mg/kg and FM 0183 Milk fats at \*0.0005 mg/kg. It is noted that the animal commodity MRLs recommendations were based on the estimated exposure through apple pomace only. The grazing withholding period “Do Not allow livestock to graze in treated areas” is recommended to prevent livestock exposure to milbemectin via the grazing of treated orchards.

With the exception of pending EU MRLs for terrestrial animal tissue and milk at \*0.02 mg/kg, that will enter the EU MRL standard on 6 July 2014, animal commodity MRLs have not been established for milbemectin in overseas markets. As MRLs are recommended at LOQ for all animal commodities it is unlikely that the establishment of these animal commodity MRLs will result in any trade issues. The overall risk to export trade in animal commodities is considered to be low.

### 3 CONCLUSIONS

The establishment of milbemectin MRLs in Pome fruit and the animal commodities Edible offal (Mammalian), Meat [mammalian] [in the fat], Milks and Milk Fats is proposed. Comment is sought on the potential for milbemectin residues resulting from the proposed use of *Milbeknock Miticide* on pome fruit to unduly prejudice Australian trade, and the ability of industry systems to manage any identified risk.