



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



## TRADE ADVICE NOTICE

on Clothianidin in the Product Sumitomo Shield Systemic Insecticide

APVMA Product Number 60689

FEBRUARY 2010

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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 vary the registration of **SUMITOMO SHIELD SYSTEMIC INSECTICIDE containing the active constituent clothianidin** 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. 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 **11 March 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)**<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:

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Australian Pesticides and Veterinary Medicines Authority  
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Symonston ACT 2609

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## 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>

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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 Sumitomo Chemical Australia Pty Ltd, to vary the registration of SUMITOMO SHIELD SYSTEMIC INSECTICIDE, containing 200 g/L Clothianidin to the extend the use to include a sub-surface soil application on sugar cane for the control of cane grub pests.

The potential for clothianidin residues in sugar cane and processed commodities to unduly prejudice Australian trade is discussed below.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Raw and refined sugar as well as commodities of animal origin which may be derived from livestock feeding on treated cane tops are exported, and are considered to be major export commodities as listed in Appendix 1 of Part 5B of Ag MORAG. Australia exports raw sugar in bulk, raw sugar in bags and refined sugar. Residues in these commodities resulting from the use of Sumitomo Shield Systemic Insecticide have the potential to unduly prejudice trade.

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

### 2.2 Destination and value of exports

The total exports of Australian raw sugar in bulk, raw sugar in bags and refined sugar was 3600 kt worth \$0.94 billion in 2007/2008

The major export markets for Australian raw sugar in bulk by volume, the volume of raw sugar in bags & refined sugar as well as the total value of Australian sugar commodities are shown below (Australian Commodity Statistics (2008)).

Table 1: Major Export markets by volume for raw sugar

DESTINATION	VOLUME OF AUSTRALIAN EXPORTS OF SUGAR, BY DESTINATION (KT)							
	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08
RAW SUGAR IN BULK								
Canada	512.1	477.5	329.3	381.2	332.9	110.0	50.0	N/A
China	60.0	230.0	367.7	99.8	179.0	192.9	59.8	N/A
Chinese Taipei	120.3	122.7	157.7	133.6	279.0	306.0	238.0	N/A
Indonesia	55.5	66.6	163.7	152.3	362.2	529.8	536.9	N/A
Iran	80.0	0.0	84.0	0.0	0.0	227.5	610.5	N/A
Japan	474.5	762.6	729.0	517.1	434.7	493.2	1004.5	N/A
Korea, Rep. of	504.8	569.8	795.4	980.3	1003.5	1066.5	520.0	N/A
Malaysia	654.9	771.1	798.8	1015.6	1026.9	469.0	220.6	N/A
New Zealand	209.5	245.6	218.6	220.4	243.5	192.2	132.0	N/A



Saudi Arabia	171.7	169.3	212.0	219.5	132.0	132.0	132.0	N/A
United States	62.9	83.2	88.0	108.3	83.5	126.7	130.0	N/A
Other countries	60.1	0.5	30.8	102.8	76.1	50.	17.8	N/A
TOTAL	2966	3499	3975	3932	4153	3896	3520	N/A
RAW SUGAR IN BAGS	7.2	6.3	6.3	7.0	3.7	1.9	2.4	2.1
REFINED SUGAR	113.1	138.5	138.5	121.6	113.7	169.5	191.2	218.9
TOTAL SUGAR EXPORT	3087	3644	3644	4061	4271	4067	3714	3600
VALUE OF SUGAR EXPORTS (\$M)								
TOTAL	1,178	1,430	1,220	982	1,140	1,597	1,510	941

Source: ABARE 2008, Australian commodity statistics 2008, Canberra

## 2.3 Proposed Australian use-pattern

The proposed use pattern for Sumitomo Shield Systemic Insecticide is presented below:

Table 2: Proposed use pattern for Sumitomo Shield Systemic Insecticide (200 g/L clothianidin)

CROP	PEST	RATE	CRITICAL COMMENTS
Sugar cane (plant cane)	Greyback canegrub <i>(Dermolepida albohirtum)</i>	2.5 L/ha  This applies to dual row planting.  (equivalent to 38 mLs per 100 m of single row cane with a 1.52 m spacing)  (or 7.6 g ai / 100 m)	Apply as a band spray on late plant or during fill-in stage between the months of October to December. In dual rows the amount required per hectare should be split and applied to both rows  Refer to <b>APPLICATION</b> directions under <b>GENERAL INSTRUCTIONS</b> .

Sugar cane (ratoon cane)	Greyback canegrub <i>(Dermolepida albohirtum)</i>	1.75 – 2.5 L/ha  (equivalent to 27 – 38 mL per 100 m of cane row with a 1.52 m spacing)  (or 5.4 – 7.6 g ai / 100 m)	Use the higher rate where higher pressure is expected (more than 2 grubs/stool) to fields at high risk of greyback damage. Apply while stools are small enough to avoid excessive damage. This is generally from October to December. In areas where early beetle flights occur application should be made early in this period.  Apply as a subsurface soil application with coulters.  Refer to <b>APPLICATION</b> directions under <b>GENERAL INSTRUCTIONS</b> .
	Childers canegrub <i>Antitrogus parvulus</i>	1.25 – 1.75 L/ha  (equivalent to 19 – 27 mL per 100 m of cane row with a 1.52 m spacing)  (or 3.8 – 5.4 g ai / 100 m)	Monitor for the presence of grubs starting in September and apply immediately grub numbers reach an economic threshold (about 3 grubs/stool). Early application will be more effective than late.  Use the high rate when grub populations are high (e.g. an average of more than 5 grubs/stool) or if application is after damage has become visible.  Refer to <b>APPLICATION</b> directions under <b>GENERAL INSTRUCTIONS</b> .

<b>Restrains :</b>	DO NOT apply more than one soil application of Shield per crop per season. DO NOT apply as a foliar application.
<b>Withholding periods:</b>	
Harvest:	Do not harvest for 21 weeks after application.
Grazing:	Do not graze or cut for stock food for 21 weeks after application.

## 2.4 Results from residue trials presented to the APVMA

In Australian trials, the proposed soil treatment with clothianidin resulted in the following residue levels in sugar cane billets and tops at 20-25 weeks after application.

APPLICATION RATE	CLOTHIANIDIN RESIDUE (mg/kg)		
	BILLETS	TOPS	
		FRESH WEIGHT	DRY WEIGHT
7.5 g ai/100m row (1x the proposed rate)	<0.01, <0.02, 0.02, 0.02, 0.04	<0.01, 0.02, 0.04, 0.07, 0.10	0.08, 0.15, 0.17, 0.27
15 g ai/100m row (2x the proposed rate)	<0.01, 0.03, 0.05, 0.06	<0.01, 0.03, 0.06, 0.07	0.27, 0.34, 0.38

As the observed HR and STMR for sugar cane billets are 0.04 mg/kg and 0.02 mg/kg respectively, a MRL of 0.1 mg/kg is recommended for Sugar cane, GS 0659.

A processing factor of 3.5x to raw sugar was derived. Clothianidin residues were not observed to concentrate into molasses or juice. The HR-P is estimated to be 0.14 mg/kg (3.5 x 0.04 mg/kg). An MRL of 0.3 mg/kg is recommended for Sugar, raw.

## 2.5 Overseas registration and approved label instructions

The applicant has indicated that clothianidin products are not registered for use on sugar cane overseas.

## 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. Clothianidin is scheduled for evaluation by the JMPR in 2010, however sugar cane is a commodity that has not been nominated for evaluation.

With the exception of a EU MRL at LOQ (\*0.02 mg/kg) for clothianidin in sugar cane<sup>2</sup>, no overseas residue MRL/ tolerance has been established for clothianidin in sugar cane or sugar cane products. It is however noted that a clothianidin MRL for beet, sugar, molasses has been established in the US at 0.05 mg/kg<sup>3</sup>.

## 2.7 Current and proposed Australian MRLs for Clothianidin

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

MRL Standard: Table 1

COMPOUND	FOOD	MRL (mg/kg)
CLOTHIANIDIN		
MO 0105	Edible offal (mammalian)	*0.02
MM 0095	Meat (mammalian)	*0.02
ML 0106	Milks	*0.01
GS 0659	Sugar cane	T0.2

<sup>2</sup> [http://ec.europa.eu/sanco\\_pesticides/public/index.cfm?event=activesubstance.selection&a=1](http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection&a=1)

<sup>3</sup> [http://www.access.gpo.gov/nara/cfr/waisidx\\_08/40cfr180\\_08.html](http://www.access.gpo.gov/nara/cfr/waisidx_08/40cfr180_08.html)

MRL Standard: Table 3

COMPOUND	RESIDUE
CLOTHIANIDIN	Clothianidin

MRL Standard: Table 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
CLOTHIANIDIN		
	Cotton seed by-products	T*0.01
AM 0659	Sugar cane fodder	T0.5
AV 0659	Sugar cane forage	T0.5

**Proposed Amendments to the MRL Standard**

MRL Standard: Table 1

COMPOUND	FOOD	MRL (mg/kg)
CLOTHIANIDIN		
DELETE:		
GS 0659	Sugar cane	T0.2
ADD:		
GS 0659	Sugar cane	0.1
	Sugar, raw	0.3

MRL Standard: Table 4

COMPOUND	FOOD	MRL (mg/kg)
CLOTHIANIDIN		
DELETE:		
AM 0659	Sugar cane fodder	T0.5
AV 0659	Sugar cane forage	T0.5

COMPOUND	FOOD	MRL (mg/kg)
ADD:		
AM 0659	Sugar cane fodder	0.5
AV 0659	Sugar cane forage	0.5

## 2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of clothianidin 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 HR of 0.04 mg/kg and a STMR of 0.02 mg/kg in sugar cane billets support the establishment of a MRL at 0.1 mg/kg for GS 0659 Sugar cane. The processing study found that clothianidin residues accumulate by 3.5x during the processing from sugar cane billets to raw sugar. The HR-P and STMR-P are therefore calculated to be 0.14 and 0.07 mg/kg respectively and an MRL has been proposed at 0.3 mg/kg for Sugar, raw.

Given that detectable residues of clothianidin may occur in sugar cane and processed sugar commodities as a result of the proposed use, and as overseas markets do not have MRLs or tolerances established for clothianidin in sugar cane or sugar commodities, the proposed use of clothianidin may prejudice Australian trade in sugar products.

Comment is sought on the potential for the proposed uses of Sumitomo Shield Systemic Insecticide to prejudice Australian trade in sugar.

### 3 CONCLUSIONS

Comment is sought on the potential for the proposed uses of Sumitomo Shield Systemic Insecticide to prejudice Australian trade in sugar.