Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on clothianidin in the product Sumitomo Samurai Systemic Insecticide

APVMA Product Number 60687

JUNE 2016

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

Telephone: +61 2 6210 4988

Email: communications@apvma.gov.au

This publication is available from the APVMA website: www.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 **Sumitomo Samurai Systemic Insecticide** 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 **Monday 5 July 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 Sumitomo Chemical Australia Pty Ltd to vary the registration of Sumitomo Samurai Systemic Insecticide. The application is for approval of new uses or variation of the current uses of *Sumitomo Samurai Systemic Insecticide* containing *clothianidin* on *table grapes, persimmon, pome fruit, stone fruit and fruiting vegetables (cucurbits and non-cucurbits, except mushrooms and sweet corn)* to control fruit fly. Only table grapes, pome fruit and stone fruit are major export commodities requiring consideration in this notice. Samurai is currently registered for use as a foliar application for control of mealybug in table grapes, mealybug, woolly aphid and codling moth in apples and pears, and green peach aphid and oriental fruit moth in peaches and nectarines. Current withholding periods for the same rates as the fruit fly uses are 21 days for apples, pears, peaches and nectarines, and six weeks for foliar application to grapes. The proposed new WHP for table grapes, pome fruit and stone fruit for the fruit fly use is seven days.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Table grapes, pome fruit 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 Sumitomo Samurai Insecticide may have the potential to unduly prejudice trade. However, no changes are required to the current animal commodity MRLs for clothiandin or to the current MRL for grapes [excluding wine-grapes]. Only pome and stone fruit require further consideration with respect to trade.

2.2 Destination and value of exports

Grapes [excluding wine-grapes]

Exports of dried vine fruit amounted to 2.5 kt in 2014-15 and were worth $10.3 million (ABARES). Recent export figures and destinations for table grapes are not readily available.

Pome fruit

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] APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B)

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

Stone fruit

Australia exported $1.4 million worth of apricots, $31.5 million worth of cherries, $18.2 million worth of nectarines and peaches and $7.1 million worth of plums in the 2012-2013 financial year. The major markets are summarised below:

APRICOTS	CHERRIES
DESTINATION	DESTINATION
United Arab Emirates	Hong Kong
Hong Kong	Taiwan
Singapore	Singapore
Saudi Arabia	Malaysia
Netherlands	United Arab Emirates
France	Vietnam
Russia	Indonesia
Kuwait	China
Bahrain	United Kingdom
-	Netherlands
NECTARINES AND PEACHES	PLUMS
DESTINATION	DESTINATION
Hong Kong	Hong Kong
United Arab Emirates	Singapore
Singapore	Malaysia
New Caledonia	United Arab Emirates
Taiwan	Vietnam
Saudi Arabia	Russia
Kuwait	Kuwait
Qatar	Indonesia
Malaysia	New Caledonia
Indonesia	Papua New Guinea
Source of data: Australian Bureau of Statistics	

2.3 Proposed Australian use-pattern

Sumitomo Samurai Systemic Insecticide (500 g/kg clothianidin)

CROP	PEST	RATE	CRITICAL COMMENTS
Pome fruit, Persimmon Stone fruit Table grapes	Queensland Fruit Fly, Mediterrean Fruit Fly	40 g/100 L + MAXX Organosilicone surfactant at 50 mL/100 L	Apply three consecutive foliar sprays seven days apart when monitoring indicates fruit fly activity. For the effective management of fruit fly this product is required to be used as part of a broader program involving other products approved for the control of fruit fly in conjunction with appropriate pest monitoring and orchard hygiene. Efficacy of such programs may be dependent upon the level of pest pressure during the season. Orchard floors with flowering weeds must be mown just prior to application. Beekeepers that are known to have hives in, or nearby, the area to be sprayed should be notified no less than 48 hours prior to the time of planned application so that bees can be removed or otherwise protected prior to spraying.
Fruiting vegetables (including cucurbits)	Queensland Fruit Fly Cucumber Fruit Fly	40 g/100 L + MAXX Organosilicone surfactant at 50 mL/100L	Apply three consecutive foliar sprays seven days apart when monitoring indicates fruit fly activity. For the effective management of fruit fly this product is required to be used as part of a broader program involving other products approved for the control of fruit fly in conjunction with appropriate pest monitoring and orchard hygiene. Efficacy of such programs may be dependent upon the level of pest pressure during the season. Ensure there are no flowering plants that are attractive to bees in or next to the crop. Beekeepers that are known to have hives in, or nearby the area to be sprayed should be notified no less than 48 hours prior to the time of planned application so that bees can be removed or otherwise protected prior to spraying.

Withholding periods:

Harvest:

GRAPES (foliar application), POME FRUIT, STONE FRUIT (including CHERRIES), PERSIMMON, FRUITING VEGETABLES, including CUCURBITS (except mushrooms and sweet corn)

DO NOT harvest for 7 days after the last application.

2.4 Results from residues trials presented to the APVMA

Table grapes

In trials from the USA, residues in grapes at 0 days after the last of 2 applications at 111 g ai/ha were 0.042, 0.053, 0.074, 0.090, 0.098, 0.11, 0.13, 0.13, 0.14, 0.28, 0.33 and 0.41 mg/kg. The proposed application

concentration of 20 g ai/100 L would correspond to a rate of 200 g ai/ha for a spray volume of 1000 L/ha. Scaled for application rate residues in the US trials are 0.076, 0.095, 0.13, 0.16, 0.18, 0.20, 0.23, 0.23, 0.25, 0.50, 0.59 and 0.74 mg/kg. No changes are required to the current MRL of 3 mg/kg for clothianidin on FB 0269 Grapes [excluding Wine-grapes] to support the new fruit fly use in conjunction with a 7 day harvest WHP.

Pome fruit

In Australian trials 2-4 applications were made to apples and pears, 14 days apart, at a concentration of 20-30 g ai/100 L (1-1.5× the proposed concentration). Clothianidin residues 7 days after the last application were 0.20, 0.21, 0.22, 0.25, 0.25, 0.26, 0.27, 0.28, 0.30, 0.32, 0.36, 0.45, 0.56, 0.60, 0.64, 0.64, 0.66 and 0.88 mg/kg.

In trials from the US a single application of clothianidin was made to apples at a rate of 15-24 g ai/100 L (0.75-1.2× the proposed concentration). Clothianidin residues 6–7 days after the last application were <0.005, 0.01, 0.02, 0.03, 0.05, 0.09, 0.09, 0.10, 0.10, 0.12, 0.15, 0.16 and 0.34 mg/kg.

It is recommended that the current temporary MRL of T2 mg/kg for clothianidin on FP 0009 pome fruit be made permanent, in conjunction with a 7 day WHP.

Stone fruit

In Australian trials, residues in cherries at 7 days after the last of three applications (6–8 days apart) at 30 g ai/100 L (1.5×) were 0.46 and 0.52 mg/kg. In Canadian trials, residues in cherries at 7 days after one application at 219–228 g ai/ha, (approximately 1.1× for a spray volume of 1000 L/ha) residues were 0.05, 0.10, 0.11, 0.14 and 0.14 mg/kg.

In Australian trials 3–4 applications were made to nectarines and peaches, 14 days apart, at a concentration of 20-30 g ai/100 L (1-1.5× the proposed concentration). Clothianidin residues 7 days after the last application were 0.31, 0.56, 0.57, 0.60, 1.00, 1.41, 1.5, 1.5, 1.52 and 1.64 mg/kg.

It is proposed that the current temporary clothianidin MRLs of T3 mg/kg for FS 0012 Stone fruits [except Cherries] and T5 mg/kg for FS 0013 Cherries be replaced with a stone fruit group MRL of 3 mg/kg, in conjunction with a 7 day WHP.

2.5 Overseas registration and approved label instructions

The applicant indicated that clothianidin products are registered for use in many countries. It is used either as a seed treatment, a soil application or a foliar application.

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 has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for clothianidin.

Table 1: Codex and overseas MRLs for clothianidin

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF CLOTHIANIDIN (MG/KG)						
	AUSTRALIA	CODEX	EU	JAPAN	KOREA	TAIWAN	USA
Residue definition	Clothianidin	Clothianidin	Clothianidin	Clothianizine is a metabolite of thiamethoxam. MRLs for clothianizine include the clothianizine residues resulting from the use of the parent thiamethoxam as well as residues from use of clothianizine itself.			Clothianidin
Grapes	3 [except wine]	0.7	0.7	5	2	1	0.6
Dried grapes	10	1				1 (Raisin)	
Pome fruit	T2 (2 proposed)	0.4	0.4		1.0		1
Apple				1		1.0	
Japanese pear				1			
Pear				1		1	
Quince				1			
Loquat				1			
Stone fruit	T3 (except cherries) (3 proposed, include cherries)	0.2					
Cherries	T5 (proposed remove)		0.1	5	0.5	1	
Peach			0.1	0.7	0.5	1	0.8
Nectarine				2		1	

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF CLOTHIANIDIN (MG/KG)						
	AUSTRALIA	CODEX	EU	JAPAN	KOREA	TAIWAN	USA
Apricot			0.1	3		1	
Plum			0.02*		0.5 (also for Korean plum)	1	
Prune						1	
Japanese plum (including prune)				0.3			
Mume plum				5			

2.7 Current and proposed Australian MRLs for clothianidin

Table 2: Current MRL Standard

COMPOUND		FOOD	MRL (MG/KG)
CLOTHIANIDIN			
FS	0013	Cherries	T5
DF	0269	Dried grapes (=Currants, Raisins and Sultanas)	10
MO	0105	Edible offal (Mammalian)	*0.02
PE	0112	Eggs	*0.02
VC	0045	Fruiting vegetables, Cucurbits	T1
VO	0050	Fruiting vegetables, other than Cucurbits [except Sweet corn (corn on the cob) and mushrooms]	T0.7
FB	0269	Grapes [excluding Wine-grapes]	3
MM	0095	Meat (mammalian)	*0.02
ML	0106	Milks	*0.01
FI	0352	Persimmon, American	T2
FT	0307	Persimmon, Japanese	T2
FP	0009	Pome fruits	T2
PO	0111	Poultry, Edible offal of	*0.02
PM	0110	Poultry meat	*0.02
FS	0012	Stone fruits [except Cherries]	T3
VO	0447	Sweet corn (corn on the cob)	0.02
FB	1236	Wine-grapes	*0.02

Table 3: Proposed MRL Standard

COMPOUND		FOOD	MRL (MG/KG)
CLOTHIANIDIN			
OMIT:			
FS	0013	Cherries	T5
VC	0045	Fruiting vegetables, Cucurbits	T1
VO	0050	Fruiting vegetables, other than Cucurbits [except Sweet corn (corn on the cob) and mushrooms]	T0.7

COMPOUND		FOOD	MRL (MG/KG)
FI	0352	Persimmon, American	T2
FT	0307	Persimmon, Japanese	T2
FP	0009	Pome fruits	T2
FS	0012	Stone fruits [except Cherries]	T3
INSERT:			
VC	0045	Fruiting vegetables, Cucurbits	0.5
VO	0050	Fruiting vegetables, other than Cucurbits [except Sweet corn (corn on the cob) and Mushrooms]	0.7
FI	0352	Persimmon, American	2
FT	0307	Persimmon, Japanese	2
FP	0009	Pome fruits	2
FS	0012	Stone fruits	3

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.

It is proposed that the temporary clothianidin MRLs of T3 mg/kg for stone fruit (except cherries) and T2 mg/kg for pome fruit be made permanent, with the new stone fruit MRL to include cherries. No changes are required to the Australian MRL for grapes [excluding wine-grapes]. The Australian MRLs are generally higher than those established by international authorities. The Codex MRLs are 0.4 mg/kg for pome fruit and 0.2 mg/kg for stone fruit (including cherries). The EU MRLs are 0.4 mg/kg for pome fruit, 0.1 mg/kg for apricots, peaches and cherries and *0.02 mg/kg for other stone fruit. The Japanese MRLs are 1 mg/kg for pome fruit, 0.3 mg/kg for Japanese plum, 0.7 mg/kg for peach, 2 mg/kg for nectarine, 3 mg/kg for apricot and 5 mg/kg for mume plum and cherry. The US MRLs are 1 mg/kg for pome fruit and 0.8 mg/kg for peach.

The draft Samurai label has the following trade advice statement:

Treated fruit for export to particular destinations outside Australia may require a longer interval before harvest to comply with residues standards of importing countries. Please contact your industry body, exporter or Sumitomo Chemical Australia before using Sumitomo SAMURAI Systemic Insecticide.

3 CONCLUSIONS

Sumitomo Chemical Australia Pty Ltd have applied to vary the registration of Sumitomo Samurai Systemic Insecticide. The application is for approval of new uses or variation of the current uses of *Sumitomo Samurai Systemic Insecticide* containing *clothianidin* on *table grapes, persimmon, pome fruit, stone fruit and fruiting vegetables (cucurbits and non-cucurbits, except mushrooms and sweet corn)*. Only table grapes, pome fruit and stone fruit are major export commodities. Comment is sought on the potential for Sumitomo Samurai Systemic Insecticide to prejudice Australian trade when used on table grapes, pome and stone fruit.