



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



TRADE ADVICE NOTICE

on flonicamid in the product Mainman 500 WG Insecticide

APVMA Product Number 66373

NOVEMBER 2016

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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, Department of the Environment and Energy, 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 Mainman 500 WG 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 Wednesday 14 December 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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 APVMA has before it an application from Ishihara Sangyo Kaisha, Ltd, to vary the registration of Mainman 500 WG Insecticide (containing 500 g/kg flonicamid) to add a use on pears. Mainman 500 WG Insecticide is currently registered for use on apples with the same maximum spray concentration and withholding period as proposed for pears.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Pome fruit including pears are considered to be major export commodities², as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated pome fruit. Residues in these commodities resulting from the use of Mainman 500 WG Insecticide may have the potential to unduly prejudice trade.

It is noted that the livestock dietary burden will be unchanged if the proposed use on pears is supported and the current animal commodity MRLs established at the LOQ will remain acceptable. Further consideration of the risk to trade in animal commodities is not required.

2.2 Destination and value of exports

According to APAL (Apple and Pear Australia Ltd) Australia has recently exported 16.5 per cent of the total marketable production of pears. The leading markets for Australian pears in 2015 were New Zealand, Indonesia, Canada, Hong Kong and Singapore.³

² APVMA regulatory guidelines—data guidelines: agricultural—overseas trade (Part 5B)

³ apal.org.au/selling/export-markets/

2.3 Proposed Australian use-pattern

MAINMAN 500 WG INSECTICIDE (500 g/kg FLONICAMID)

CROP	PEST	RATE	WHP	CRITICAL COMMENTS
Tree crops				
Apply by dilute or concentrate spraying equipment. Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. Refer to application section of the label.				
Apples	Woolly apple aphid (<i>Eriosoma lanigerum</i>)	Dilute spray: 10–14 g/100 L water Concentrate spray: Refer to application section	21 days	Water quantities to be used depend on size of trees, development stage of trees and spraying equipment used. Use the higher rate under high pest pressure. A minimum re-treatment interval of 2 weeks must be observed. Do not apply more than 3 applications. Where applicable, use the higher rate under high pest pressure or to provide longer residual control.
	Tuber mealybug (<i>Pseudococcus viburni</i>)	Dilute spray: 14–20 g/100 L water Concentrate spray: Refer to application section		
Pears	Longtailed mealybug (<i>Pseudococcus longispinus</i>)	Dilute spray: 14–20 g/100 L water (7–10 g ai/100 L) Concentrate spray: Refer to application section		

Withholding periods:

Apples, pears: do not harvest for 21 days after application.

Do not graze or feed treated crops to animals.

Export of treated produce

Growers should note that suitable MRLs or import tolerances do not exist in all markets for produce treated with Mainman 500 WG Insecticide. In some situations export requirements may be met by limiting application number and/or imposing a longer withholding period than specified above. If you are growing produce for export, please check with UPL Australia Limited for the latest information on any potential trade issues and their management before using Mainman 500 WG Insecticide.

2.4 Results from residues trials presented to the APVMA

Details of 13 Australian residue trials (8 on apples and 5 on pears) in addition to 15 residue trials from the USA (11 on apples and 4 on pears) are available.

In Australian trials on pome fruit three applications of flonicamid were made at 10 g ai/100 L (1× the proposed rate). Flonicamid residues in apples 21 days after the last treatment were 0.14, 0.18 (×2), 0.21, 0.22, 0.29, 0.33 and 0.38 mg/kg. Residues in pears 21 days after the last treatment were 0.08, 0.10, 0.16, 0.17 and 0.28 mg/kg.

Trials from the USA on pome fruit involved three applications of flonicamid made at 100 g ai/ha (1× the proposed rate assuming a spray volume of 1000 L/ha). Treatment of apples with flonicamid resulted in residues 21 days after the last application of 0.04, 0.06 (×2), 0.07 (×2), 0.08 (×4), 0.09 and 0.15 mg/kg. Flonicamid residues in pears 21 days after the last treatment were 0.03 (×2), 0.04 and 0.06 mg/kg.

It is proposed that the current MRL of 0.7 mg/kg for flonicamid on FP 0226 Apple be replaced with an MRL for FP 0009 Pome fruits at the same level, in conjunction with a 21 day WHP.

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. Flonicamid has been considered by Codex, however no Codex MRLs relevant to pome fruit have been established. The 2015 JMPR recommended a Pome fruits MRL of 0.8 mg/kg which is currently being held at step 4. The following relevant overseas MRLs have been established for flonicamid:

Table 1: Relevant overseas MRLs for flonicamid

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLONICAMID (mg/kg)				
	AUSTRALIA	EU	JAPAN	USA	CANADA
PLANT COMMODITIES					
Residue definition	Flonicamid Sum of flonicamid, TFNG and TFNA, expressed as flonicamid.	Flonicamid Sum of flonicamid, TFNG and TFNA, expressed as flonicamid.	Flonicamid Sum of flonicamid, TFNG and TFNA, expressed as flonicamid.	Flonicamid Sum of flonicamid, TFNG, TFNA and TFNA-AM, calculated as the stoichiometric equivalent of flonicamid.	Flonicamid Sum of flonicamid, TFNG, TFNA and TFNA-AM, calculated as the stoichiometric equivalent of flonicamid.
Pome fruit	0.7 (Proposed)	0.3		0.2	0.2
Apple	0.7 (Current)		1		

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLONICAMID (mg/kg)				
Japanese pear			0.5		
Pear			0.5		
Quince			0.2		
Loquat			0.2		

TFNG (*N*-(4-trifluoromethylnicotinoyl)glycine), TFNA (4-trifluoromethylnicotinic acid),

TFNA-AM (4-trifluoromethylnicotinamide)

2.6 Current and proposed Australian MRLs for flonicamid

Table 2: Current MRL standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
Flonicamid		
FP 0226	Apple	0.7
MO 0105	Edible offal (Mammalian)	*0.02
MM 0095	Meat [mammalian]	*0.02
ML 0106	Milks	*0.02

Table 3: Proposed changes to MRL standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
Flonicamid		
DELETE:		
FP 0226	Apple	0.7
ADD:		
FP 0009	Pome fruits	0.7

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of flonicamid 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 draft label includes the following trade advice statement:

Export of treated produce

Growers should note that suitable MRLs or import tolerances do not exist in all markets for produce treated with Mainman 500 WG Insecticide. In some situations export requirements may be met by limiting application number and/or imposing a longer withholding period than specified above. If you are growing produce for export, please check with UPL Australia Limited for the latest information on any potential trade issues and their management before using Mainman 500 WG Insecticide.

The EU and USA have established MRLs for flonicamid in pome fruit of 0.3 and 0.2 mg/kg respectively, below the proposed Australian MRL of 0.7 mg/kg. The residue considered as the highest residue in pome fruits was 0.38 mg/kg and the supervised trial median was 0.09 mg/kg. It is noted that the proposed pome fruit MRL is at the same level as that currently established for apples.

The Australian residue definition is the same as that established in the EU and Japan. In Canada and the USA the residue definition also includes the TFNA-AM metabolite (4-trifluoromethylnicotinamide). In the available pome fruit residue trials the TFNA-AM metabolite was generally below the limit of detection, so this difference in residue definitions is not expected to be significant with respect to pears.

3 CONCLUSIONS

Ishihara Sangyo Kaisha, Ltd has applied for approval of a new use of Mainman 500 WG Insecticide containing flonicamid on pears. The proposed use pattern for pears is the same as that currently registered for apples. Comment is sought on the potential risk to trade in pears from the proposed use.