



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



TRADE ADVICE NOTICE

on Pyrimethanil in the product Philabuster 400 SC
Janssen Fungicide Suspension Concentrate

APVMA Product Number P63124

FEBRUARY 2012

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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 for the registration of **Philabuster** containing the existing active constituents imazalil and pyrimethanil 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 **19 March 2012** 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:

Contact Officer, Pesticides
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Phone: 02 6210 4748

Fax: 02 6210 4776

Email: pesticides@apvma.gov.au

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>

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 Janssen-Cilag Pty Limited for the registration of the product, Philabuster 400 SC Janssen Fungicide Suspension Concentrate, containing 200 g/L imazalil and 200 g/L pyrimethanil. The product is proposed for use on citrus to control post harvest storage decay. The proposed use requires establishment of an MRL for pyrimethanil in citrus. An MRL for imazalil on citrus is already established and application rates of imazalil are less than currently registered. Imazalil will not be considered further in this notice.

The potential for pyrimethanil residues in citrus to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus fruit are considered to be a major export commodity, as are animal commodities derived from livestock that may be fed citrus pulp. However, quantifiable residues are not expected to occur in animal commodities as a result of the proposed use and no changes are required to the pyrimethanil animal commodity MRLs which are established at *0.05 mg/kg for meat and offal and *0.01 mg/kg for milk. Further consideration of the risk to trade in animal commodities is not required.

2.2 Destination and value of exports

Australia exported \$136 million worth of citrus fruits such as oranges, mandarins, lemon, limes, grapefruit and other citrus in the 2010-2011 financial year. The major export markets and value of citrus exported to each country in the 2010-2011 financial year are shown below.

Table 1: Value of Australian citrus exports by destination

DESTINATION	VALUE, \$ MILLION
Japan	36.3
United States	22.5
Hong Kong	18.6
Indonesia	9.0
New Zealand	7.9
Singapore	6.7
United Arab Emirates	5.7
Canada	5.0
Malaysia	4.1
Taiwan	3.7
India	1.6
Other	14.9
TOTAL	136.0

Source of data: Australian Bureau of Statistics

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for Philabuster 400 SC Janssen Fungicide Suspension Concentrate is summarised below.

Table 2: Proposed use pattern

Philabuster 400 SC Janssen Fungicide Suspension Concentrate (200 g/L imazalil and 200 g/L pyrimethanil)

CROP	PEST	RATE	CRITICAL COMMENTS
Citrus	Blue mold (<i>Penicillium italicum</i>), Green mould (<i>Penicillium digitatum</i>)	Apply dilution to citrus fruit preferably within 24 hours of harvest. Ensure good coverage. Use the higher rates when previous disease history is high.	
		Bulk dip, flood etc 200 mL/100 L water (0.4 g imazalil/L + 0.4 g pyrimethanil/L)	Use as bulk dip, flood or spray before waxing. Treatment time should be at least 30 seconds and not greater than 2 minutes. 1L of solution will treat approximately 200-250 kg of fruit. 200 mL/100 L of water provides 400 ppm of each active constituent.
		Non-return spray 0.5-1.0 L/100 L water (2 g imazalil/L + 2 g pyrimethanil/L)	Use as a non-return spray before waxing. 1L of solution will treat 1000-1300 kg of fruit. 1L/100L of water provides 2000 ppm of each active constituent.
		In wax treatment 1.0-1.5 L/100 L wax (3 g imazalil/L + 3 g pyrimethanil/L)	Apply in wax (without further dilution in water) using conventional waxing equipment. Do not 'top up' wax. 1L of wax will treat 1000 kg of fruit. 1.5 L/100L of wax provides 3000 ppm of each active constituent.

WITHHOLDING PERIOD

Not required when used as directed.

2.4 Results from residues trials presented to the APVMA

Pyrimethanil residues in citrus fruits (grapefruit, lemon, mandarin, orange, tangelo and tangerine) treated at or around the proposed application concentration ($\pm 25\%$) for all three application methods (dip n=12, non-return spray n=2, wax n=6) in rank order are: 0.2, 0.90, 0.93, 0.97, 1.0, 1.0, 1.0, 1.1, 1.3, 1.3, 1.4, 1.4, 1.7, 1.9, 2.1, 2.2, 2.6, 2.7, 2.9 and 3.2 mg/kg. The STMR for pyrimethanil residues was 1.3 mg/kg. The highest pyrimethanil residue was 3.2 mg/kg after a single application of pyrimethanil at the proposed application concentration (1.25 x). A pyrimethanil citrus MRL of 7 mg/kg is proposed. Based on the HR of 3.2 mg/kg and the highest calculated dried citrus pulp processing factor of 0.51 mg/kg, residues of 1.6 mg/kg are estimated for citrus pulp, dry. A Table 4 entry of 3 mg/kg for citrus pulp is proposed.

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. Pyrimethanil has been considered by Codex.

The following overseas MRLs / tolerances have been established pyrimethanil on citrus.

Table 3: Overseas residue MRLs/tolerances for pyrimethanil on citrus

	CODEX	AUSTRALIA	US	CANADA	EU	JAPAN	KOREA	TAIWAN
Citrus fruits	7(Po)	7†	10		10			7
Orange				10	10	15		
Mandarin					10		1	
Lemon			11	10	10	15		7
Lime				10	10	15		
Grapefruit				10	10	15		7
Other citrus fruit					10	15		
Residues definition	parent	parent	parent +met.	parent+met.	parent	parent		

Po accommodates post harvest treatment; † Proposed

Residue definitions:

US= tolerances are established on the parent product in raw agricultural commodities, and tolerances are for the combined parent residue and its metabolite 4-[4,6-dimethyl-2-pyrimidinyl)amino]phenol in or on animal commodities. In milk parent + 4,6-dimethyl-2-(phenylamino)-5-pyrimidinol.

Canada= All food crops, parent. All livestock commodities except milk= parent+ phenol, 4-[(4,6-dimethyl-2-pyrimidinyl)amino]. In milk= parent+5-pyrimidinol, 4,6-dimethyl-2-(phenylamino).

2.6 Current and proposed Australian MRLs for pyrimethanil

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

Table 4: Current relevant entries in the MRL Standard - Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (MG/KG)
PYRIMETHANIL		
MO 0105	Edible offal (mammalian)	*0.05
MM 0095	Meat (mammalian)	*0.05
ML 0106	Milks	*0.01

MRL Standard: TABLE 3

COMPOUND	RESIDUE
Pyrimethanil	Pyrimethanil

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (MG/KG)
PYRIMETHANIL		
AB 0269	Grape pomace, dry	40
	Pome fruit pomace, dry	0.3

The following changes are proposed to Australian pyrimethanil MRLs:

Table 5: Proposed changes to the MRL Standard - Table1 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (MG/KG)
PYRIMETHANIL		
ADD:		
FC 0001	Citrus fruits	7

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (MG/KG)
PYRIMETHANIL		
ADD:		
AB 0001	Citrus pulp, dry	3

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of pyrimethanil 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 proposed Australian MRL for citrus at 7 mg/kg is at the same level as that set by Codex. The major export destinations for Australian citrus which have established residue limits (Japan, USA, Canada and the EU) have MRLs greater than 7 mg/kg. The risk to Australian trade in citrus as a result of the proposed use of pyrimethanil is expected to be low.

3 CONCLUSIONS

It is proposed to establish an MRL for pyrimethanil on citrus. Comment is sought on the potential for pyrimethanil in Philabuster 400 SC Janssen Fungicide Suspension Concentrate to prejudice Australian trade when it is used on citrus for the control of post harvest decay.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at (02) 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609

Office hours: 9.00am–5.00pm (EST) Monday to Friday