Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on pyrimethanil in the product Penbotec 400 SC Fungicide for use on citrus and pome fruits

APVMA product number 88115

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Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

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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.

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 Trade Advice Notice 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 Penbotec 400 SC Fungicide 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 **26 May 2020** 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)
- submission date.

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

GPO Box 3262

Sydney NSW 2001

Phone: +61 2 6770 2300

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.

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The APVMA has before it an application from Janssen Pharmaceutica N.V for the registration of Penbotec 400 SC Fungicide for use of pyrimethanil on citrus and pome fruits as a post-harvest treatment.

Philabuster 200 SC Janssen Fungicide Suspension Concentrate (200 g/L imazalil and 200 g/L pyrimethanil) is registered for use on citrus with use patterns involving one application as a bulk dip/spray (0.4 g ai/L), a non-return spray (1–2 g ai/L) or a subsequent wax application (2–3 g ai/L). The proposed use of Penbotec 400 SC Fungicide on citrus is an increase on of the bulk dip/spray from 0.4 g au/L to 1 g ai/L and the wax application from 3 g ai/L to 4 g ai/L. The non-return spray at 2 g ai/L remains the same at 2 g ai/L.

This trade advice notice will discuss the potential risk to international trade for citrus fruit associated with the proposed new uses which requires an increase to the established MRL.

While a new use of pyrimethanil in pome fruit as a dip, drench or flood at 0.5 g ai/L is proposed, a fogging use is currently registered. The pome fruits MRL at 15 mg/kg is not increasing and an MRL at 5 mg/kg (based on the results of 21 trials which found a STMR and HR of 0.88 and 3.6 mg/kg respectively) would have been appropriate for this proposed use pattern. Therefore the potential risk to international trade[2] is lower than that previously considered acceptable and no further trade consideration is require for the proposed use on apples and pears.

As the mammalian dietary burden through consumption of citrus pulp derived from treated citrus fruit should be no greater than previously considered, noting the current citrus pulp MRL at 3 mg/kg remains appropriate for this use. No changes are required to the established animal commodity MRLs for pyrimethanil. The risk to trade in animal commodities is unchanged and does not require further consideration.

[2] Trade Advice Notice on pyrimethanil in the product Campbell ecoFOG-160 PYR Fungicide for use on apples and pears: apvma.gov.au/node/55971

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus is considered to be major export commodities[3], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated pyrimethanil. Residues in these commodities resulting from the use of Penbotec 400 SC Fungicide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Australian exports of citrus fruit totalled approximately 214 kt, 218 kt and 258 kt (value $297 million, $332 million and $429 million) in 2015–16, 2016–17 and 2017–18 respectively[4].

Table 1: Major destinations for Australian citrus fruit exports in 2017–18

Citrus crop	Major destinations
Oranges	China, Japan, Hong Kong, Malaysia, Singapore
Mandarins	China, Thailand, Hong Kong, New Zealand, USA
Grapefruit	Japan, Canada, China, New Zealand, Philippines
Lemon	Indonesia, Philippines, Malaysia, Singapore, Canada

2.3 Proposed Australian use-pattern

Table 2: Proposed use pattern

Crop	Pest	Rate/concentration	Critical comments
Citrus	Post harvest storage decays *Penicillium italicum* (Blue mould) *Penicillium digitatum*	Apply dilution to citrus fruit preferably within 24 hours of harvest. Ensure good coverage.	
		Bulk dip, flood etc 250 mL/100 L water (1 g ai/L)	Use as bulk dip, drench or flood. Treatment time should be at least 30 seconds and not greater than 2 minutes. 250 mL/100 L of water provides 1000 ppm of active constituent.
		Non-return spray 0.5L/100 L water (2 g ai/L)	Use as a non-return spray. 0.5 L/100 L of water provides 2000 ppm of active constituent.

[3] APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

[4] Australian Horticulture Statistics Handbook: Fruit 2017–18

Crop	Pest	Rate/concentration	Critical comments
	(Green mould)	**In wax treatment** 1 L/100 L wax (4 g ai/L)	Apply in wax (without further dilution in water) using conventional waxing equipment. Do not 'top up' wax. 1 L/100L of wax provides 4000 ppm of active constituent.
Pome fruits	Post harvest storage decays *Penicillium expansum* (Blue mould) *Botrytis cinerea* (Grey mould) *Phlyctema vagabunda and Neofabraea malicorticis (vis perennans*) (Target rot and spot diseases)	**Bulk dip, drench, flood etc** 125 mL/100 L water (0.5 g ai/L)	Use as bulk dip, drench or flood. Treatment time should be at least 30 seconds and not greater than 2 minutes. 125 mL/100 L of water provides 500 ppm of active constituent.

Penbotec 400 SC Fungicide (400 g/L pyrimethanil).

Withholding periods:

Harvest: Not required when used as directed.

Restraints: DO NOT apply more than one application of PENBOTEC 400 SC per fruit.

2.4 Results from residues trials presented to the APVMA

The proposed use pattern for citrus is a maximum of one application of either a bulk dip, drench or flood at 1 g ai/L, non-return spray at 2 g ai/L or In wax treatment at 4 g ai/100L wax with a harvest WHP of 'Not required when used as directed'. In support of the application the applicant has provided GLP trials of the three proposed treatment methods from Australia and overseas on orange, mandarin, lemon and grapefruit.

The residue results of citrus trials (orange, mandarin, lemon and grapefruit) treated as a bulk dip/flood application are: 0.9, 1.4, 1.5, 1.7, 1.8, 1.8, 2.6, 2.6, 2.6, 2.8, 2.8, 2.8, 3.1, 3.1, 3.2, 3.3 and 3.6 mg/kg (n=17). The OECD MRL calculator recommends an MRL of 8 based on this dataset. The STMR for bulk dip/flood application is therefore 2.6 mg/kg.

The residue results of citrus trials (orange lemon and mandarin), treated as a non-return spray application are: 0.11, 0.17, 0.29, 0.37, 0.69, 0.78, 1.2, 2.0, 2.1, 2.4, 2.6, 3.1 and 3.5 mg/kg (n=13). The OECD MRL calculator recommends an MRL of 7 based on this dataset. The STMR for a non-return spray application is therefore 1.2 mg/kg. It is noted the proposed non-return spray application (2 g ai/L) is not increased from the rate currently registered (Philabuster 200 SC Janssen Fungicide Suspension Concentrate).

The residue results of citrus trials (orange lemon and mandarin) treated as a wax application (4 g ai/L) are: 1.3, 1.8, 3.2, 3.5, 4.3 and 5.1 mg/kg. It is noted that the two highest observations were from Australian trials. The OECD MRL calculator recommends an MRL of 10 based on this dataset. The STMR for a wax application is therefore 3.4 mg/kg.

Residues found in spray treated fruit are similar to those seen in fruit dipped in solution, however residues in the wax application are higher. The residues from the wax treatment (4 g ai/L) will be used for the MRL estimation as it is the critical GAP. The OECD MRL calculator recommends an MRL of 10 mg/kg. It is recommended the citrus MRL increase from 7 mg/kg to 10 mg/kg. The harvest WHP of 'Not required when used as directed is supported. The HR-P for citrus pulp was estimated at 2.6 mg/kg and the currently established MRL for citrus pulp at 3 mg/kg remains appropriate.

2.5 Overseas registration and approved label instructions

The applicant has not provided details of overseas registrations.

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

Table 3: Codex MRL—Current and proposed Australian and overseas MRLs/tolerances for pyrimethanil

Commodity	Tolerance for residues arising from the use of pyrimethanil: (mg/kg)					
	Australia*	EU[5]	Japan[6]	Codex[7]	USA[8]	China
Residue definition	Pyrimethanil	Pyrimethanil	Pyrimethanil (for crops)	Pyrimethanil (for plant commodities).	Pyrimethanil (for plant commodities)	Pyrimethanil

[5] ec.europa.eu

[6] m5.ws001.squarestart.ne.jp

[7] codexalimentarius.net

[8] ecfr.gov

Commodity	Tolerance for residues arising from the use of pyrimethanil: (mg/kg)					
	Australia*	EU[5]	Japan[6]	Codex[7]	USA[8]	China
Citrus	10 (proposed) [currently is 7]	8	10	7	10	7

**A MRL at 10 mg/kg for citrus (excluding lemon) and 11 (lemon) mg/kg is established for pyrimethanil in Schedule 20 of the Australian Food Standards Code.*

2.7 Current and proposed Australian MRLs for pyrimethanil

Table 4: Current MRL Standard—Table1

COMPOUND		FOOD	MRL (mg/kg)
PYRIMETHANIL			
FC	0001	Citrus fruits	7
MO	0105	Edible offal (mammalian)	*0.05
MO	0095	Meat (mammalian)	*0.05
MO	0106	Milks	*0.01

Table 5: Proposed MRL Standard—Table1

COMPOUND		FOOD	MRL (mg/kg)
PYRIMETHANIL			
DELETE:			
FC	0001	Citrus fruits	7
ADD:			
FC	0001	Citrus fruits	10

2.8 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 MRL of 10 mg/kg for pyrimethanil on citrus is the same as those established by Japan and the USA. It is noted the Codex, Chinese and EU MRLs at 7 or 8 mg/kg are lower than the proposed MRL, but are higher than the HR (5.1 mg/kg) found in the submitted trials. The risk to trade is considered to be low.

3 CONCLUSION

Janssen Pharmaceutica N.V have made an application to register the use of Penbotec 400 SC Fungicide on citrus, requiring an increase to the citrus fruits MRL from 7 mg/kg to 10 mg/kg.

Comment is sought on the potential for Penbotec 400 SC Fungicide to prejudice Australian trade when used on citrus according to the proposed label directions.