



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



Trade advice notice

on Pyrimethanil in the product Campbell ecoFOG-160 PYR Fungicide for use on
apples and pears

APVMA product number 87843

OCTOBER 2019

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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 **Campbell ecoFOG-160 PYR 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 **Wednesday 13 November 2019** 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
Risk Assessment Capability
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: 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 Colin Campbell (Chemicals) Pty Ltd to register the use of Campbell ecoFOG-160 PYR Fungicide as a post-harvest treatment for apples and pears. The product contains 160 g/L Pyrimethanil as its active ingredient.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Pome fruits are considered to be major export commodities, 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 Campbell ecoFOG-160 PYR Fungicide may have the potential to unduly prejudice trade.

As no changes are required to the current animal commodity MRLs for pyrimethanil which are established at the method LOQ, the risk to trade in animal commodities does not require further consideration.

2.2 Destination and value of exports

Australia typically exports between 2000–5000 tonnes of apples per year (Australian Horticulture Statistics Handbook 2017–18). For the year ending 2018, Australia exported 5060 tonnes. The main markets were Papua New Guinea, the United Kingdom, Italy, Sri Lanka and Hong Kong.

For the year ending 2018, Australia exported 12 467 tonnes of pears. The main markets were New Zealand, Indonesia, Canada, Singapore and India.

2.3 Proposed Australian use pattern

Table 1: Proposed use pattern

Campbell ecoFOG-160 PYR Fungicide (160 g/L Pyrimethanil)

Crop	Pest	Rate	Critical Comments
Apples and Pears	Moulds caused by <i>Penicillium</i> spp , <i>Botrytis</i> spp., <i>Neofabrea</i> spp	30–60g per tonne of fruit (4.8–9.6 g ai/tonne)	Apply to fruit as soon after harvest as possible and no more than 15 days after harvest, prior to placing in storage. Treat only dry fruit as received from the field. Before treatment, protect fruit in bins at the top of each stack with plastic liners, cardboard or Kraft paper sheets. Also protect fruit directly in front of the fogging equipment with liners or sheets from top to bottom. When treating rooms that are less than 75% full, calculate the dosage of eco-FOG 160 by adding a tonnage value of 20% of the empty volume to the real tonnage in the storage room. Refer to GENERAL INSTRUCTION section for technique of operation of the electrofogger.

Restrains:

APPLY only with an electrofog machine approved by Colin Campbell (Chemicals) Pty Ltd.

DO NOT apply more than one application of ecoFOG-160 PYR.

Withholding period: Not required when used as directed.

2.4 Results from residues trials presented to the APVMA

In the available GLP trials, highest residues in apples and pears after treatment at 8–12.8 g ai/tonne (0.83–1.3x proposed) were 0.88, 0.95, 1.1, 1.6, 1.6, 1.7, 1.8, 2.3 and 4.0 mg/kg.

In the supporting non-GLP trials, highest residues in apples and pears after application at 9.6 g ai/tonne (1x proposed) were 1.4 and 3.5 mg/kg. After application at 6.4 g ai/tonne (0.67x proposed) highest residues were 2.5, 4.0, 5.0, 5.3 and 6.3 mg/kg. After application at 4.8 g ai/tonne (0.5x proposed) highest residues were 3.0, 3.6, 7.8 and 7.9 mg/kg.

In European trials summarised by the 2007 JMPR highest residues in apples and pears after treatment at 7.2–8.0 g ai/ton (0.75–0.83x) were 1.0, 1.1, 1.4, 1.4, 1.5, 1.6, 1.6, 1.8 and 3.5 mg/kg. The 2013 JMPR considered additional data for a fogging treatment matching the EU GAP of 5.6–8 kg ai/1000 kg fruit with residues of 4.9, 6.4 and 7.1 mg/kg. It is noted that the Codex MRL of 15 mg/kg was based on this data.

Based on the GLP dataset at the 1x treatment rate of 9.6 g ai/tonne, the OECD calculator recommends an MRL of 6 mg/kg. However, one of the GLP trials at approximately 0.5x the proposed rate showed a residue of 3.9 mg/kg or 7.8 mg/kg when scaled for application rate and the non-GLP trials often showed higher residues (HR = 7.9 mg/kg after application at 0.5x proposed maximum rate). An MRL of 15 mg/kg for FP 0009 Pome fruits is supported.

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 relevant Codex CXLs and overseas MRLs have been established for Pyrimethanil.

Table 2: Overseas MRLs

Commodity	Tolerance for residues arising from the use of pyrimethanil (mg/kg)					
	Australia	EU	Japan	Codex	Canada	USA
Residue Definition	Pyrimethanil	Pyrimethanil	Pyrimethanil (for crops)	Pyrimethanil (for plant commodities)	4,6-dimethyl-N-phenyl-2-pyrimidinamine = parent (for all food crops)	Pyrimethanil (for plant commodities)
Pome fruits	T15 (current) ^a 15 (proposed)	15	14 (Apple, Pear, Quince) 1 (Japanese pear)	15	15 (Apples, pears)	15

^aNote: a permanent MRL of 15 mg/kg is established for pyrimethanil on pome fruit in schedule 20 of the Food standards code.

2.6 Current and proposed Australian MRLs for Pyrimethanil

Table 3: Current MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
PYRIMETHANIL		
MO 0105	Edible offal (mammalian)	*0.05
MM 0095	Meat (mammalian)	*0.05
ML 0106	Milks	*0.01
FP 0009	Pome fruits	T15

Table 4: Proposed MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
PYRIMETHANIL		
DELETE:		
FP 0009	Pome fruits	T15
ADD:		
FP 0009	Pome fruits	15

Table 5: Proposed MRL Standard—Table4

COMPOUND	Animal Feed Commodity	MRL (mg/kg)
PYRIMETHANIL		
DELETE:		
	Pome fruit pomace, dry	T100
ADD:		
	Pome fruit pomace, dry	50

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 MRL of 15 mg/kg for pyrimethanil on pome fruits is the same as those established by Codex and also in the EU and North America. It is also noted that a permanent MRL at 15 mg/kg is established for pyrimethanil in Schedule 20 of the Australian Food Standards Code, and given that this is a post-harvest treatment knowledge of such treatment should be well known to the supply chain. The risk to trade is considered to be low based on overseas tolerances.

3 CONCLUSION

Colin Campbell (Chemicals) Pty Ltd have made an application to register Campbell ecoFOG-160 PYR Fungicide containing pyrimethanil as its active ingredient. The product is proposed for the post-harvest treatment of apples and pears, requiring the establishment of a permanent MRL at 15 mg/kg for these commodities.

Comment is sought on the potential for Campbell ecoFOG-160 PYR Fungicide to prejudice Australian trade when used on pome fruit according to the proposed label directions.