



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



TRADE ADVICE NOTICE

on Propiconazole in the product Chairman Fungicide (80887)

FEBRUARY 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, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, 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 the APVMA's Regulatory Guidelines.

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 regarding the proposed registration of Chairman Fungicide. 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 11 March 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

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

Symonston ACT 2609

Phone: +61 2 6210 4701

Email: enquiries@apvma.gov.au

Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained via the contact details provided above.

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 Syngenta Australia Pty Ltd to register the new product Chairman Fungicide, which contains fludioxonil and propiconazole. The product is for post-harvest treatment of citrus fruit against blue mould, green mould and sour rot. Residues of fludioxonil are expected to be lower than those resulting from use of currently registered products, and no changes to fludioxonil MRLs are proposed. Fludioxonil will not be discussed further.

The potential for propiconazole residues arising from the proposed use to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus fruit, is considered to be a major export commodity², as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated citrus fruits.

2.2 Destination and value of exports

In 2014–15, Australia exported 107 kt of Navel oranges, (\$125m), 13.5 kt of Valencia oranges (\$13m), 31.6 kt of mandarins (\$55m), 2.7 kt of lemons and limes (\$6.1m) and 0.2 kt of grapefruit (\$0.3m) (Australian Commodity Statistics 2015³). Information provided by the applicant sourced from the UN Comtrade Database indicates that major export destinations for Australian citrus fruit between 2010 and 2013 were Japan, Hong Kong, the USA, Malaysia, Singapore, Indonesia, United Arab Emirates, New Zealand, China, Canada, and Thailand.

The significant export markets for animal commodities are defined in Part 5B of the Data Guidelines.

2.3 Proposed Australian use-pattern

Chairman Fungicide (240 g/L fludioxonil and 102.5 g/L propiconazole).

CROP	PEST	RATE	CRITICAL COMMENTS
Citrus (post-harvest)	Blue mould (<i>Penicillium italicum</i>) Green mould (<i>Penicillium digitatum</i>) Sour rot (<i>Galactomyces citri-auranti</i>)	Dip and high volume spray: 250 mL per 100 L water (600 mg fludioxonil + 256 mg propiconazole per L)	Apply as a dip, drench or flood spray. Ensure fruit is immersed in dip or exposed to solution for a minimum of 30 seconds. Ensure thorough and even coverage of all surfaces of the fruit.

² APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B) (www.apvma.gov.au/node/1017)

³ *Agricultural Commodity Statistics 2015*, Australian Bureau of Agricultural and Resource Economics and Sciences, Department of Agriculture and Water Resources, Australian Government, December 2015

2.4 Results from residues trials presented to the APVMA

Citrus fruits

Residue data were provided from post-harvest trials conducted in the USA for propiconazole in citrus fruit.

After 2 × ~480 mg ai/L (ppm) dip applications (2× proposed dip concentration) to oranges, mandarins, grapefruit, and lemons post-harvest, residues of propiconazole in the fruit were 0.93, 0.96, 1.4, 2.3 (2), 2.4, 2.5 (2), 3.2, 3.4, 4.9, and 5.7 mg/kg (STMR = 2.45 mg/kg).

After 2 spray applications at 1.6–1.7 g ai/1000 kg fruit (8× proposed spray solution concentration) to post-harvest oranges, mandarins, grapefruit and lemons, residues of propiconazole were 0.94, 1.1 (3), 1.4, 1.5, and 2.3 mg/kg (STMR = 1.25 mg/kg). The spray concentration used in these trials was 1918-2093 ppm.

A permanent MRL of 7 mg/kg is proposed for propiconazole in citrus fruit to replace the current temporary MRL at the same level. The proposed withholding period statement of 'not required when used as directed' is supported.

Processed citrus commodities

Residues of propiconazole are not expected to concentrate in citrus fruit juice.

Using the processing factor of 1.4 for dried citrus pulp, STMR-P and HR-P values of 3.4 and 8.0 mg/kg were calculated from the citrus fruit data listed above.

A permanent MRL of 10 mg/kg, replacing the current temporary limit at the same level, is proposed for propiconazole in citrus pulp, dry.

Animal commodities

Citrus pulp that may be derived from citrus fruit treated from the proposed use may be fed to mammalian livestock.

At the 15 ppm feeding level in a lactating cattle feeding study, only liver contained finite propiconazole residues, at a maximum of 0.14 mg/kg. Scaling for the maximum feeding level for cattle of 5.0 ppm (based on a diet of 30% citrus pulp and 70% ryegrass) gives a liver residue of 0.05 mg/kg, well below the current MRL of 1 mg/kg for propiconazole in edible offal (mammalian). Cattle fed dried citrus pulp as the only feed component containing residues of propiconazole would have a dietary burden no greater than 1.1 ppm. Scaling from the feeding study for animals consuming 1.1 ppm propiconazole would give an expected liver residue of 0.01 mg/kg propiconazole.

Residues in milk and other tissues besides liver were below LOQ at the 15 ppm feeding level (<0.05 mg/kg for tissues and <0.01 mg/kg for milk), therefore residues in milk and tissues other than liver of livestock consuming 5.0 ppm propiconazole would not exceed the LOQ, or the current MRLs.

Existing mammalian animal commodity MRLs for propiconazole remain appropriate.

Dried citrus pulp is not commonly fed to poultry; therefore the proposed new use pattern is not expected to increase the dietary burden of propiconazole in poultry. Existing poultry commodity MRLs remain appropriate.

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. The following relevant Codex and overseas country MRLs have been established for propiconazole.

Table 1: Comparison of proposed propiconazole MRL in citrus fruit with overseas MRLs

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF PROPICONAZOLE (mg/kg)					
	AUSTRALIA	EU ⁴	JAPAN ⁵	CODEX ⁶	CANADA ⁷	USA ⁸
Residue Definition	Propiconazole	Propiconazole	Propiconazole	For compliance with MRL for plant and animal commodities: propiconazole For dietary risk assessment for plant and animal commodities: Propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole	Propiconazole	Residues convertible to 2,4-dichlorobenzoic acid, expressed as the stoichiometric equivalent of propiconazole
Citrus fruit	T7 (7 proposed)	6	0.05	-	8	8
Oranges, Sweet, Sour (including Orange-like hybrids): several cultivars	-	-	-	9	-	-

⁴ ec.europa.eu⁵ www.m5.ws001.squarestart.ne.jp⁶ www.codexalimentarius.net⁷ www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/food-nourriture/mrl-lmr-eng.php⁸ www.ecfr.gov It is noted that the US residue definition is a complex definition based on a common moiety method. For post-harvest treatments, it is not expected that residues would be substantially higher when expressed according to the complex residue definition.

2.6 Current and proposed Australian MRLs for propiconazole

The MRL standard contains the following relevant entries:

A full listing of MRLs can be found at www.apvma.gov.au/node/10806.

Table 2: Current entries in the MRL Standard

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
Propiconazole		
FC 0001	Citrus fruits	T7
MO 0105	Edible offal [mammalian]	1
MM 0095	Meat [mammalian]	0.1
ML 0106	Milks	*0.01

MRL STANDARD: TABLE 3

COMPOUND	RESIDUE
Propiconazole	Propiconazole

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Propiconazole		
AB 0001	Citrus pulp, dry	T10

The following changes are proposed to Australian MRL standard:

Table 3: Proposed changes to the MRL Standard—Table 1

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
Propiconazole		
DELETE:		
FC 0001	Citrus fruits	T7
ADD:		
FC 0001	Citrus fruits	7

Table 4: Proposed changes to the MRL Standard—Table 4

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Propiconazole		
DELETE:		
AB 0001	Citrus pulp, dry	T10
ADD:		
AB 0001	Citrus pulp, dry	10

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of propiconazole 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.

No changes have been recommended to existing propiconazole MRLs for mammalian or poultry commodities. Residues are not expected to be higher than those resulting from currently registered use patterns. Therefore the risk to Australian trade associated with propiconazole residues in animal commodities arising from the proposed use has not changed.

The draft label includes the following advice regarding export of treated fruit:

Export of treated produce: Growers should note that maximum residues limits (MRLs) or import tolerances may not exist in all markets for citrus treated with CHAIRMAN. If you are growing citrus for export, please check with Syngenta, your industry body and/or your export organisation, for the latest information on MRLs and import tolerances before using CHAIRMAN.

In relation to major export markets for citrus fruit, it is noted that residues of propiconazole are expected to be below the Canadian and US MRLs for citrus fruit, and below the Codex MRL for oranges, while New Zealand accepts Australian MRLs under the Trans Tasman Mutual Recognition Agreement.

Residues in treated fruit are likely to exceed the Japanese MRL for propiconazole, while no Codex MRL is established for citrus fruit other than oranges. The proposed use pattern for propiconazole in citrus fruit may therefore result in some risk to Australian exports, particularly to Japan for citrus fruit generally, or to markets which accept Codex MRLs for citrus fruit other than oranges.

3 CONCLUSIONS

Syngenta Australia Pty Ltd has made an application to register *Chairman Fungicide* containing 240 g/L fludioxonil and 102.5 g/L propiconazole as the active constituents for use in citrus fruit post-harvest.

Residues of fludioxonil are expected to be lower than those resulting from existing registered use patterns, and no changes to fludioxonil MRLs are required.

The proposed use will require the establishment of an MRL of 7 mg/kg for propiconazole in citrus fruit to replace the current temporary MRL of 7 mg/kg. An MRL of 10 mg/kg for propiconazole in dried citrus pulp will replace the current temporary limit at 10 mg/kg. No changes to animal commodity MRLs, or to the fludioxonil MRLs for citrus fruit, are proposed.

The applicant has proposed including the following statement on the label:

Export of treated produce: Growers should note that maximum residues limits (MRLs) or import tolerances may not exist in all markets for citrus treated with CHAIRMAN. If you are growing citrus for export, please check with Syngenta, your industry body and/or your export organisation, for the latest information on MRLs and import tolerances before using CHAIRMAN.

The APVMA proposing to consider that the risk to trade associated with the proposed new use of propiconazole on citrus fruit is manageable under established industry systems, Comment is sought on this proposed decision.