Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Prothioconazole in the Product Brumby 480 SC Fungicide

APVMA Product Number P68332

SEPTEMBER 2013

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Comments and enquiries regarding copyright:

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +612 6210 4701
Email: communications@apvma.gov.au.

This publication is available from the APVMA website: www.apvma.gov.au.

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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 Ageing, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), 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 publication *Ag MORAG: Manual of Requirements and 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 as to whether the application to register the new agricultural product **Brumby 480 SC Fungicide** containing the existing active constituent prothioconazole 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 **16 October 2013** 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 Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +612 6210 4748
Fax: +612 6210 4776
Email: pesticides@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 Bayer CropScience Pty Ltd to register *Brumby 480 SC Fungicide* containing 480 g/L prothioconazole for use by foliar application in peanuts for control of early leaf spot, late leaf spot and rust. The new proposed use requires establishment of peanut and peanut fodder MRLs and an increase to prothioconazole MRLs in mammalian edible offal and meat (in the fat).

The potential for prothioconazole residues in animal commodities arising from the proposed use to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Commodities of animal origin are considered to be a major export commodity,[2] such as meat, offal and dairy products, which may be derived from livestock fed feed containing residues arising from the proposed use.

2.2 Destination and value of exports

The significant export markets for animal commodities are defined in Part 5B of Ag MoRaG.

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Brumby 480 SC Fungicide* (480 g/L prothioconazole) in peanuts is summarised below.

Table 1: Proposed use pattern of *Brumby 480 SC Fungicide* (480 g/L prothioconazole)

CROP	PEST	RATE	CRITICAL COMMENTS
Peanuts (QLD, NSW, WA and NT only)	Early leaf spot, Late leaf spot, Rust	250–400 mL/ha (120–192 g ai/ha)	Begin spraying at 3-4 weeks after emergence. Repeat applications at 10–14 day intervals. Under high disease pressure and/or prolonged wet weather and/or heavy rains, use the high rate and shortest spray interval. In localities with frequent and persistent rainfall, or in irrigated crops, it is recommended that Brumby 480 SC Fungicide usage should be integrated with a base program of protectant fungicide applications for best control of leaf diseases. Make no more than four applications of Brumby per season. **Ground application** Ensure thorough coverage of foliage and apply in a spray volume of 150-400 L of water per hectare.

RESTRAINTS:

DO NOT apply if heavy rain is likely to cause surface runoff has been forecast within 48 hours.
DO NOT apply if soil is waterlogged.
DO NOT irrigate past the point of runoff for 48 hours after application to minimise surface runoff.

WITHHOLDING PERIODS:

Harvest: Do not harvest for 4 weeks after application.
Grazing: Do not graze or cut for stock food for 4 weeks after application.

[2] http://www.apvma.gov.au/morag_ag/vol_3/part_05b_trade.php

2.4 Results from residues trials presented to the APVMA

The proposed GAP for peanuts in Australia is 4 × 192 g ai/ha, with a WHP of 4 weeks for both harvest and grazing.

Peanut fodder

A series of twelve residue trials were conducted on peanuts in the USA during the 2000 growing season. At all trial sites, four applications of prothioconazole were made at a rate of 202 g ai/ha (1.05× the proposed rate) and a re-treatment interval of 14 ± 2 days. Residues of prothioconazole (sum of prothioconazole and prothioconazole-desthio, expressed as prothioconazole) in hay harvested 14 days after the last application were 1.45, 2.70, 3.30, 3.53, 3.64, 3.97, 4.52, 5.08, 5.34, 5.89, 6.35 and 7.08 mg/kg (dry weight basis).

A series of four trials were conducted in Australia during the 2011/2012 growing season. Residues of prothioconazole in peanut fodder collected 28 days after 4 × 192 g ai/ha late season foliar applications were 1.8, 2.0, 15, and 23 mg/kg on a dry weight basis.

The data package shows that an MRL of 30 mg/kg is appropriate for prothioconazole in peanut fodder, in conjunction with a 28-day grazing withholding period.

Animal Commodities

The maximum livestock dietary burden for cattle will be as a result of the consumption of treated peanut fodder with an estimated dietary burden of 14 ppm in the feed. The predicted residues in animal commodities derived from livestock fed treated feeds are summarised below.

Table 2: Predicted prothioconazole residues in tissues and milk

COMMODITY	PREDICTED MAXIMUM RESIDUE (mg/kg)	CURRENT MRL (mg/kg)	PROPOSED MRL (mg/kg)
Milk	<0.004	*0.004	*0.004
Kidney	0.094	0.1	0.2
Liver	0.15	0.1	0.2
Muscle	<0.01	*0.01 (in the fat)	0.02 (in the fat)
Fat	0.0097	*0.01	0.02

No depuration data were provided which would indicate the decline of residues in animal commodities after withdrawal from dosing.

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. Prothioconazole has been considered by Codex. The following relevant international MRLs have been established for prothioconazole:

Table 3: Comparison of prothioconazole MRLs (mg/kg) for animal commodities

		AUSTRALIA	CODEX	EU	JAPAN	USA
Residue definition (animal commodities)		Sum of prothioconazole, prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, and prothioconazole-4-hydroxy-desthio, expressed as prothioconazole.	Prothioconazole-desthio.	Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio.	Sum of prothioconazole, prothioconazole-desthio and glucronic acid conjugates of prothioconazole and prothioconazole-desthio, calculated as prothioconazole.	Prothioconazole, prothioconazole-desthio, and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent.
Meat (mammalian)	Meat (mammalian)	0.02 (fat) (proposed)	0.01			
	Cattle fat			0.05	0.1	0.1
	Sheep fat			0.05		0.1
	Other terrestrial mammals fat				0.1	
	Cattle meat			0.05	0.02	0.02
	Sheep meat			0.05		0.02
	Other terrestrial mammals muscle				0.02	
Milk	Milk	*0.004	*0.004	*0.01	0.02	0.02
Edible offal	Edible offal, mammalian	0.2 (proposed)	0.5			
	Cattle kidney			0.5	0.2	
	Sheep kidney			0.5		
	Other terrestrial mammals kidney				0.2	
	Cattle liver			0.5	0.2	
	Sheep liver			0.5		
	Other terrestrial mammals liver				0.2	
	Cattle mbyp (except liver)					0.2
	Sheep mbyp (except liver)					0.2

Note: animal commodity MRLs are not established for prothioconazole in China, Korea, Russia or Taiwan.

2.6 Current and proposed Australian MRLs for prothioconazole

Current relevant MRLs and the residue definition for prothioconazole are presented below. A full listing of MRLs can be found at 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)
PROTHIOCONAZOLE			
MO	0105	Edible offal (mammalian)	0.1
MM	0095	Meat (mammalian) [in the fat]	*0.01
ML	0106	Milks	*0.004

MRL Standard: TABLE 3

COMPOUND	RESIDUE
PROTHIOCONAZOLE	For commodities of plant origin: sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole. For commodities of animal origin: sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1*H*-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole.

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
PROTHIOCONAZOLE			
		Cereal forage and fodder	7
AL	0197	Peanut fodder	T10

The following changes are proposed to Australian prothioconazole MRLs:

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

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
PROTHIOCONAZOLE			
DELETE:			
MO	0105	Edible offal (mammalian)	0.1
MM	0095	Meat (mammalian) [in the fat]	*0.01
ADD:			
MO	0105	Edible offal (mammalian)	0.2
MM	0095	Meat (mammalian) [in the fat]	0.02

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
PROTHIOCONAZOLE			
DELETE:			
AL	0197	Peanut fodder	T10
ADD:			
AL	0197	Peanut fodder	30

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of prothioconazole 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 Australian prothioconazole residue definition for animal commodities (the sum of prothioconazole, prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, and prothioconazole-4-hydroxy-desthio) is different to that established in other export markets. The Codex residue definition is prothioconazole-desthio only, while the EU includes prothioconazole-desthio and glucuronide conjugates. Both the US and Japan include prothioconazole, prothioconazole-desthio and glucuronide conjugates. The analytical method used in the animal transfer studies for establishing the Australian MRLs involved an acid hydrolysis step, which would convert the glucuronide conjugates into prothioconazole and prothioconazole-desthio equivalents. Therefore, the Australian prothioconazole MRLs are directly comparable with those of the US, Japan and the EU.

The proposed use requires an increase in the prothioconazole MRL for mammalian meat (fat) to levels below those established in the EU, Japan and the USA. The Codex MRL is not established on a fat basis and residues in meat arising from the proposed use are not expected to exceed the codex MRL.

The proposed use requires an increase in the prothioconazole MRL for edible offal, mammalian to the same level as that established in Japan and the USA. The proposed MRL is lower than that currently established by Codex and the EU.

While several overseas countries have established prothioconazole MRLs in animal commodities, some key Australian export markets, notably Taiwan have not. As detectable residues may occur in animal commodities fed treated peanut fodder there is a potential risk to trade. Bayer CropScience Pty Ltd have indicated that Bayer are making application for prothioconazole import tolerances in Taiwan in late 2013. Bayer expect a decision on that application to be made in 2014.

3 CONCLUSIONS

It is proposed to increase the MRLs for prothioconazole in meat (mammalian) (in the fat) and edible offal (mammalian). Comment is sought on the potential for prothioconazole residues resulting from the proposed use of *Brumby 480 SC Fungicide* on peanuts to prejudice Australian trade when treated crops are fed to animals.