Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Cyprodinil and Fludioxonil in the Product Switch Fungicide

APVMA Product Number P51797

JULY 2013

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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 Aging, Office of Chemical Safety (OCS), Department of Sustainability Environment, Water, Population and Communities (DSEWPaC), 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 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 for registration of an 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.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found on the APVMA website: www.apvma.gov.au.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of *Switch Fungicide* containing the existing active constituents cyprodinil and fludioxonil 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, 7 August, 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:

Pesticide Contact Officer
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Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4748
Fax: +61 2 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: 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 Syngenta Crop Protection Ltd to vary the registration of the product, *Switch Fungicide* containing 375 g/kg cyprodinil and 250 g/kg fludioxonil, for use on capsicum, cucumber, leafy vegetables, lettuce, onions, green peas, green beans and strawberries for the control of various fungal diseases.

Meat and dairy products from animals that have been fed feeds containing residues arising from the use of Switch Fungicide on legume animal feeds may be exported. The potential for cyprodinil and fludioxonil residues in livestock feeds arising from the proposed use on green beans and green peas to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Commodities of animal origin, such as meat, offal and dairy products are considered major export commodities[1], which may be derived from livestock fed on treated legume animal feeds.

2.2 Destination and value of exports of Cereal and Oilseed Products

The significant export markets for Australian beef, sheep and pig meat and offals are listed in Appendix 3 of Part 5B of Ag MORAG. Australia exports significant quantities of dairy products (~$2275m in 2010–11) with the main markets being Japan and other countries in Asia.

2.3 Proposed Australian use-pattern

Table 1: Proposed use pattern

CROP	PEST	RATE	CRITICAL COMMENTS
Green beans	Grey Mould (Botrytis cinerea)	800 g to 1kg/ha (300–375g ai/ha cyprodinil and 200–250g ai/ha fludioxonil)	Apply SWITCH prior to or at the onset of disease development. Apply a second application 7 to 10 days later if conditions continue to remain favourable for disease development. Use 7 day spray interval and high rate under high disease pressure or where conditions are conducive for disease. DO NOT apply more than 2 consecutive applications of SWITCH with no more than 3 applications of SWITCH per crop.
	Sclerotinia (Sclerotinia minor and Sclerotinia sclerotiorium)		
Green peas Including Garden peas, Snow peas, and Sugar Snap peas	Grey Mould (Botrytis cinerea)	800 g to 1kg/ha (300–375g ai/ha cyprodinil and 200–250g ai/ha fludioxonil)	Apply SWITCH prior to or at the onset of disease development. Apply a second application 7 to 10 days later if conditions continue to remain favourable for disease development. Use 7 day spray interval and high rate under high disease pressure or where conditions are conducive for disease. DO NOT apply more than 2 applications of SWITCH per crop.
	Sclerotinia (Sclerotinia minor and Sclerotinia sclerotiorium)		

Withholding periods:

Harvest: Beans: DO NOT harvest for 7 days after application.
Harvest: Green peas: DO NOT harvest for 14 days after application.
Grazing: DO NOT cut or graze legume animal feeds for 7 days after application.

2.4 Results from residues trials presented to the APVMA

The proposed use involves up to 3 foliar applications of Switch Fungicide on green beans at a rate of 800 g–1 kg/ha with a re-treatment interval of 7 to 10 days. A harvest WHP of 7 days is proposed.

In support, the applicant has provided details of 6 residue trials conducted on green beans in Australia (4) and Spain (2) that involved using Switch Fungicide applied as 3 foliar applications with 7 to 10 day intervals at a rate approximately 1x the maximum proposed.

For peas (including garden peas, snow peas, sugar peas and snap peas), the proposed use involves up to 2 foliar applications of Switch Fungicide at a rate of 800g–1kg/ha with a re-treatment interval of 7 to 10 days. A harvest WHP of 14 days is proposed.

In support, the applicant has provided details of 5 residue trials conducted on green peas in Europe that involved using Switch Fungicide applied as 2 foliar applications with 10–14 day intervals at a rate approximately 1x the maximum proposed.

Legume Animal Feeds

Cyprodinil: At PHI of 7 days (proposed bean WHP), residues of cyprodinil on bean trash following 3 foliar applications at a rate 1x the maximum proposed were in rank order 3.4, 3.6, 5.7 and 7.5 mg/kg on a dry weight basis.

At PHI of 14 days (proposed green pea WHP), residues of cyprodinil on pea trash following 2 foliar applications at a rate approximately 1x the maximum proposed were 0.3 and 0.5 mg/kg on a dry weight basis.

At PHI of 14 days, residues of cyprodinil on bean trash following 3 foliar applications at a rate approximately 1x the maximum proposed were in rank order 2.2, 2.5, 3.9 and 4.5 mg/kg on a dry weight basis.

Based on the available information, a Table 4 entry of 15 mg/kg for legume animal feeds is considered appropriate for the proposed use pattern.

The MRLs and trade risk are considered on the basis of the proposed use based on bean at 7 day WHP.

Livestock dietary burdens of beef and dairy cattle resulting from the proposed use are estimated below:

Cyprodinil:

Beef cattle—500 kg bw, 20 kg DM/day

COMMODITY	% IN DIET	FEED INTAKE (KG)	RESIDUE, MG/KG	% DM	LIVESTOCK BURDEN		
					MG/ANIMAL	PPM IN THE FEED	MG/KG BW
Green bean forage	60	12	7.5 (HR)	100	90	4.5	0.18
Grape Pomace	20	4	0.41* (STMR)	20	8.2	0.41	0.016
Total Residues						4.91	

* Estimated from residues on grapes at the proposed GAP (Product no 51797)

Dairy cattle—500 kg bw, 20 kg DM/day

COMMODITY	% IN DIET	FEED INTAKE (KG)	RESIDUE, MG/KG	% DM	LIVESTOCK BURDEN		
					MG/ANIMAL	PPM IN THE FEED	MG/KG BW
Green bean forage	70	14	7.5 (HR)	100	105	5.2	0.21
Grape Pomace	20	4	0.41* (STMR)	20	8.2	0.41	0.016
Total Residues						5.61	

* Estimated from residues on grapes at the proposed GAP (Product no 51797)

No cyprodinil residues above the LOQ (0.01 mg/kg) were detected in edible animal commodities or in milk at a feeding level of up to 15 ppm. Thus based on the available information no changes to the current cyprodinil animal commodity MRLs are considered appropriate for the proposed use.

Fludioxonil:

At PHI of 7 days (proposed bean WHP), residues of fludioxonil on bean trash following 3 foliar applications at a rate 1x the maximum proposed were in rank order 11, 13, 16 and 22 mg/kg on a dry weight basis.

At PHI of 14 days (proposed green pea WHP), residues of fludioxonil on pea trash following 2 foliar applications at a rate approximately 1x the maximum proposed were 0.3 (2) mg/kg on a dry weight basis.

At PHI of 14 days, residues of fludioxonil on bean trash following 3 foliar applications at a rate approximately 1x the maximum proposed were in rank order 10, 13, 15 and 17 mg/kg on a dry weight basis.

Based on the available information, a Table 4 fludioxonil entry of 30 mg/kg for legume animal feeds is considered appropriate for the proposed use pattern.

Livestock burdens resulting from the proposed use are estimated here.

Fludioxonil:

Beef cattle—500 kg bw, 20 kg DM/day

COMMODITY	% IN DIET	FEED INTAKE (KG)	RESIDUE, MG/KG	% DM	LIVESTOCK BURDEN		
					MG/ANIMAL	PPM IN THE FEED	MG/KG BW
Green bean forage	60	12	22 (HR)	100	264	13.2	0.528
Apple pomace#	20	4	6.3 (STMR-P)	40	63	3.15	0.126
Total Residues						16.35	

Other sources of fludioxonil considered at the time of evaluation of 63391/45488.

Dairy cattle—500 kg bw, 20 kg DM/day

COMMODITY	% IN THE DIET	FEED INTAKE (KG)	RESIDUE, MG/KG	% DM	LIVESTOCK BURDEN		
					MG/KG	PPM IN THE FEED	MG/KG BW
Green bean forage	70	14	22 (HR)	100	308	15.4	0.616
Apple pomace#	20	4	6.3 (STMR-P)	40	63	3.15	0.126
Total Residues						18.55	

Other sources of fludioxonil considered at the time of evaluation of 63391/45488.

A new fludioxonil animal transfer study was provided with this application to estimate the level of residues in animal tissues and milk. Dairy cows (3 per feeding level, 1 control) were dosed a nominal rates of 0, 20 or 100 ppm in the feed for 28 days. Milk from the 20 ppm level was analysed for residues throughout the dosing period and animal tissues (muscle, liver, kidney and fat) were analysed for residues after 28 days of dosing. Fludioxonil residues in milk plateaued at 3 day and ranged from 0.01 to 0.03 mg/kg over the 28 day feeding study. Fludioxonil residues were <0.01 mg/kg in muscle and ranged from 0.03–0.08 mg/kg, 0.04–0.08 mg/kg and <0.01–0.01 mg/kg in liver, kidney and fat respectively at 20 ppm feeding level.

The estimated fludioxonil residues in edible animal commodities for the estimated livestock burden are:

Beef cattle—500 kg bw, 20 kg DM/day

Fludioxonil:

DOSE RATE IN DIET (ppm)	MUSCLE	LIVER	KIDNEY	FAT
20	0.01	0.08	0.08	0.01
16.3*	0.008	0.06	0.06	0.008

**Predicted feeding level*

Lactating dairy cattle—500 kg bw, 20 kg DM/day

Fludioxonil:

DOSE RATE IN DIET (ppm)	MILK
20	0.03
18.5*	0.028

**Predicted feeding level*

Based on the available information, the current animal commodity MRLs of edible offal and milk will be amended to 0.1 and 0.05 mg/kg respectively.

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 residue tolerances for fludioxonil have been established:

Table 2: Current and proposed Australian and overseas MRLs/tolerances for Fludioxonil

COUNTRY	COMMODITY	TOLERANCE, MG/KG	REFERENCE
Australia	Green bean	0.7	This evaluation
	Edible offal (mammalian)	0.1	
	Milks	0.05	
Codex	Green bean	0.3	Codex Alimentarius Commission, www.codexalimentarius.net
	Edible offal (mammalian)	0.05	
	Milks	0.01	

COUNTRY	COMMODITY	TOLERANCE, MG/KG	REFERENCE
Japan	Green bean	-	Japan Food Chemical Research Foundation, Japan Ministry of Health, Labour and Welfare, Food and Agricultural Materials Inspection Centre
	Edible offal (mammalian)	0.05	
	Milks	0.01	
EU	Green bean	1	EU Pesticides Database
	Edible offal (mammalian)	0.05	
	Milks	0.05	
US	Green bean	0.4	http://www.ecfr.gov
	Edible offal (mammalian)	0.05	
	Milks	0.01	

2.6 Current and proposed Australian MRLs for cyprodinil and fludioxonil

The Australian residue definition for cyprodinil is: cyprodinil and for fludioxonil: commodities of animal origin: sum of fludioxonil and oxidizable metabolites, expressed as fludioxonil; commodities of plant origin: fludioxonil

Table 3: Current Relevant Food MRLs in the MRL Standard (Table 1)

COMPOUND	FOOD		MRL (MG/KG)
Cyprodinil	MO 0105	Edible offal (Mammalian)	*0.01
	ML 0106	Milks	*0.01
Fludioxonil	MO 0105	Edible offal (Mammalian)	*0.05
	ML 0106	Milks	*0.01

Table 4: Current Relevant Animal Feed Commodities in the MRL Standard (Table 4)

COMPOUND	ANIMAL FEED COMMODITY		MRL (MG/KG)
Fludioxonil	AL 0528	Pea vines (green)	T4

Table 5: Proposed changes for Switch Fungicide in the MRL Standard (Table 1)

COMPOUND	FOOD		MRL (MG/KG)
Cyprodinil			
ADD:	VP 0526	Common bean	0.7
Fludioxonil			
DELETE:	MO 0105	Edible offal (mammalian)	*0.05
	MM 0095	Milks	*0.01
ADD:	VP 0526	Common bean	0.7
	MO 0105	Edible offal (mammalian)	0.1
	MM 0095	Milks	0.05

Table 6: Proposed changes for Switch Fungicide in the MRL Standard (Table 4)

COMPOUND	ANIMAL FEED COMMODITY		MRL (MG/KG)
Cyprodinil			
ADD:		Legume animal feeds	15
Fludioxonil			

COMPOUND	ANIMAL FEED COMMODITY		MRL (MG/KG)
DELETE:	AL 0528	Pea vines (green)	T4
ADD:	AL 0157	Legume animal feeds	30

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of cyprodinil and fludioxonil 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 use on legume vegetables requires increases in the established fludioxonil MRLs for mammalian offal and milks.

For mammalian offal, the proposed MRL is 0.1 mg/kg, based on an estimated high residue of 0.06 mg/kg. The estimated high residue, conservatively based on feeding legume vegetable forage and apple pomace containing the highest estimate of residues resulting from treatment at the proposed and approved maximum GAP is marginally above the MRLs established in major export markets. The estimated high residue in liver or kidney based on feeding legume forage containing residues at the highest level observed following treatment at the maximum GAP, with other components of the diet not containing fludioxonil residues, is 0.05 mg/kg, the same as established overseas MRLs. The risk to trade in mammalian offals associated with the proposed use is considered to be low and acceptable.

For milks, the proposed MRL is 0.05 mg/kg, based on an estimated high residue of 0.03 mg/kg. The estimated high residue, conservatively based on feeding legume vegetable forage and apple pomace containing the highest estimate of residues resulting from treatment at the maximum proposed or approved GAP is marginally above the MRLs established by Codex, Japan and the US (0.01 mg/kg), but lower than the MRL established in the EU (0.05 mg/kg). Residues in milk arising from feeding legume vegetable forage containing residues at the STMR, which could be considered a more realistic estimate of potential dairy herd exposure, is estimated as 0.02 mg/kg (assuming no contribution from treated apple pomace). Given the conservative nature of these calculations and that milk residues are likely to be diluted during processing, the risk to trade in milk is considered to be low.

3 CONCLUSIONS

It is proposed to amend the current edible animal commodity MRLs for fludioxonil following the proposed use of Switch Fungicide on legume vegetables. Comment is sought on the potential for the proposed use to prejudice Australian trade in animal commodities.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at +612 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609

Office hours: (EST) Monday to Friday