Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on cyprodinil and fludioxonil in the product Switch Fungicide for use on apples

APVMA product number 51797

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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 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 Switch 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 Wednesday 6 April 2022 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 organisation name (if relevant)
- email or postal address (if available)
- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, 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 Trade Advice Notices can be found on the APVMA website: apvma.gov.au.

Introduction

The APVMA has before it an application from Syngenta Australia Pty Ltd to vary the registration of Switch Fungicide containing cyprodinil and fludioxonil to add a use on apples.

The registered use of cyprodinil in apples and pears (Chorus Foliar Fungicide, P49660) allows a maximum of 4 foliar applications of cyprodinil per crop per season at 20 g ai/100 L applied between spur burst and petal fall in conjunction with a harvest withholding period of 'Not required when used as directed'. A cyprodinil Maximum Residue Limit (MRL) for pome fruits at 0.05 mg/kg was established based on the registered use.

The registered use of fludioxonil in pome fruits (Scholar Fungicide, P63391) allows a post-harvest application either as a drip or drench by dipping fruits in prepared solution at a concentration of up to 60 g ai/100 L for 30 to 60 seconds in conjunction with a harvest withholding period of 'Not required when used as directed'. A fludioxonil MRL for pome fruits at 5 mg/kg was established based on the registered use.

Trade considerations

Commodities exported

Apples are considered to be major export commodities[1], 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 Switch Fungicide may have the potential to unduly prejudice trade. As the maximum livestock dietary burden for cyprodinil and fludioxonil will not increase from the proposed use, noting the existing animal feed commodity MRLs listed in Table 7, the risk to trade in animal commodities remains unchanged and does not require further consideration.

Destination and value of exports

Australia typically exports between 2,000 and 5,000 tonnes of apples per year [2]. For the year ending June 2021, Australia exported 2,147 tonnes of apples valued at $5.9 million.

Table 1: Major destinations for Australian Apples[2] (year ending June 2021)

Crop	Major destinations
Apples	Papua New Guinea, Italy, Hong Kong, Thailand and India

Proposed Australian use pattern

Table 2: Proposed use pattern – Switch Fungicide (375 g/kg cyprodinil+ 250 g/kg fludioxonil)

Crop	Pest	Rate/concentration	Critical comments
Apples	Alternaria leaf and fruit blotch	80 g/100 L (30 g ai/100 L cyprodinil+ 20 g ai/100 L fludioxonil)	Apply SWITCH prior to the onset of disease. Repeat application at 7- to 14-day intervals if conditions continue to remain favourable for disease development. DO NOT apply more than 3 applications of SWITCH per crop. DO NOT apply any post-harvest treatment which contains fludioxonil such as SCHOLAR.

[1] Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B)*, APVMA website, 20 July 2020, accessed February 2022.

[2] Hort Innovation, *Australian Horticulture Statistics Handbook 2020–21 – Fruit*, Hort Innovation website, accessed February 2022.

Withholding periods

Harvest: DO NOT harvest for 14 days after application. DO NOT process into stock food for 14 days after application.

Grazing: DO NOT allow livestock to graze treated orchards or cut pasture within treated orchards for stock food.

Results from residues trials presented to the APVMA

The proposed use in apples allows a maximum of 3 applications of cyprodinil and fludioxonil applied 7 to14 days apart at a concentration of 30 g ai/100 L cyprodinil+ 20 g ai/100 L fludioxonil in conjunction with a harvest withholding period (WHP) of 14 days and "DO NOT process into stock food for 14 days after application" and a grazing restraint of "DO NOT allow livestock to graze treated orchards or cut pasture within treated orchards for stock food".

In 4 Australian apple trials conducted in 2019, 3 applications of cyprodinil and fludioxonil were made at 30 g ai/100 L cyprodinil+ 20 g ai/100 L fludioxonil (1× the proposed concentration). Cyprodinil and fludioxonil residues were determined in apple fruits taken at 0, 7 and 14 to 15 days after last application (DALA).

In 2 French apple trials conducted in 2002, 3 foliar applications of A-9219 B (formulation code for Switch Fungicide) were made using 1,000 g product/ha (600 g ai/ha cyprodinil+ 400 g ai/ha fludioxonil, ~0.63× the proposed rate using a typical spray volume of 2,000 L/ha for apples). Cyprodinil and fludioxonil residues were determined in apple fruits taken at 0 days before last application and 0, 3, 7, 10 and 14 DALA.

Apple fruit

Cyprodinil

The results of the French trials were scaled to the proposed rate and were combined with the Australian trials to estimate a MRL. The combined dataset suitable for MRL estimation is, in ranked order: 0.10, 0.13, 0.14, 0.19, 0.30 and 0.43 mg/kg (n=6). The Supervised Trials Median Residue (STMR) is 0.17 mg/kg. The Organisation for Economic Co-operation and Development (OECD) MRL calculator estimates an MRL of 0.8 mg/kg, noting the uncertainty due to the small dataset.

A cyprodinil MRL of 1 mg/kg for FP 0226 Apple is considered appropriate for the proposed use of cyprodinil on apples in conjunction with a 14-day harvest withholding period (WHP). The cyprodinil MRL for FP 0009 Pome fruits currently established at 0.05 mg/kg should be changed from 'FP 0009 Pome fruits' to 'FP 0009 Pome fruits {except apples}'.

Fludioxonil

The results of the French trials were scaled to the proposed rate and were combined with the Australian trials to estimate an MRL. The combined dataset suitable for MRL estimation is, in ranked order: 0.11, 0.15, 0.16, 0.30 (2) and 0.66 mg/kg (n=6). The STMR is 0.23 mg/kg. The OECD MRL calculator estimates an MRL of 1.5 mg/kg, noting the uncertainty due to the small dataset. The current fludioxonil MRL of 5 mg/kg for

FP 0009 Pome fruits remains appropriate and will cover the proposed use of fludioxonil on apples in conjunction with a 14-day harvest WHP.

Processing

In a cyprodinil processing study conducted in apples in the USA, apples collected from 2 sites were processed to produce washed apples, wet pomace and juice. Cyprodinil residues were determined in unwashed apples and in the processed apple commodities and a mean processing factor of 4.0 for wet pomace was calculated.

Animal Feeds

Cyprodinil

The Highest Residues-Processed (HR-P) and STMR-P in apple pomace (dry) is estimated to be 4.3 mg/kg and 1.7 mg/kg, respectively. A cyprodinil MRL of 10 mg/kg for AB 0226 Apple Pomace, dry is considered appropriate for the proposed use of cyprodinil on apple in conjunction with a harvest WHP of 14 days.

Fludioxonil

Using a processing factor of 6.64 for wet apple pomace from earlier evaluations and noting that apple pomace (wet) contains 40% dry matter, the HR-P and STMR-P in apple pomace (dry) is estimated to be 11.0 mg/kg and 3.8 mg/kg, respectively. The currently established fludioxonil MRL of 100 mg/kg for AB 0226 Apple Pomace remains appropriate and will cover the potential fludioxonil residues arising from the proposed use of fludioxonil on apple in conjunction with a harvest WHP of 14 days.

Overseas registration and approved label instructions

The applicant indicated that Switch Fungicide is registered for use on apple and pome fruits in numerous countries in the European Union, Chile, United Arab Emirates and the United Kingdom.

Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. 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. Cyprodinil and fludioxonil have been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for cyprodinil and fludioxonil.

Table 3: Current and proposed Australian and overseas MRLs/tolerances for cyprodinil

Commodity	Tolerance for residues arising from the use of cyprodinil (mg/kg)					
	Australia	EU[3]	Japan[4]	Codex[5]	Canada[6]	USA[7]
Residue definition	Cyprodinil	Cyprodinil	Cyprodinil	Cyprodinil	Cyprodinil	Cyprodinil
Apple	0.05 (Pome fruits – current) 1 (Apple – proposed)	2	5	2 (Pome fruits)	1.7	1.7 (Fruit, pome group 11–10)

Table 4: Australian and overseas MRLs/tolerances for fludioxonil

Commodity	Tolerance for residues arising from the use of fludioxonil (mg/kg)					
	Australia	EU[3]	Japan[4]	Codex[5]	Canada[6]	USA[7]
Residue definition	Fludioxonil	Fludioxonil	Fludioxonil	Fludioxonil	Fludioxonil	Fludioxonil
Apple	5 (Pome fruits – current)	5	5	5 (Pome fruits)	5	5 (Fruit, pome group 11–10)

[3] European Commission, *EU Pesticide residue(s) and maximum residue levels (mg/kg).* European Commission website, accessed February 2022.

[4] Japanese Food Chemistry Research Foundation, *Table of MRLs for Agricultural Chemicals.* JFCRPF website, accessed February 2022.

[5] Food and Agriculture Organization of the United Nations, *Codex Alimentarius, International Food Standards.* FAO website, accessed February 2022.

[6] Health Canada, *Maximum Residue Limits for Pesticides.* Health Canada website, accessed February 2022.

[7] Electronic Code of Federal Regulations, *USA Electronic Code of Federal Regulations.* eCFR website, accessed February 2022.

Current and proposed Australian MRLs for cyprodinil and fludioxonil

Table 5: Current MRL Standard – Table 1

Compound		Food	MRL (mg/kg)
Cyprodinil			
FP	0009	Pome fruits	0.05
Fludioxonil			
FP	0009	Pome fruits	5

Table 6: Proposed MRL Standard – Table 1

Compound		Food	MRL (mg/kg)
Cyprodinil			
Delete:			
FP	0009	Pome fruits	0.05
Add:			
FP	0226	Apple	1
FP	0009	Pome fruits {except apples}	0.05

Table 7: Current MRL Standard – Table 4

Compound		Food	MRL (mg/kg)
Cyprodinil			
		Almond hulls	0.2
AL	0157	Legume animal feeds	15
Fludioxonil			
AB	0226	Apple pomace, dry	100

Table 8: Proposed MRL Standard – Table 4

Compound		Food	MRL (mg/kg)
Cyprodinil			
Add:			
AB	0226	Apple pomace, dry	10

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 recommended MRL of 1 mg/kg for cyprodinil on apples is lower than those established internationally. The currently established MRL of 5 mg/kg for fludioxonil on pome fruits (to cover post-harvest use, noting that apples treated with Switch will not receive a post-harvest treatment) is equivalent to those established internationally.

Conclusion

Syngenta Australia Pty Ltd has applied to vary the registration of Switch Fungicide containing cyprodinil and fludioxonil to add a use on apples.

Comment is sought on the potential for the use of Switch Fungicide on apples to prejudice Australian trade when used according to the proposed label instructions.