



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



Trade Advice Notice

on pydiflumetofen in the product
Miravis Prime Adepidyn Technology Fungicide for use on cherries

APVMA product number 88887

January 2024

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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 Miravis Prime Adepidyn Technology 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 31 January 2024 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
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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 Miravis Prime Adepidyn Technology Fungicide to allow use on cherries. The product contains 250 g/L fludioxonil and 150 g/L pydiflumetofen as the only active ingredients.

Trade considerations

Commodities exported

Cherries are considered to be a major export commodity¹. Residues in cherries resulting from the use of Miravis Prime Adepidyn Technology Fungicide may have the potential to unduly prejudice trade.

As the established fludioxonil MRL for FS 0012 Stone fruits (except Apricots; Peaches) at 5 mg/kg, which covers residues from the registered post-harvest use on stone fruit except apricots and peaches at up to 59.8 g fludioxonil/100 L, will also cover residues from the proposed use on cherries at a maximum of 25 g fludioxonil/100 L in conjunction with the proposed 3 days WHP, no further consideration of the proposed use of fludioxonil on cherries is considered necessary. The trade consideration herein relates to the use of pydiflumetofen on cherries as a new finite MRL is recommended.

Destination and value of exports

Australia is now a net exporter of fresh cherries, after recent increases to export volumes, with the majority of this volume exported to Vietnam and Hong Kong. For the year ending June 2022, Australia imported 1,147 tonnes of fresh cherries, primarily from the United States, and exported 3,885 tonnes².

For the year ending June 2022, approximately 27% of exported fresh cherries were sent to Hong Kong (1,040 tonnes), 20% to Vietnam (792 tonnes), 13% to Singapore (498 tonnes), 12% to Taiwan (459 tonnes) and 7% to China (278 tonnes), with other countries constituting 21% of exports².

¹ Australian Pesticides and Veterinary Medicines Authority (APVMA), 2014. [Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade \(Part 5B\)](#), APVMA website.

² Hort Innovation, 2022. [Australian Horticulture Statistics Handbook 2021–22](#), Hort Innovation website, accessed 10 October 2023.

Proposed Australian use pattern

Table 1: Proposed use pattern for cherries being considered by the APVMA

Crop	Pest	Concentration	Critical comments
Cherries	Grey mould (<i>Botrytis</i> spp.)	Dilute spraying: 60 to 100 mL/100 L (=15 to 25 g fludioxonil/100 L plus 9 to 15 g pydiflumetofen/100 L) Concentrate spraying: refer to the mixing/application section	Apply Miravis Prime Fungicide as part of a protectant program. Begin applications when conditions favour disease development and before the onset of symptoms. Critical timings for control of grey mould are at flowering and preharvest. If consecutive applications are made, apply at 7 to 10 days intervals. If conditions are conducive to further disease infection, additional application of fungicides from other mode of action groups may be required. Use the higher rate under conditions of high disease pressure and/or where a longer period of control is desired. Apply in an appropriate volume of water to thoroughly cover all parts of the crop canopy. DO NOT apply more than 2 applications per crop DO NOT apply more than 2.6 L product/ha/year This use is subject to a CropLife Australia fungicide resistance strategy

Withholding periods

Harvest

DO NOT harvest for 3 days after application.

Grazing

DO NOT graze or cut treated crops, treated crop stubble or orchards/vineyards for stock food.

Restrictions

DO NOT apply more than 2 applications per crop

Trade advice

Export of treated produce

Other crops:

Crops treated with Miravis® Prime Fungicide may contain finite (measurable) residues of pydiflumetofen and fludioxonil and may pose a risk to trade in situations where no residue tolerance (import tolerance) is established in the importing country or where residues in Australian commodities are likely to exceed a residue tolerance (import tolerance) established in the importing country. For further information, please contact your export organisation or Syngenta Australia for the latest information on MRLs and import tolerances before using Miravis® Prime.

Results from residues trials presented to the APVMA

In 3 Australian trials conducted in 2021–22, residues observed in cherries at 3 days after last application (DALA) or later if higher residues were observed, after 2 foliar applications of pydiflumetofen at 15.1 g a.i./100 L (1.01× the maximum proposed application concentration) and a 6 to 7 days RTI were, in rank order:

0.102, 0.219 and 0.744 mg/kg (n=3)

In one other Australian trial conducted in 2021, residues observed in cherries at 0 DALA, after 2 foliar applications of fludioxonil at pydiflumetofen at 15.1 g a.i./100 L (1.01× the maximum proposed application concentration) and an 8 days RTI were:

0.190 mg/kg

In 2 USA trials conducted in 2016–17, residues observed in cherries at 2 to 3 DALA, after 4 foliar applications of pydiflumetofen at 72.9 to 77.4 g a.i./ha (7.86 to 8.58 g a.i./100 L= 0.52 to 0.57× the maximum proposed application concentration) and a 7 to 8 days RTI were, in rank order, after conversion to expected residues at 1× the maximum proposed application concentration and calculated based on the last application rate:

0.299 and 0.650 mg/kg (n=2)

The combined dataset (Australian 0 and 3 DALA data and USA 2 to 3 DALA data) considered to be suitable for MRL estimation is, in rank order:

0.102, 0.190, 0.219, 0.299, 0.650 and 0.744 mg/kg (STMR= 0.259 mg/kg, n=6)

The OECD MRL calculator estimates an MRL of 1.5 mg/kg with the proviso 'High uncertainty of MRL estimate due to small dataset'.

A pydiflumetofen MRL of 1.5 mg/kg for FS 0013 Cherries, is recommended for the proposed use on cherries (noting the availability of residues data on sweet and sour cherry varieties), in conjunction with the proposed 3 days WHP.

Overseas registration and approved label instructions

The Applicant indicated that Miravis Prime Fungicide is registered for use on cherries in Armenia and Chile.

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.

Pydiflumetofen has been considered by Codex. The following relevant Codex CXLs and international MRLs have been established for pydiflumetofen.

Table 2: Relevant international MRLs for pydiflumetofen on cherries

Commodity	Tolerance for residues arising from the use of pydiflumetofen (mg/kg)								
	Australia	Codex ³	Japan ⁴	Korea ⁵	Malaysia	Singapore	Taiwan ⁶	Thailand	USA ⁷
Residue definition	Parent	Parent	Parent	–	–	–	–	–	Parent
Cherries	1.5	2 Cherries (subgroup)	2	2.0	2 ⁸ Sweet cherry	2 ⁸	2.0	2 ⁸ Sweet cherry	2 Cherry subgroup 12–12A

It is noted that no relevant MRLs are established in China⁹, the EU¹⁰, Hong Kong¹¹ or Vietnam⁸.

Current and proposed Australian MRLs for pydiflumetofen

Table 3: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Pydiflumetofen	All other foods	0.05

³ Food and Agriculture Organisation of the United Nations (FAO), 2024. [Codex Alimentarius: 309 – Pydiflumetofen](#), FAO website, accessed 13 October 2023.

⁴ Japanese Food Chemistry Research Promotion Foundation (JFCRPF), 2024. [Table of MRLs for Agricultural Chemicals](#), JFCRPF website, accessed 13 October 2023.

⁵ Ministry of Food and Drug Safety Korea, 2015. [Pesticide MRLs for agricultural commodities](#), FSK website, accessed 13 October 2023.

⁶ Food and Drug Administration Taiwan, [Food and Drug Administration Taiwan, Standards for Pesticide Residue Limits in Foods](#), accessed 13 October 2023.

⁷ Electronic Code of Federal Regulations (eCFR), 2023. [Tolerances and Exemptions for Pesticide Chemical Residues in Food](#), eCFR website, accessed 13 October 2023.

⁸ The Bryant Christie website indicates that Malaysia, Singapore and Thailand have adopted the relevant Codex MRL.

⁹ United States Department of Agriculture (USDA) Foreign Agricultural Service, 24 August 2021. [China: Maximum Residue Limits for Pesticides in Foods, Global Agricultural Information Network report](#), accessed 13 October 2023.

¹⁰ European Commission (EC), 2024. [EU Pesticide residue\(s\) and maximum residue levels \(mg/kg\)](#), European Commission website, accessed 13 October 2023.

¹¹ The Government of the Hong Kong Special Administrative Region Centre for Food Safety, 2017. [Hong Kong Pesticide MRL Database](#), Centre for Food Safety website, accessed 13 October 2023.

Table 4: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Pydiflumetofen		
Add:		
FS 0013	Cherries	1.5

Potential risk to trade

The proposed use of pydiflumetofen requires the establishment of a finite MRL for pydiflumetofen on cherries.

The proposed MRL at 1.5 mg/kg is lower than the Codex MRL at 2 mg/kg and established MRLs in Japan, Korea, Malaysia, Singapore, Taiwan, Thailand and the USA. Some major markets do not have established MRLs (e.g. China, Hong Kong and Vietnam), which presents a potential risk to international trade to these markets.

It is noted that the following statement which is on the registered label for Miravis Prime Adepidyn Technology Fungicide to mitigate trade risk, remains appropriate for the proposed use of the product on cherries:

Export of treated produce

Other crops:

Crops treated with Miravis® Prime Fungicide may contain finite (measurable) residues of pydiflumetofen and fludioxonil and may pose a risk to trade in situations where no residue tolerance (import tolerance) is established in the importing country or where residues in Australian commodities are likely to exceed a residue tolerance (import tolerance) established in the importing country. For further information, please contact your export organisation or Syngenta Australia for the latest information on MRLs and import tolerances before using Miravis® Prime Fungicide.

The applicant has indicated that they can provide guidance to industry concerning a use pattern which will lead to residues of <0.01 mg/kg to comply with countries without MRL coverage.

Conclusion

Syngenta Australia Pty Ltd has applied for registration of the use of pydiflumetofen on cherries.

Comment is sought on the potential for the proposed use to prejudice Australian trade of cherries and the ability of industry to manage any potential trade risk.