



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



## **Trade Advice Notice**

on fludioxonil and pydiflumetofen in the product  
Miravis Prime Fungicide for use on grapes and rotational crops

APVMA product number 88887

August 2020

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## CONTENTS

<b>PREFACE</b>	<b>1</b>
<b>About this document</b>	<b>1</b>
<b>Making a submission</b>	<b>1</b>
<b>Further information</b>	<b>2</b>
<b>1 INTRODUCTION</b>	<b>3</b>
<b>2 TRADE CONSIDERATIONS</b>	<b>3</b>
<b>2.1 Commodities exported</b>	<b>3</b>
<b>2.2 Destination and value of exports</b>	<b>3</b>
<b>2.3 Proposed Australian use-pattern</b>	<b>4</b>
<b>2.4 Results from residues trials presented to the APVMA</b>	<b>5</b>
Pydiflumetofen	5
Processing: pydiflumetofen	5
Fludioxonil	5
Processing: fludioxonil	6
Rotational cropping	6
<b>2.5 Overseas registration and approved label instructions</b>	<b>7</b>
<b>2.6 Codex Alimentarius Commission and overseas MRLs</b>	<b>7</b>
<b>2.7 Current and proposed Australian MRLs for fludioxonil and pydiflumetofen</b>	<b>8</b>
<b>2.8 Potential risk to trade</b>	<b>10</b>
Export of treated produce	10
<b>3 CONCLUSION</b>	<b>10</b>

## LIST OF TABLES

Table 1: Proposed use pattern for grapes—Miravis Prime Fungicide (containing 150 g/L pydiflumetofen and 250 g/L fludioxonil)	4
Table 2: Overseas MRLs/tolerances for pydiflumetofen	7
Table 3: Overseas MRLs/tolerances for fludioxonil	8
Table 4: Current MRL Standard—Table 1	8
Table 5: Current MRL Standard—Table 4	8
Table 6: Proposed MRL Standard—Table 1	9
Table 7: Proposed MRL Standard—Table 4	9

## 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 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 vary the registration of Miravis Prime 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 Thursday 24 September 2020 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)
- submission date.

All personal and *confidential commercial information (CCI)*<sup>1</sup> 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  
Scientific Assessment and Chemical Review  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

**Phone:** +61 2 6770 2300

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au).

## Further information

Further information can be obtained via the contact details provided above.

Further information on public release summaries can be found on the [APVMA website](#).

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<sup>1</sup> A full definition of 'confidential commercial information' is contained in the Agvet Code.

## 1 INTRODUCTION

The APVMA has before it an application from Syngenta Australia Pty. Ltd to register a new product, Miravis Prime Fungicide (containing 150 g/L pydiflumetofen and 250 g/L fludioxonil), for use on grapes including wine grapes, table grapes and grapes grown for dried grape production.

In this Trade Advice Notice (TAN) the potential for residues arising from the proposed use on grapes to unduly prejudice trade is discussed. No amendments to the current pydiflumetofen and fludioxonil animal commodity MRLs are required. Trade risks relating to animal commodities remain unchanged and are not discussed further within this TAN.

The registration application also contains proposed uses on leafy vegetables, potatoes and strawberries, which are not directly discussed in this TAN as they are not considered to be major export commodities. Rotational cropping residues data has however been considered in the context of these proposed use patterns and the pydiflumetofen MRLs for 'All other foods' and 'Primary feed commodities' which are required to cover potential residues in following crops will be discussed here.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Grapes (including dried grapes) and wine are considered major export commodities<sup>2</sup>.

### 2.2 Destination and value of exports

In 2018–19, Australia exported 813 ML of wine worth \$3 billion. The major export markets for wine included China (\$1076 million), the USA (\$447 million), the United Kingdom (\$397 million), Canada (\$198 million), the European Union (EU) (\$142 million), Hong Kong (\$139 million), New Zealand (\$101 million), Singapore (\$91 million), Japan (\$55 million) and Malaysia (\$39 million)<sup>3</sup>.

Australia exports table grapes primarily to Asia. In 2018–19 146 kt of table grapes worth \$555 million were exported<sup>4</sup>.

Dried grapes are exported worldwide; in 2018–19, Australia exported 5.4 kt worth \$25 million<sup>4</sup>.

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<sup>2</sup> Overseas Trade (Part 5B) [apvma.gov.au/node/1017#Major\\_export\\_food\\_commodity\\_groups](http://apvma.gov.au/node/1017#Major_export_food_commodity_groups)

<sup>3</sup> Australian Commodity statistics 2019 [agriculture.gov.au/abares/research-topics/agricultural-outlook/data#2019](http://agriculture.gov.au/abares/research-topics/agricultural-outlook/data#2019)

<sup>4</sup> Australian Horticulture Statistics Handbook 2018–19 [horticulture.com.au/growers/help-your-business-grow/research-reports-publications-fact-sheets-and-more/grower-resources/ha18002-assets/australian-horticulture-statistics-handbook/](http://horticulture.com.au/growers/help-your-business-grow/research-reports-publications-fact-sheets-and-more/grower-resources/ha18002-assets/australian-horticulture-statistics-handbook/)

## 2.3 Proposed Australian use-pattern

**Table 1: Proposed use pattern for grapes—Miravis Prime Fungicide (containing 150 g/L pydiflumetofen and 250 g/L fludioxonil)**

Crop	Pest	Rate/concentration	Critical comments
Grapes, wine, table and dried fruit production	Botrytis bunch rot/Grey mould ( <i>Botrytis cinerea</i> )  Application for grey mould will also result in control of:  Powdery mildew ( <i>Erysiphe necator</i> )	100 mL/100 L  (15 g pydiflumetofen/100 L + 25 g fludioxonil/100 L)	Apply Miravis Prime within a protectant fungicide program aimed at controlling botrytis bunch rot/grey mould. Critical timings for control of botrytis bunch rot/grey mould are 5% capfall, 80% capfall, pre-bunch closure and veraison. When applied for control of botrytis bunch rot/grey mould, MIRAVis PRIME will also control powdery mildew.  Apply by dilute or concentrate spraying equipment applying the same total amount of product to the crop. Refer to Application Section for calculations. DO NOT apply at more than 3x concentration. Ensure thorough coverage of the crop canopy regardless of application method.  <b>This use is subject to a CropLife Australia Fungicide Resistance Management strategy.</b>

Withholding periods:

Grapes including wine grapes, table grapes and dried fruit

Harvest: DO NOT harvest for 14 days after application.

Restrains:

DO NOT apply with aircraft.

DO NOT apply if heavy rains or storms that are likely to cause environmental runoff are forecast within 3 days.

DO NOT irrigate to the point of environmental runoff for at least 3 days after application.

DO NOT apply more than 1.35 L product per hectare per application and 2.7 L product per hectare per year.

Trade advice:

Grapes: Growers should note that appropriate MRLs or import tolerances may not be established in all markets for fruit harvested from Miravis Prime treated plants. If you are growing grapes for export (either fresh, dried or as wine), please check with your export agent (in regards to fresh), the Australian Wine Research Institute (in regards to wine) or Syngenta Australia for the latest information on MRLs and import tolerances before using Miravis Prime.

## 2.4 Results from residues trials presented to the APVMA

The proposed use of pydiflumetofen and fludioxonil on grapes involves foliar applications at 100 mL/100 L (15 g pydiflumetofen/100 L and 25 g fludioxonil/100 L) applied to the point of runoff at a maximum seasonal rate of 2.7 L of product per hectare per year. A harvest-withholding period of 14 days is proposed.

The Applicant has provided details four Australian table grape trials that are relevant to the critical use pattern supported by twenty relevant pydiflumetofen trials (eight European trials and 12 United States trials) and 36 relevant European fludioxonil trials conducted on grapes. Pydiflumetofen and fludioxonil residues were determined in grapes and its processed commodities of raisins, juice, wine and pomace.

### Pydiflumetofen

In the Australian trials, at 13–15 days after last application, following two applications of pydiflumetofen at 20 g ai/100 L (~1.3x proposed) residues in grapes were 0.31, 0.34, 0.36 and 0.98 mg/kg (n=4).

In the European trials, at 14 days after last application, following two applications of pydiflumetofen at 200 g ai/ha (~1.3x proposed for a spray volume of 1000 L/ha) residues in grapes were 0.23, 0.30, 0.43, 0.48, 0.49, 0.51, 0.54 and 1.2 mg/kg (n=8).

In the US trials, at 14 days after last application, following of two applications of pydiflumetofen at 200 g ai/ha (~1.3x proposed for a spray volume of 1000 L/ha) residues in grapes were <0.01, 0.06, 0.16, 0.19, 0.21 (2), 0.39, 0.42, 0.45, 0.55, 0.65 and 0.85 mg/kg (n=12).

Based on the combined data set the OECD MRL calculator recommends an MRL of 1.5 mg/kg (STMR = 0.41 mg/kg). A pydiflumetofen MRL of 2 mg/kg for grapes (FB 0269) is considered appropriate for the proposed wine and table grape uses in conjunction with a harvest-withholding period of 14 days.

### Processing: pydiflumetofen

Residues of pydiflumetofen did not concentrate in wine or juice. Residues of pydiflumetofen arising in wine and juice will be covered by the recommended grape MRL.

Wine: Processing factors were 0.18 and 0.33x. Based on a HR in grapes of 1.2 mg/kg, the HR-P for wine is calculated to be 0.39 mg/kg. The STMR-P for wine is calculated to be 0.1 mg/kg.

Dried grapes: Based on the highest processing factor of 3.1 in raisins, the HR-P is estimated to be 3.7 mg/kg. A pydiflumetofen MRL of 5 mg/kg for dried grapes (DF 0269) is considered appropriate.

Grape pomace: Based on the highest processing factor of 29 in dry pomace, the HR-P is estimated to be 34 mg/kg. A pydiflumetofen MRL of 50 mg/kg is considered appropriate for dry grape pomace (AB 0269). The STMR-P for grape pomace dry is 6.1 mg/kg.

### Fludioxonil

In the Australian trials, at 13–15 days after the last application, following two applications of fludioxonil at 25 g ai/100 L (1x proposed) residues were 0.42 (2), 0.47 and 0.95 mg/kg (n=4).

In the European trials, at 14±2 days after last application, or later if higher residues were observed, following two applications of fludioxonil at 238–508 g ai/ha (~1 to 2× proposed for a spray volume of 1000 L/ha). Scaled to the proposed rate of 250 g fludioxonil/ha (or 25 g fludioxonil/100 L with a spray volume of 1000 L/ha) results in expected pydiflumetofen residues at 0.03, 0.05, 0.06, 0.10 (3), 0.11, 0.12, 0.16, 0.17 (2), 0.19 (2), 0.26 (2), 0.27, 0.30, 0.31, 0.32, 0.35, 0.37, 0.38 (2), 0.39, 0.41, 0.42, 0.44, 0.60, 0.63, 0.73, 0.76, 0.77, 0.99, 1.1, and 1.4 (2) mg/kg (n=36).

Based on the combined dataset the OECD MRL calculator recommends an MRL of 2 mg/kg. The established fludioxonil MRL of 2 mg/kg for grapes (FB 0269) remains appropriate for the proposed wine and table grape uses in conjunction with a harvest-withholding period of 14 days.

### Processing: fludioxonil

Residues of fludioxonil did not concentrate in wine. Residues of fludioxonil arising in wine and juice will be covered by the recommended grape MRL.

Wine: Processing factors ranged between 0.01 to 0.43×. Based on a HR in grapes of 1.4 mg/kg, the HR-P for wine is calculated to be 0.59 mg/kg. The STMR-P for wine is calculated to be 0.08 mg/kg.

Dried grapes: It is noted that current fludioxonil registrations are for grapes (except grapes grown for dried fruit production). Based on the highest processing factor of 2.2 in raisins, the HR-P is estimated to be 3 mg/kg. A fludioxonil MRL of 5 mg/kg for dried grapes (DF 0269) is considered appropriate.

Grape pomace: Based on the highest processing factor of 22 in dry pomace, the HR-P is estimated to be 30 mg/kg. A fludioxonil MRL of 50 mg/kg is considered appropriate for dry grape pomace (AB 0269). The STMR-P for grape pomace dry is  $0.36 \times 11 = 4.0$  mg/kg.

### Rotational cropping

Due to the proposed uses on leafy vegetables, strawberries and potatoes residues data on rotational crops were also considered.

Switch Fungicide (containing fludioxonil) is currently registered on numerous rotational crops at comparable or higher rates. The potential for residues of fludioxonil in succeeding crops is not expected to increase as a result of the proposed uses.

For pydiflumetofen, five crop rotational studies were considered. Low residues may be expected to occur in vegetable crops (up to 0.03 mg/kg in spinach leaves) grown after primary potato, lettuce or strawberry crop that was treated according to the proposed use patterns (two applications at 150 g ai/ha). Residues above the LOQ of 0.01 mg/kg are not expected to occur in grain from cereal, oilseed or pulse crops grown as following crops, but may be expected in forage and fodder from grain crops (up to 0.09 mg/kg in straw, or up to 0.01 mg/kg (fresh weight) in forage).

To cover the possibility of residues of pydiflumetofen in succeeding crops an 'All other foods' MRL of 0.05 mg/kg and a 'Primary feed commodity {except rape seed [canola] forage; rape seed [canola] straw and fodder, dry}' MRL of at 0.2 mg/kg are proposed for pydiflumetofen. Pydiflumetofen MRLs for cereal, pulse

and oilseed grain at \*0.01 mg/kg are considered appropriate for the proposed use in rotational crops but it is noted that higher MRLs are currently established for cereals, pulses and rape seed to cover residues which may occur following use under a research permit.

## 2.5 Overseas registration and approved label instructions

The applicant indicated that Miravis Prime is registered on grapes in the United States, Canada, Chile, Argentina and Israel. Registration is being sought in Europe, New Zealand, and China.

## 2.6 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. Pydiflumetofen and fludioxonil have been considered by Codex. The following relevant Codex CXLs have been established for pydiflumetofen and fludioxonil.

**Table 2: Overseas MRLs/tolerances for pydiflumetofen**

Commodity	MRLs/Tolerances for residues arising from the use of pydiflumetofen (mg/kg)					
	Australia <sup>5</sup>	Codex <sup>6</sup>	USA <sup>7</sup>	Canada <sup>8</sup>	Japan <sup>9</sup>	Korea <sup>10</sup>
Grapes	T2 (current) 2 (proposed)	1.5 Small fruit vine climbing (FB 2008)	1.5 Small fruit vine climbing, except fuzzy kiwifruit, Subgroup 13-07F	1.5	(2 proposed)	1.5
Dried grapes (=currants, raisins and sultanas)	T5 (current) 5 (proposed)	4	2 (raisins)	2 (raisins)	-	-

*Pydiflumetofen has not been considered by China<sup>11</sup>, the EU or Taiwan.*

<sup>5</sup> [legislation.gov.au/Details/F2020C00713](http://legislation.gov.au/Details/F2020C00713)

<sup>6</sup> [codexalimentarius.net](http://codexalimentarius.net)

<sup>7</sup> [ecfr.gov](http://ecfr.gov)

<sup>8</sup> [pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php](http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php)

<sup>9</sup> [G/SPS/N/JPN/767: docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S005.aspx](http://G/SPS/N/JPN/767: docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S005.aspx)

<sup>10</sup> [foodsafetykorea.go.kr/residue/main.do](http://foodsafetykorea.go.kr/residue/main.do)

<sup>11</sup> [apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=National%20Food%20Safety%20Standard%20%20Maximum%20Residue%20Limits%20for%20Pesticides%20in%20Foods%20\\_Beijing\\_China%20-%20Peoples%20Republic%20of\\_11-18-2019](http://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=National%20Food%20Safety%20Standard%20%20Maximum%20Residue%20Limits%20for%20Pesticides%20in%20Foods%20_Beijing_China%20-%20Peoples%20Republic%20of_11-18-2019)

**Table 3: Overseas MRLs/tolerances for fludioxonil**

Commodity	MRLs/Tolerances for residues arising from the use of pydiflumetofen (mg/kg)						
	Australia <sup>5</sup>	Codex <sup>6</sup>	USA <sup>7</sup>	Canada <sup>8</sup>	EU <sup>12</sup>	Japan <sup>13</sup>	China <sup>11</sup>
Grapes	2 (current)	2	2.0 Small fruit vine climbing, except fuzzy kiwifruit, Subgroup 13-07F	2	5.0 (Table grapes) 4.0 (Wine grapes)	5	2
Dried grapes (=currants, raisins and sultanas)	T5 (current) 5 (proposed)	-	-	-	-	-	-

MRLs for grapes are also established in Taiwan<sup>14</sup> at 2 mg/kg and Korea<sup>10</sup> at 5 mg/kg. MRLs for dried grapes are not established in overseas markets.

## 2.7 Current and proposed Australian MRLs for fludioxonil and pydiflumetofen

**Table 4: Current MRL Standard—Table 1**

COMPOUND	FOOD	MRL (mg/kg)
FLUDIOXONIL		
FB 0269	Grapes	2
PYDIFLUMETOFEN		
	All other foods	T0.05
DF 0269	Dried grapes (=currants, raisins and sultanas)	T5
FB 0269	Grapes	T2

**Table 5: Current MRL Standard—Table 4**

COMPOUND	FOOD	MRL (mg/kg)
PYDIFLUMETOFEN		
AB 0269	Grape pomace, dry	T50
	Primary feed commodities {except rape seed [canola] forage; rape seed [canola] straw and fodder, dry}	T0.2
	Rape seed [canola] forage	3
	Rape seed [canola] straw and fodder, dry	0.1

<sup>12</sup> [ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN](http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN)

<sup>13</sup> [db.ffcr.or.jp/front/](http://db.ffcr.or.jp/front/)

<sup>14</sup> [fda.gov.tw/ENG/law.aspx?cid=16](http://fda.gov.tw/ENG/law.aspx?cid=16)

Table 6: Proposed MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
FLUDIOXONIL		
ADD:		
DF 0269	Dried grapes (=currants, raisins and sultanas)	5
PYDIFLUMETOFEN		
DELETE:		
	All other foods	T0.05
DF 0269	Dried grapes (=currants, raisins and sultanas)	T5
FB 0269	Grapes	T2
ADD:		
	All other foods	0.05
DF 0269	Dried grapes (=currants, raisins and sultanas)	5
FB 0269	Grapes	2

Table 7: Proposed MRL Standard—Table 4

COMPOUND	FOOD	MRL (mg/kg)
FLUDIOXONIL		
ADD:		
AB 0269	Grape pomace, dry	50
PYDIFLUMETOFEN		
DELETE:		
AB 0269	Grape pomace, dry	T50
	Primary feed commodities {except rape seed [canola] forage; rape seed [canola] straw and fodder, dry}	T0.2
ADD:		
AB 0269	Grape pomace, dry	50
	Primary feed commodities {except rape seed [canola] forage; rape seed [canola] straw and fodder, dry}	0.2

## 2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of fludioxonil and pydiflumetofen 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.

For pydiflumetofen, MRLs/Tolerances are established by Codex, the USA, Canada and Korea at 1.5 mg/kg and proposed at 2 mg/kg in Japan. The risk to trade of grapes and wine is considered low to these markets noting the HR in grapes from the proposed Australian use at 1.2 mg/kg.

Pydiflumetofen has not been considered by the EU, China or Taiwan. There is a risk of finite residues in fresh table grapes, dried grapes and wine following treatment of vines with Miravis Prime that presents a potential risk to international trade for exported grape products to these markets.

For fludioxonil, international MRLs/Tolerances are established in most markets at the same or higher levels as the existing Australian MRL for grapes at 2 mg/kg. With respect to fludioxonil, the risk to trade for table grapes and wine remains unchanged from the existing uses for Switch Fungicide, however the proposed use does represent a new Australian use for grapes grown for dried grape production and international MRLs are not established in dried grapes in any international market.

The Applicant has proposed the following trade advice statement to ensure appropriate advice is sought prior to the use of this product on grapes.

### Export of treated produce

#### *Grapes*

Growers should note that appropriate MRLs or import tolerances may not be established in all markets for fruit harvested from Miravis Prime treated plants. If you are growing grapes for export (either fresh, dried or as wine), please check with your export agent (in regards to fresh and dried grapes), the Australian Wine Research Institute (in regards to wine) or Syngenta Australia for the latest information on MRLs and import tolerances before using Miravis Prime.

## 3 CONCLUSION

Syngenta Australia Pty. Ltd to register a new product, Miravis Prime Fungicide (containing 150 g/L pydiflumetofen and 250 g/L fludioxonil), for use on grapes (including wine and table grapes and dried grapes).

Comment is sought on the potential for Miravis Prime Fungicide to prejudice Australian trade when used on wine and table grapes according to the proposed label directions.