



Australian Government
Australian Pesticides and
Veterinary Medicines Authority



TRADE ADVICE NOTICE

on difenoconazole in the Product Nufarm Digger Fungicide for use on wine
grapes

APVMA Product Number 65130

NOVEMBER 2018

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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, Department of the Environment and Energy, 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 regulatory guidance published on the APVMA website.

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 vary the registration of Nufarm Digger 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 **Friday, 14 December 2018** 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:

Residues and Trade
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Phone: +61 2 6210 4701
Email: 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:
<http://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 Nufarm Australia Limited, to vary the registration of Nufarm Digger Fungicide to change the use pattern on wine grapes.

Nufarm Digger Fungicide is currently approved for use on wine grapes with application up to growth stage EL 25 (80% cap fall) and table grapes with application up to EL 32 (beginning of bunch closure). It is currently proposed to change the wine grape use to be the same as that approved for table grapes.

No change to the registered use on table grapes or dried grapes is proposed and therefore these commodities will not be discussed further.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Grapes and wine are considered to be major export commodities², as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from grape pomace from treated crops.

2.2 Destination and value of exports

Wine is a significant export commodity. In 2016–17 Australia exported 789 ML of wine worth \$2.4 billion².

Table 1: Major destinations for Australian wine²

CROP	MAJOR DESTINATIONS
Wine	China, United States, United Kingdom, Canada, Hong Kong, New Zealand, Singapore, Netherlands, Malaysia and Japan

The significant export markets for Australian beef, sheep, pig meat and offal are listed in the APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B).

² <http://agriculture.gov.au/abares/research-topics/agricultural-commodities/agricultural-commodities-trade-data#2017>

2.3 Proposed Australian use-pattern

NUFARM DIGGER FUNGICIDE (250 g/L DIFENOCONAZOLE)

CROP	PEST	RATE/ CONCENTRATION	CRITICAL COMMENTS
Grapes - Including Table, Wine and dried	Powdery mildew (Erysiphe necator)	Dilute spraying: 25 mL/100L (6.25 g ai/100L) Concentrate spraying: Refer to the Application section	Apply as part of a five spray programme: When shoots are 10-20 cm long. Pre-flowering. Flowering After fruit set. Before bunch closure. Do not allow spray intervals to exceed 21 days. In some seasons, additional non-schedule sprays may be necessary later in the season. This use is subject to a CropLife Australia Fungicide Resistance Management Strategy: DO NOT apply more than two consecutive sprays of a Group 3 fungicide. DO NOT apply more than three Group 3 sprays per season. DO NOT use Group 3 fungicides curatively. Apply by dilute or concentrate spraying equipment. Apply the same total amount of product to the target crop whether applying this product by dilute or concentrate spraying methods. Do not use in equipment that requires rates greater than 125mL of chemical/100L water (5x). Do not apply in volumes less than 250L/ha.

Restrains:

DO NOT apply more than the number of applications of Digger per season as indicated in the Critical Comments for the relevant crop.

The effect of Digger could be diminished if rain falls within 2 hours of application.

DO NOT apply by aircraft to grapevines.

Withholding periods:

Harvest: DO NOT harvest for 4 weeks after application.

Grazing: DO NOT allow livestock to graze treated vineyards for 2 days after application. Livestock used for grazing inter-rows or leaf plucking must then not be sent for slaughter until 6 weeks after removal from the vineyard.

Trade advice: EXPORT OF TREATED FRUIT OR WINE

Growers should note that suitable MRLs or import tolerances may not be established in all markets for produce treated with Digger. Additionally, some export markets have established MRLs different to those in Australia. If growing fruit for export (either fresh, dried or for wine production) please check with your industry representative or Nufarm Australia Ltd. If growing wine grapes, contact the Australian Wine Research Institute www.awri.com.au for the latest information on MRLs and overseas import tolerances BEFORE using Digger.

2.4 Results from residues trials presented to the APVMA

The proposed use allows a maximum of three applications at 6.25 g ai/100L on wine grapes with a harvest withholding period of 4 weeks.

In support of the proposed use, six Australian GLP residue trials conducted according to GAP were assessed. Four of the trials investigated difenoconazole residues in grapes, wine, juice and pomace.

Residues of difenoconazole in grapes at the proposed rate and withholding period of 28 days were (n = 6): 0.18, 0.19, 0.42, 0.66, 0.71 and 1.0 mg/kg. At 2x the proposed rate, the highest residue reported after 28 days was 1.6 mg/kg.

Supporting data from the 2007 JMPR on wine grapes in France and Italy was also considered. The highest residue of 0.07 mg/kg was reported for samples taken at 28 days after 4 applications at 0.8x the proposed concentration and similar spray volumes to those used in Australia.

In wine, difenoconazole residues from grapes treated with 1x the proposed concentration with a 28 day PHI were <0.005 (2), 0.010 and 0.013 mg/kg. The processing factors from these trials in wine were ≤0.03x. Based on the HR of 1.0 mg/kg, the HR-P for wine is ~0.03 mg/kg. As residues should not concentrate in wine, a separate MRL is not required.

In grape juice, difenoconazole residues from grapes treated with 1x the proposed concentration with a 28 day PHI were 0.006, 0.009, 0.015 (2) mg/kg. The processing factors from these trials in juice were ≤0.04x. Based on the HR of 1.0 mg/kg, the HR-P for juice is ~0.04 mg/kg. As residues should not concentrate in juice, a separate MRL is not required.

In dry grape pomace, difenoconazole residues from grapes treated with 1x the proposed concentration with a 28 day PHI were 0.19, 1.4, 2.2 and 3.4 mg/kg. The processing factors from these trials in dry pomace were 4.1, 4.7, 5.4 and 8.2x (median = 5.1x). Based on the highest residue in grapes (1.0 mg/kg), and the highest dry grape pomace processing factor of 8.2x, the highest predicted residue value (HR-P) in dry grape pomace was 8.2 mg/kg and therefore a MRL for grape pomace at 10 mg/kg is proposed.

Grape pomace can form 20% of the diet for beef and dairy cattle in Australia. An STMR-P of 2.76 mg/kg (0.541 x 5.1x) for grape pomace gives an estimated dietary burden of 0.6 ppm. In a dairy cattle feeding study evaluated by the 2007 JMPR, difenoconazole residues in milk, liver, muscle, fat and kidney did not exceed the LOQ of 0.01 mg/kg (tissues and fat) and 0.005 mg/kg (milk) at a level of 1 ppm in the feed. Consumption of grape pomace containing difenoconazole residues as a result of proposed use should not result in residues above current animal commodity MRLs of *0.05 mg/kg for edible offal (mammalian) and meat (mammalian) or *0.01 mg/kg for milk.

In a submitted study, difenoconazole was applied to grapes with 4 applications at 62.5 g ai/ha before sheep grazed the treated vineyard from 2-16 days after treatment and were sacrificed 6, 7 and 8 weeks after removal from the treated vineyard. No residues were detected (<0.01) in muscle, liver, kidney, peri-renal fat and subcutaneous fat from the samples collected 6, 7 and 8 weeks after removal from the treated vineyard. The recommended 6 week clean feed interval for animals that have grazed treated vineyards should prevent detectable residues in animal commodities.

2.5 Overseas registration and approved label instructions

The applicant has indicated that difenoconazole products are registered for use on grapevines in the USA to control powdery mildew and other diseases at a rate of 91 – 128 g ai/ha (7 day WHP). Difenoconazole products are also registered in Canada and the EU (France, Germany, Italy) to control powdery mildew on grapes at 73 g ai/ha (7 day WHP).

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. Difenoconazole has been considered by Codex. The following relevant international MRLs have been established for difenoconazole.

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

Commodity	Tolerance for residues arising from the use of difenoconazole (mg/kg)						
	Australia	EU ³	Japan ⁴	Codex ⁵	USA ⁶	Canada ^{7&8}	China
Residue Definition	difenoconazole	difenoconazole	Plant origin: difenoconazole Animal origin: sum of difenoconazole and metabolite, 1-[2-chloro-4-(4-chlorophenoxy)phenyl]-2-[1,2,4]triazol-1-yl-ethanol, calculated as difenoconazole	Plant origin: difenoconazole Animal origin: sum of difenoconazole and 1-[2-chloro-4-(4-chlorophenoxy)phenyl]-2-(1,2,4-triazol)-1-yl-ethanol, expressed as difenoconazole	Plant origin: difenoconazole Animal origin: 1-[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, and its metabolite, CGA-205375, 1-[2-chloro-4-(4-chlorophenoxy)phenyl]-2-[1,2,4]triazol-1-yl-ethanol	Plant origin: difenoconazole Animal origin: 1-[[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole, including the metabolite α -[2-chloro-4-(4-chlorophenoxy)phenyl]-1H-1,2,4-triazole-1-ethanol	difenoconazole
Grapes	Wine grapes 0.02 (2 proposed) Table grapes 2	3 (table and wine grapes)	4 Grapes	3 Grapes	6 Grapes, raisin	4 Grapes	Not established
Mammalian offal	*0.05	0.2	2	1.5	0.4	0.1	
Mammalian meat	*0.05	0.05	2	0.2	0.05	0.05	
Milk	*0.01	*0.005	0.02	0.02	0.02	0.01	

New Zealand follows Food Standard Australia New Zealand (current grape MRL = 4 mg/kg).

Singapore and Malaysia follow Codex for MRL compliance.

³ <http://ec.europa.eu>

⁴ <http://www.m5.ws001.squarestart.ne.jp>

⁵ <http://www.codexalimentarius.net>

⁶ <http://www.ecfr.gov>

⁷ <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/pesticides-food/residue-definitions-chemicals-maximum-residue-limits-regulated-under-pest-control-products-act.html>

⁸ <http://pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php>

2.7 Current and proposed Australian MRLs for difenoconazole

TABLE 3: CURRENT MRL STANDARD - TABLE1

COMPOUND	FOOD	MRL (MG/KG)
DIFENOCONAZOLE		
DF 0269	Dried grapes (= Currants, Raisins and Sultanas)	6
MO 0105	Edible offal (Mammalian)	*0.05
PE 0112	Eggs	*0.05
MM 0095	Meat (mammalian)	*0.05
ML 0106	Milks	*0.01
PM 0110	Poultry meat	*0.05
PO 0111	Poultry, Edible offal of	*0.05
FB 1235	Table-grapes	2
FB 1236	Wine-grapes	0.02

TABLE 4: PROPOSED MRL STANDARD - TABLE1

COMPOUND	FOOD	MRL (MG/KG)
DIFENOCONAZOLE		
DELETE:		
FB 1235	Table-grapes	2
FB 1236	Wine-grapes	0.02
ADD:		
FB 0269	Grapes	2

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of difenoconazole 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.

No changes to the established mammalian meat and offal MRLs at *0.05 mg/kg and milk MRL at *0.01 mg/kg are proposed. The potential risk to the international trade of animal commodities is considered to be low.

The proposed Australian grape MRL for difenoconazole is lower than that established by Codex, EU, Japan, Canada and the USA, therefore the risk to trade to these markets is low. China has not established a MRL for difenoconazole in grapes. The HR-P for wine was ~0.03 mg/kg following the proposed use pattern.

The proposed label has the following trade advice statement which is considered acceptable:

EXPORT OF TREATED FRUIT OR WINE

Growers should note that suitable MRLs or import tolerances may not be established in all markets for produce treated with Digger. Additionally, some export markets have established MRLs different to those in Australia. If growing fruit for export (either fresh, dried or for wine production) please check with your industry representative or Nufarm Australia Ltd. If growing wine grapes, contact the Australian Wine Research Institute www.awri.com.au for the latest information on MRLs and overseas import tolerances BEFORE using Digger.

3 CONCLUSIONS

Nufarm Australia Limited have made an application to vary the registration of Nufarm Digger Fungicide containing difenoconazole on wine grapes.

Comment is sought on the potential for Nufarm Digger Fungicide to prejudice Australian trade when used on wine grapes according to the amended label instructions.