



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

APRIL 2017

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CONTENTS

PREFACE	4
About this document	4
Making a submission	4
Further information	5
INTRODUCTION	6
1 TRADE CONSIDERATIONS	6
1.1 Commodities exported	6
1.2 Destination and value of exports	6
1.3 Proposed Australian use-pattern	7
1.4 Results from residues trials presented to the APVMA	8
1.5 Overseas registration and approved label instructions	8
1.6 Codex alimentarius commission and overseas MRLs	8
1.7 Current and proposed Australian MRLs for difenoconazole	9
1.8 Potential risk to trade	10
2 CONCLUSION	11

LIST OF TABLES

Table 1: Major destinations for Australian wine in 2015–2016 ³	6
Table 2: Nufarm Digger Fungicide (250 g/L difenoconazole)	7
Table 3: Relevant overseas MRLs for difenoconazole	9
Table 4: Current relevant entries in the MRL Standard—Table 1	9
Table 5: Proposed changes to MRL Standard—Table 1	9
Table 6: Proposed changes to MRL Standard—Table 4	10

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 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 Tuesday 9 May 2017 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

Symonston ACT 2609

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 www.apvma.gov.au.

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

INTRODUCTION

The APVMA has before it an application from Nufarm Australia Limited, to vary the registration of Nufarm Digger Fungicide, to allow use on wine grapes. The product is currently registered for use on table grapes and grapes for drying, with a use pattern different to that proposed for wine grapes.

1 TRADE CONSIDERATIONS

1.1 Commodities exported

Wine is considered to be a major export commodity², as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated by-products of wine grape processing. Residues in these commodities resulting from the use of Nufarm Digger Fungicide may have the potential to unduly prejudice trade.

It is noted that the livestock dietary burden will be no higher than currently considered acceptable if the proposed use on wine grapes is supported and the current animal commodity MRLs established at the LOQ will remain unchanged, noting that an MRL of 1 mg/kg is established for difenoconazole on apple pomace, dry, which is higher than the proposed grape pomace MRL. Further consideration of the risk to trade in animal commodities is not required.

1.2 Destination and value of exports

Australia exported 727 ML of wine during 2015–2016 with a value of \$2184 million.³

Major export markets for Australian wine in 2015–2016 are presented below.

Table 1: Major destinations for Australian wine in 2015-2016³

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

² APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

³ Agricultural commodity statistics 2016, Department of Agriculture and Water Resources ABARES, December 2016
data.daff.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022016_Sn9Dg/ACS_2016_v1.0.0.pdf

1.3 Proposed Australian use-pattern

Table 2: Nufarm Digger Fungicide (250 g/L difenoconazole)

CROP	PEST	CONCENTRATION	CRITICAL COMMENTS
Grapes– Wine	Powdery mildew (<i>Erysiphe necator</i>)	Dilute spraying: 25 mL/100 L (6.25 g ai/100 L) Concentrate spraying: Refer to the 'Special Instructions for grapevines' in the Application section.	Apply as part of a protectant program. Apply a maximum of 2 applications per season either as consecutive sprays or in alternation with other fungicides. DO NOT apply after growth stage EL25 (80% cap fall). DO NOT allow spray intervals to exceed 21 days. Shorter intervals between sprays may be warranted if Digger is being applied during periods of rapid vine growth. If applying consecutive applications of Digger, a minimum spray interval of 7 days is required. 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 125 mL of chemical/100 L water (5x). Do not apply in volumes less than 250 mL/ha

Withholding periods:

Harvest: Not required when used as directed

Grazing: DO NOT graze vineyards after application

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

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.

1.4 Results from residues trials presented to the APVMA

The proposed use of difenoconazole on wine grapes involves up to two applications until growth stage EL25 (80% cap fall) made at a minimum of 7 days and a maximum of 21 days apart, at a concentration of 6.25 g ai/100 L (dilute spray) and a harvest WHP of “Not required when used as directed”.

In four submitted Australian trials, residues detected at commercial harvest, after two applications were made 7–14 days apart with the last application at 80% capfall (E-L 25), at 1× the proposed concentration, were in rank order (n = 4): <0.001, <0.005, 0.006 and 0.006 mg/kg (STMR = 0.0055 mg/kg). A higher residue (0.007 mg/kg) was observed at one site after only one application.

Based on the available information, and noting the small dataset, an MRL of 0.02 mg/kg is recommended for use of difenoconazole on FB 1236 Wine-grapes, in combination with the proposed harvest WHP of ‘Not required when used as directed’.

Processing studies (juice, wine, grape pomace) following application of difenoconazole to wine grapes have been previously submitted to the APVMA by the applicant. Four trials were conducted covering a range of red and white grape varieties across various wine grape growing regions.

Available wine grape processing factors showed that residues of difenoconazole did not concentrate in either the juice (median processing factor 0.030×) or wine (median processing factor 0.022×), while a median dry grape pomace processing factor of 5.1× was also determined.

Based on the highest residues of 0.007 mg/kg detected in wine grapes and the processing factors observed, detectable residues would not be expected to be present in juice or wine. Therefore separate MRLs are not necessary for juice and wine.

Based on the highest residue in grapes (0.007 mg/kg), and the median dry grape pomace processing factor of 5.1×, the highest predicted residue value (HR-P) in dry grape pomace is 0.036 mg/kg.

An MRL of 0.1 mg/kg is recommended for difenoconazole on AB 0269 Grape pomace, dry.

1.5 Overseas registration and approved label instructions

The applicant 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).

1.6 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 3: Relevant overseas MRLs for difenoconazole

COUNTRY/ STATUS	RESIDUE DEFINITION	COMMODITY	TOLERANCE (mg/kg)
Australia	Difenoconazole	Wine grapes	0.02 (proposed)
Canada	Difenoconazole (plant commodities)	Grapes	4
China	Difenoconazole	Grapes	1.0 (proposed)*
CODEX	Difenoconazole (plant commodities)	Grapes	3
EU	Difenoconazole	Table grapes and wine grapes	3
Japan	Difenoconazole (plant commodities)	Grape	4
USA	Difenoconazole (plant commodities)	Grape	4

*Information from the applicant

1.7 Current and proposed Australian MRLs for difenoconazole

Table 4: Current relevant entries in the MRL Standard—Table 1

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

Table 5: Proposed changes to MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
Difenoconazole		
ADD:		
FB 1236	Wine-grapes	0.02

Table 6: Proposed changes to MRL Standard—Table 4

COMPOUND	FOOD	MRL (mg/kg)
Difenoconazole		
ADD:		
AB 0269	Grape pomace, dry	0.1

1.8 Potential risk to trade

The residue definition for plant commodities in Australia and overseas is difenoconazole.

Detectable difenoconazole residues are not expected in wine based on the highest residue observed in wine grapes (0.007 mg/kg) and a median processing factor for wine of 0.022x. Many overseas countries have established difenoconazole MRLs in grapes above the proposed Australian MRL of 0.02 mg/kg for wine grapes. The CODEX and EU MRLs are 3 mg/kg for grapes and wine grapes respectively, while the USA, Japan and Canada all have a grapes MRL established at 4 mg/kg. As detectable residues are not expected to occur in wine if the product is used as directed, the potential risk to trade is considered to be low.

The applicant has proposed the following label statement to mitigate the risk to trade in wine. It is appropriate and 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.

2 CONCLUSION

Nufarm Australia Limited, has applied for a variation of the registration of Nufarm Digger Fungicide to allow use on wine grapes. Comment is sought on the potential risk to trade in wine from the proposed use and the ability of the industry to manage any potential risk.