Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on difenoconazole in the product Nufarm Digger Fungicide for use on table grapes

APVMA Product Number 65130

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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 and Aging, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), 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 Thursday, 21 April 2016 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:

Scientific Assessment and Chemical Review
Residues and Trade
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.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Nufarm Australia Limited, to register Nufarm Digger Fungicide for use on table grapes for the control of powdery mildew.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Table grapes (including dried grapes) are considered to be major export commodities[2]. Residues in these commodities resulting from the use of Nufarm Digger Fungicide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

In 2013, Australia exported more than 70,000 tonnes of fresh table grapes valued at $200 million. Hong Kong, Indonesia, Vietnam, New Zealand, Thailand, Singapore, Malaysia, the UAE, China and Russia were the major export destinations.[3]

Australia exported 2.5 kt of dried vine fruit worth $10.3 million during 2014–2015.[4] In 2012–13 and 2013–14, Australia exported 2000–2500 tonnes of dried fruit (principally dried sultana grapes), valued at approximately $8 million. Dried grapes were primarily exported to Europe.

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

[3] Australian Table Grape Association: Australian Table Grapes the pick of the bunch, HAL0462 Grapes Industry Booklet

[4] Australian Bureau of Agricultural and Resource Economic Sciences (ABARES), Agricultural Commodity Statistics, December 2015: http://data.daff.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022015/ACS_2015_1.0.0.pdf

2.3 Proposed Australian use-pattern

Table 1: Proposed use pattern

CROP	PEST	RATE	CRITICAL COMMENTS
Grapes—table and dried (excluding wine) All states	Powdery mildew *(Erysiphe necator)*	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 five spray programme: 1. When shoots are 10–20 cm long. 2. Pre-flowering. 3. Flowering 4. After fruit set. 5. 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 125 mL of chemical/100 L water (5×). Do not apply in volumes less than 250 mL/ha.

Restraints

DO NOT apply by aircraft to grapevines

Withholding periods

Harvest: DO NOT harvest for 4 WEEKS after application.

Grazing: DO NOT graze vineyards after application

Trade advice

Trade advice information: 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 or dried) please check with your industry representative or Nufarm Australia Ltd.

2.4 Results from residues trials presented to the APVMA

The applicant submitted details of six GLP trials for Australian grapes conducted in 2013 and 2014. Three applications of difenoconazole were made ≈ 10 days apart at 1× and 2× the proposed label rate to the limit of runoff. Samples were collected nominally at 0, 14, 28, 42 and 56 DALA (reverse decline trials) and at 28 and 56 DALA (single point trials).

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 2× the proposed withholding period, 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 0.8× the proposed concentration and similar spray volumes to those used in Australia.

Residues of difenoconazole may concentrate in raisins and sultanas on drying of grapes. A theoretical processing factor of 5 was applied to the HR value for raw grapes (1.0 mg/kg) to give a HR-P of 5 mg/kg for dried grapes[5, 6].

It is recommended that Table 1 be updated to include an MRL for FB 1235 table-grapes of 2mg/kg and for DF 0269 Dried grapes (= currants, raisins and sultanas) of 6 mg/kg.

2.5 Overseas registration and approved label instructions

The applicant indicated that difenoconazole products are registered for use on grapevines to control powdery mildew in the USA, Canada and EU (France, Germany and Italy).

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 Codex CXLs and overseas MRLs have been established for difenoconazole.

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[5] Ruth English and Janine Lewis, Department of Community Services and Health, *Nutritional Values of Australian Foods*, Australian Government Publishing Service, Commonwealth of Australia, 1991.

[6] Joint Meeting of the Chemicals Committee and the Working Group on Chemicals, Pesticides and Biotechnology; Magnitude of Pesticide Residues in Processed Commodities, number 96: www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2008)23&doclanguage=en

Table 2: Relevant Codex and overseas MRLs for difenoconazole

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF DIFENOCONAZOLE (mg/kg)				
	AUSTRALIA	CODEX	EU	JAPAN	US
Residue definition	Difenoconazole	Difenoconazole*	Difenoconazole	Difenoconazole*	Difenoconazole*
Grapes	2 (table grapes, proposed)	3	3 (table grapes)	4	4
Dried grapes	6 (= currants, raisins and sultanas, proposed)	6 (=currants, raisins and sultanas)	-	-	6 (raisin)

*Residue definition for plant commodities listed

2.7 Current and proposed Australian MRLs for difenoconazole

Table 3: Current MRL Standard—Table1

COMPOUND		FOOD	MRL (mg/kg)
Difenoconazole			
		Anise myrtle leaves (dried)	T10
VS	0621	Asparagus	*0.05
FI	0326	Avocado	0.5
FI	0327	Banana	*0.02
VR	0574	Beetroot	T0.5
VR	0577	Carrot	0.2
VR	0578	Celeriac	T1
VS	0624	Celery	T5
GC	0080	Cereal grains	*0.01
VL	0464	Chard [silverbeet]	T3
VL	0469	Chicory leaves (green and red cultivars)	T3
		Coriander (leaves, stems and roots)	T20
SO	0691	Cotton seed	T0.05
MO	0105	Edible offal (Mammalian)	*0.05
PE	0112	Eggs	*0.05
VL	0476	Endive	T3
		Lemon myrtle leaves (dried)	T10

COMPOUND	FOOD	MRL (mg/kg)
TN 0669	Macadamia nuts	*0.01
MM 0095	Meat (mammalian)	*0.05
ML 0106	Milks	*0.01
HH 0749	Parsley	T20
FI 0350	Papaya [pawpaw]	1
FP 0009	Pome fruits	0.3
SO 0698	Poppy seed	T*0.01
VR 0589	Potato	*0.02
PM 0110	Poultry meat	*0.05
PO 0111	Poultry, Edible offal of	*0.05
	Riberries	T1
VL 0502	Spinach	T3
VO 0448	Tomato	0.5

Table 4: Proposed Changes to the MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
Difenoconazole		
ADD:		
DF 0269	Dried grapes (= Currants, Raisins and Sultanas)	6
FB 1235	Table-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.

Many overseas countries have established difenoconazole MRLs in grapes above the recommended Australian MRL of 2 mg/kg, however, some key Australian export markets for this commodity have not. The recommended MRL for dried grapes is equal to the overseas MRLs listed. As detectable residues are expected to occur if the product is used as directed this creates a potential risk to trade.

3 CONCLUSIONS

Nufarm Australia Limited have applied to vary the registration of Nufarm Digger Fungicide to include application to table grapes for the control of powdery mildew. The proposed use will require the establishment of an MRL for Table-grapes of 2 mg/kg and for Dried grapes (= currants, raisins and sultanas) of 6 mg/kg.

The applicant has proposed to include the following trade advice statement on the label:

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 or dried) please check with your industry representative or Nufarm Australia Ltd.

The APVMA proposes to be satisfied that the risk to trade associated with this new use is manageable under established industry systems. Comment is sought on the potential for Nufarm Digger Fungicide to prejudice Australian trade when used on table grapes.