



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



TRADE ADVICE NOTICE

on Difenoconazole in the Product Bogard 100 WG Foliar Fungicide

APVMA Product Number P48553

DECEMBER 2011

© Commonwealth of Australia 2011

This work is copyright. Apart from any use permitted under the *Copyright Act 1968*, no part may be reproduced without permission from the Australian Pesticides & Veterinary Medicines Authority. Requests and inquiries concerning reproduction and rights can be made to:

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Australia

Email: communications@apvma.gov.au

This document is published by the APVMA. In referencing this document the APVMA should be cited as both author and publisher.

Website: This publication is available from the APVMA website: <http://www.apvma.gov.au>

CONTENTS

PREFACE	IV
About this document	iv
Making a submission	iv
Further information	v
<hr/>	
1 INTRODUCTION	2
2 TRADE CONSIDERATIONS	3
2.1 Commodities exported	3
2.2 Destination and value of exports	3
2.3 Proposed Australian use-pattern	4
2.4 Results from residues trials presented to the APVMA	4
2.5 Codex alimentarius commission and overseas MRLs	5
2.6 Current and proposed Australian MRLs for difenoconazole	6
2.7 Potential risk to trade	7
<hr/>	
3 CONCLUSIONS	8

List of tables

Table 1: Largest Export markets by value for apples in the 2010 season	3
Table 2: Proposed use pattern	4
Table 3: Codex CXLs and overseas residue MRLs/tolerances for difenoconazole	5
Table 4: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4	6

PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator 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 proposed extensions of use for existing chemicals where there may be trade implications, as defined in *Ag MORAG: Manual of Requirements and Guidelines* Part 5B.

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 **BOGARD 100 WG FOLIAR FUNGICIDE** containing the existing active constituent difenoconazole 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. In relation to this document, these grounds relate to the **trade implications** of the extended use of the product. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on **31st January 2012** 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:

Contact Officer, Pesticides
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Phone: (02) 6210 4748

Fax: (02) 6210 4776

Email: pesticides@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: <http://www.apvma.gov.au>

¹ A full definition of "confidential commercial information" is contained in the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code).

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Syngenta Crop Protection Pty Limited to vary the registration of the product, Bogard 100 WG Foliar Fungicide, containing 100 g/kg difenoconazole, to include the claim for the suppression of powdery mildew in apples. The proposed extension of use does not require changes to the current MRL standards for difenoconazole.

The potential for difenoconazole residues in apples to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Pome fruits are considered to be major export commodities thus the presence of detectable residues has the potential to prejudice trade.

2.2 Destination and value of exports

Apples

Australia exported \$7.7 million worth of apples and \$8.0 million worth of pears in the 2010 season. The major export markets and value of apples exported to each major destination in the 2010 season are shown below.

Table 1: Largest Export markets by value for apples in the 2010 season

APPLES	
DESTINATION	VALUE, \$'000
Indonesia	1,780
Pacific Islands	1,440
India	1,330
EU	1,070
Taiwan	370
Vietnam	360
Japan	340
Sri Lanka	320
Malaysia	300
Thailand	200
TOTAL	7,730

2.3 Proposed Australian use-pattern

The use of Bogard 100 WG Foliar Fungicide (100 g/kg difenoconazole) on pome fruit is currently registered at a rate of 3.5 g ai/100 L. The proposed Australian use pattern for Bogard 100 WG Foliar Fungicide in apples is summarised below.

Table 2: Proposed use pattern

BOGARD 100 WG FOLIAR FUNGICIDE (100 G/KG DIFENOCONAZOLE)

CROP	DISEASE	CONCENTRATION	CRITICAL COMMENTS
Apples	Suppression of primary infection and control of secondary infections of Powdery Mildew (<i>Podosphaera leucotricha</i>)	Dilute spraying 50 g/100 L (5 g ai/100 L) Concentrate Spraying Refer to the Application section	Apply BOGARD 100 WG 10 days after spurburst at approximately the pink stage (late September/early October). Repeat 4 to 5 times at 10 to 14 day intervals. If susceptible varieties need further sprays after 6 applications of BOGARD 100 WG have been made, switch to an alternative Powdery Mildew fungicide. Refer to the Application section for appropriate application volumes.
<p>Restraint</p> <p>DO NOT apply more than 6 applications of this product per season. The effect of BOGARD 100 WG could be diminished if rain falls within 2 hours of application.</p> <p>NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p> <p>WITHHOLDING PERIODS:</p> <p>Apples: DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION</p>			

2.4 Results from residues trials presented to the APVMA

Pome Fruit

The proposed use of difenoconazole on apples involves up to 6 applications at a rate of 5 g ai/100 L, 10-14 days apart and a 28 day withholding period.

The Australian apple and pear data show that following 6-8 applications of difenoconazole at 5 g ai/100 L, residues in pome fruit 28 days after treatment were 0.05 (x3), 0.09 and 0.13 mg/kg.

Data from the 2007 JMPR shows that following four applications of difenoconazole at a rate of approximately 5 g ai/100 L, residues in pome fruit 14 days after treatment were 0.05, 0.07, 0.08, 0.10, 0.13, 0.14 and 0.15 mg/kg.

Based on the available data, the proposed use of difenoconazole on pome fruit (FP 0009) is supported from a residues perspective. It is considered that the established MRL of 0.3 mg/kg in conjunction with a withholding period of 28 days is appropriate for the proposed use.

Residues of difenoconazole in dry apple pomace following application of difenoconazole at 5 g ai/100 L were 0.50 and 0.65 mg/kg.

Based on the available Australian data, it is considered that the previously established MRL of 1 mg/kg for dry apple pomace remains appropriate.

Animal Commodities

Based on the maximum expected feeding level of 0.14 ppm, it is not expected that the established animal commodity MRLs for difenoconazole will be exceeded.

It is noted that the residue definition for difenoconazole in animal commodities established by Codex and the USA is the sum of difenoconazole and its metabolite CGA 205375. The residue definition established by the EU and Japan for difenoconazole in animal commodities is difenoconazole, the same as the Australian definition. Based on the maximum expected feeding level of 0.14 ppm, residues of difenoconazole and its metabolite CGA 205375 are expected to be below the limit of detection.

2.5 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. No changes are proposed to Australian animal commodity MRLs (which are established at the LOQ) and they will not be considered further. The following relevant overseas residue MRLs/ tolerances have been established for difenoconazole:

Table 3: Codex CXLs and overseas residue MRLs/tolerances for difenoconazole

COUNTRY/STATUS	COMMODITY	TOLERANCE, MG/KG
Australia	Pome fruits	0.3
Codex	Pome fruits	0.5
Canada	Apples	1.0
	Pears	1.0
EU	Apple (Crab apple)	0.5
	Pears (Oriental pear)	0.5

India	Apples	0.01
Japan	Apple	1
	Pear/Japanese pear	1
USA	Apple, wet pomace	4.5
	Fruit, pome group 11	1.0

2.6 Current and proposed Australian MRLs for difenoconazole

Current relevant MRLs and the residue definition for difenoconazole are presented below. A full listing of MRLs can be found at <http://www.apvma.gov.au/residues/standard.php>.

Table 4: Current relevant entries in the MRL Standard - Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
DIFENOCONAZOLE		
MO 0105	Edible offal (mammalian)	*0.05
PE 0112	Eggs	*0.05
MM 0095	Meat (mammalian)	*0.05
ML 0106	Milks	*0.01
FP 0009	Pome fruits	0.3
PM 0110	Poultry meat	*0.05
PO 0111	Poultry, Edible offal of	*0.05

MRL Standard: TABLE 3

COMPOUND	RESIDUE
DIFENOCONAZOLE	Difenoconazole

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
DIFENOCONAZOLE		
AB 0226	Apple pomace, dry	1

No changes to the current MRL standards for difenoconazole are necessary at this time.

2.7 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.

While several overseas countries have established difenoconazole MRLs in apples above the current Australian MRL of 0.3 mg/kg, some key Australian export markets for these commodities have not. For instance, India has established an MRL for difenoconazole in apples at 0.01 mg/kg.

3 CONCLUSIONS

It is proposed to increase the spray concentration for treatment of apples with difenoconazole from 3.5 to 5 g ai/100 L in Bogard 100 WG Foliar Fungicide. Comment is sought on the ability of industry systems to manage the risk associated with this increase in spray concentration, and the potential of the proposed use to unduly prejudice Australian trade in apples.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at (02) 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609

Office hours: 9.00 - 5.00 (EST) Monday to Friday