



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



TRADE ADVICE NOTICE

on cyantraniliprole in the product DuPont Exirel Insecticide

APVMA Product Number 64103

JANUARY 2017

© Australian Pesticides and Veterinary Medicines Authority 2017

ISBN 978-1-925390-62-9 (electronic)

Ownership of intellectual property rights in this publication

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Creative Commons licence

With the exception of the Coat of Arms and other elements specifically identified, this publication is licensed under a Creative Commons Attribution 3.0 Australia Licence. This is a standard form agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work.



A summary of the licence terms is available from www.creativecommons.org/licenses/by/3.0/au/deed.en. The full licence terms are available from www.creativecommons.org/licenses/by/3.0/au/legalcode.

The APVMA's preference is that you attribute this publication (and any approved material sourced from it) using the following wording:

Source: Licensed from the Australian Pesticides and Veterinary Medicines Authority (APVMA) under a Creative Commons Attribution 3.0 Australia Licence.

In referencing this document the Australian Pesticides and Veterinary Medicines Authority should be cited as the author, publisher and copyright owner.

Use of the Coat of Arms

The terms under which the Coat of Arms can be used are set out on the Department of the Prime Minister and Cabinet website (see www.dpmc.gov.au/pmc/publication/commonwealth-coat-arms-information-and-guidelines).

Disclaimer

The material in or linking from this report may contain the views or recommendations of third parties. Third party material does not necessarily reflect the views of the APVMA, or indicate a commitment to a particular course of action.

There may be links in this document that will transfer you to external websites. The APVMA does not have responsibility for these websites, nor does linking to or from this document constitute any form of endorsement.

The APVMA is not responsible for any errors, omissions or matters of interpretation in any third-party information contained within this document.

Comments and enquiries regarding copyright:

Director Public Affairs and Communication
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@apvma.gov.au

This publication is available from the APVMA website: www.apvma.gov.au.

CONTENTS

PREFACE	IV
About this document	iv
Making a submission	iv
Further information	v
<hr/>	
1 INTRODUCTION	6
2 TRADE CONSIDERATIONS	6
2.1 Commodities exported	6
2.2 Destination and value of exports	6
2.3 Proposed Australian use-pattern	7
2.4 Results from residues trials presented to the APVMA	7
2.5 Overseas registration and approved label instructions	8
2.6 Codex alimentarius commission and overseas MRLs	8
2.7 Current and proposed Australian MRLs for cyantraniliprole	9
2.8 Potential risk to trade	9
<hr/>	
3 CONCLUSIONS	10

LIST OF TABLES

Table 1: Largest export markets for citrus fruit in 2015	6
Table 2: Relevant overseas MRLs for cyantraniliprole	8
Table 3: Current MRL Standard – Table1	9
Table 4: Proposed changes to MRL Standard – Table1	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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, 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 DuPont Exirel Insecticide 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 Wednesday 8 February 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 or 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 APVMA has before it an application from DuPont (Australia) Pty Ltd, to vary the registration of DuPont Exirel Insecticide, to allow use on citrus fruit.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus fruits 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 treated byproducts of citrus processing. Residues in these commodities resulting from the use of DuPont Exirel Insecticide 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 citrus fruit is supported and the current animal commodity MRLs established at the LOQ will remain unchanged. Further consideration of the risk to trade in animal commodities is not required.

2.2 Destination and value of exports

In 2014–15 exports of fresh navel oranges were 106.9 kt (value \$125.3 m) and fresh Valencia oranges 13.5 kt (value \$13.1 m)³.

In 2014–15 exports of fresh and dried mandarins were 31.6 kt (value \$55.2 m)³.

In 2014–15 exports of fresh and dried lemons and limes were 2.7 kt (value \$6.1 m)³.

In 2014–15 exports of fresh and dried grapefruits were 0.2 kt (value \$0.3 m)³.

Major export markets for citrus fruit in 2015 are presented below:

Table 1: Largest export markets for citrus fruit in 2015⁴

CROP	MAJOR DESTINATIONS
Citrus fruit	China, Hong Kong, Singapore, Malaysia, the Middle East, the United States and Indonesia

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

³ Australian Commodity Statistics 2015, ABARES, December 2015.

⁴ dfat.gov.au/trade/agreements/iacepa/Documents/citrus-australia-2016.pdf

2.3 Proposed Australian use-pattern

DUPONT EXIREL INSECTICIDE (100 g/L CYANTRANILIPROLE)

CROP	PEST	RATE/100L	CRITICAL COMMENTS
Citrus	Rasping pest; Kelly's citrus thrips (<i>Pezothrips kellyanus</i>) Chewing pests; Fuller's rose weevil (<i>Asynonychus cervinus</i>) Light brown apple moth (<i>Epiphyas postvittana</i>)	Dilute spraying: 75 mL/100 L (7.5 g ai/100 L) DO NOT apply more than 3 L/ha (300 g ai/ha) Concentrate spraying: Refer to Mixing/Application section (DO NOT add a Surfactant/Wetting agent)	A maximum of two (2) applications are to be applied to any one crop per season. Monitor crops from flowering onwards for the presence of Kelly's citrus thrips and Lightbrown apple moth. Apply Exirel®, after flowering, once local pest thresholds are reached. A single application may be suitable where pest pressure is low. Continue to monitor crops and where thrips pressure is moderate to high, apply a second application, no less than 14 days after the first and prior to calyx closure. Fuller's rose weevil: Monitor for weevil emergence. Continue monitoring after spraying. Time at least one application to occur prior to the start of egg lay which usually occurs from late summer and through autumn. DO NOT retreat within fourteen (14) days. The use of Exirel® should be used in conjunction with other weevil control measures. DO NOT use for trunk band spraying.

Withholding periods:

Harvest: Nil

Grazing: DO NOT graze treated area or cut for stockfood

EXPORT OF TREATED PRODUCE: Suitable Maximum Residue Limits (MRLs) or import tolerances for produce treated with DuPont™ Exirel® insecticide may not be established in some countries. Consult with your exporter or DuPont before applying DuPont™ Exirel® to crops from which produce is to be exported.

2.4 Results from residues trials presented to the APVMA

The proposed use pattern for DuPont Exirel Insecticide on citrus fruit is for a maximum of two applications of 75 mL/100 L (7.5 g a.i./100 L) to a maximum of 3 L /ha (300g a.i./ ha) per application. A minimum retreatment interval of 14 days applies and a nil withholding period.

Residues of cyantraniliprole observed at a 0-day WHP from trials conducted on lemons, mandarins and oranges in Australia (6 trials), New Zealand (6 trials) and Europe (8 trials), in which two applications were made at a concentration of 7.6-10 g a.i./100L are, in rank order:

0.083, 0.12, 0.13, 0.16, 0.17, 0.17, 0.19, 0.19, 0.19, 0.20, 0.21, 0.22, 0.26, 0.26, 0.26, 0.29, 0.31, 0.35, 0.37 and 0.39 mg/kg (STMR = 0.205 mg/kg, n = 20).

Based on the Australian, New Zealand and European data the OECD MRL calculator estimates an MRL of 0.7 mg/kg. A cyantraniliprole MRL of 0.7 mg/kg for FC 0001 Citrus fruits, is considered appropriate, noting the variation in residue potential within the crop group.

The processing trials indicated that cyantraniliprole residues do not concentrate in juice.

Based on the observed highest residues in citrus fruit (0.39 mg/kg) and the average dry pulp processing factor of 0.51 mg/kg, highest residues of 0.20 mg/kg are estimated for citrus pulp, dry. A Table 4 entry of 0.5 mg/kg is considered appropriate for AB 0001 Citrus pulp, dry. The STMR-P is 0.10 mg/kg (0.205 × 0.51).

2.5 Overseas registration and approved label instructions

The applicant indicated that Exirel products are registered in a number of countries globally including Argentina, Australia, Canada, China, the Netherlands, New Zealand, South Africa and the USA.

The registered crops may vary between countries. For example in the USA, Exirel Insecticide is registered for use in citrus whereas in Brazil the oil-dispersion liquid cyantraniliprole product (Benevia Insecticide) has been proposed for use on oranges.

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. Cyantraniliprole has been considered by Codex, however no Codex MRLs relevant to citrus fruit have been established. The 2015 JMPR recommended a Citrus fruit MRL of 0.7 mg/kg which is currently at Step 5/8 (CCPR 2016). The following relevant overseas MRLs have been established for cyantraniliprole:

Table 2: Relevant overseas MRLs for cyantraniliprole

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF CYANTRANILIPROLE (mg/kg)						
	AUSTRALIA	EU	JAPAN	CODEX	USA	CANADA	KOREA
Residue definition	Cyantraniliprole						
Citrus fruit	0.7 ¹	*0.01 (0.9) ¹	0.7	0.7 ²	0.7	0.7	
Citrus oil, edible				4.5 ²			
Mandarins							0.7
Grapefruit							0.5 ¹
Lemons							0.6 ¹

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF CYANTRANILIPROLE (mg/kg)						
Oranges							0.7 ¹

¹ Proposed

² Proposed JMPR 2015; at step 5/8 CCPR 2016

2.7 Current and proposed Australian MRLs for cyantraniliprole

Table 3: Current MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
CYANTRANILIPROLE		
	All other foods	0.05
VA 0035	Bulb vegetables (except Onion, bulb)	7
SO 0691	Cotton seed	*0.01
MO 0105	Edible offal (Mammalian)	*0.01
PE 0112	Eggs	*0.01
VC 0045	Fruiting vegetables, Cucurbits	0.5
VO 0050	Fruiting vegetables, other than Cucurbits	2
MM 0095	Meat [mammalian] [in the fat]	*0.01
FM 0183	Milk fats	*0.01
ML 0106	Milks	*0.01
VA 0385	Onion, bulb	0.05
VR 0589	Potato	0.05
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat [in the fat]	*0.01

Table 4: Proposed changes to MRL Standard—Table1

COMPOUND	FOOD	MRL (MG/KG)
CYANTRANILIPROLE		
ADD:		
FC 0001	Citrus fruit	0.7

2.8 Potential risk to trade

The residue definition for Australia and overseas is cyantraniliprole.

An MRL for citrus fruit will be established at 0.7 mg/kg. The highest residues observed in Australian trials of the major crops in the crop group were 0.31 mg/kg.

It is noted that citrus fruit MRLs are established in several overseas countries at the same or higher levels to that proposed e.g. the USA, Canada and Japan have established MRLs at 0.7 mg/kg. An MRL at 0.7 mg/kg is proposed for CODEX (JMPR 2015), while an MRL at 0.9 mg/kg is proposed for the EU. The risk to Australia's trade in citrus fruit is expected to be low.

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

EXPORT OF TREATED PRODUCE: Suitable Maximum Residue Limits (MRLs) or import tolerances for produce treated with DuPont™ Exirel® insecticide may not be established in some countries. Consult with your exporter or DuPont before applying DuPont™ Exirel® to crops from which produce is to be exported.

3 CONCLUSIONS

DuPont (Australia) Pty Ltd, has applied for a variation of the registration of DuPont Exirel Insecticide to allow use on citrus fruit. Comment is sought on the potential risk to trade in citrus fruit from the proposed use and the ability of the industry to manage any potential risk.