

**Australian Government** 

Australian Pesticides and Veterinary Medicines Authority



# **Trade Advice Notice**

on metalaxyl-M in the product Ridomil Gold 480 SL Systemic Fungicide for use on peaches

APVMA product number 64812

January 2025

© Australian Pesticides and Veterinary Medicines Authority 2025

#### 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 4.0 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 and full licence terms are available from Creative Commons.

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 4.0 Australia Licence.

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

#### Photographic credits

Cover image: iStockphoto (www.istockphoto.com)

iStockphoto images are not covered by this Creative Commons licence.

#### 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.

#### 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:

Assistant Director, Communications Australian Pesticides and Veterinary Medicines Authority GPO Box 574 Canberra ACT 2601 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au

This publication is available from the APVMA website.

# Contents

Preface	1
About this document	1
Making a submission	1
Further information	2
Introduction	3
Trade considerations	4
Commodities exported	4
Destination and value of exports	4
Proposed Australian use pattern	5
Results from residues trials presented to the APVMA	5
Peaches	6
Codex Alimentarius Commission and overseas MRLs	6
Current and proposed Australian MRLs for metalaxyl	8
Potential risk to trade	8
Conclusion	9

# List of tables

Table 1:	Key export markets for Australian nectarines/peaches	4
Table 2:	Proposed use pattern – Ridomil Gold 480 SL Systemic Fungicide (480 g/L metalaxyl-M)	5
Table 3:	Current Australian and overseas MRLs/tolerances for metalaxyl	7
Table 4:	Current MRL Standard – Table 1	8
Table 5:	Proposed MRL Standard – Table1	8

## 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.

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 Trade Advice Notice indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered agricultural 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 Ridomil Gold 480 SL Systemic 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 24 February 2025 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 organisation name (if relevant)
- email or postal address (if available)
- the date you made the submission.

**Please note**: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the <u>public consultation coversheet</u>).

Please lodge your submission using the <u>public consultation coversheet</u>, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act* 1982 and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment Capability Australian Pesticides and Veterinary Medicines Authority GPO Box 574 Canberra ACT 2601 Australia

Phone: +61 2 6770 2300 Email: enquiries@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: <u>apvma.gov.au</u>.

## Introduction

The APVMA has before it an application from Syngenta Australia Pty Ltd to vary the registration of Ridomil Gold 480 SL Systemic Fungicide (Product number 64812) containing 480 g/L metalaxyl-M Soluble Concentrate to add a use on peaches.

The registered use of metalaxyl-M on peaches (Product number 50120, Granular formulation) involves application around the base of the tree trunk, applied in autumn and again in spring at a rate of 2.5 g ai/tree in conjunction with a harvest withholding period (WHP) of 6 weeks. The current metalaxyl Maximum Residue Limit (MRL) of 0.2 mg/kg for FS 0012 Stone fruits was established during the February 1984 Pesticides and Agricultural Chemicals Standing Committee (PACSC) meeting based on residue data on stone fruits.

It is noted that the registered use on peaches is for a different formulation type (Granular) than proposed (Soluble Concentrate). Extrapolation between these formulation types was not considered appropriate. New data relevant to the proposed formulation type was considered in support of the proposed use.

Based on the submitted data and the recommended harvest WHP of 21 days, the establishment of a metalaxyl MRL for FS 0247 Peach at 0.6 mg/kg is considered necessary. The current metalaxyl MRL for FS 0012 Stone fruits at 0.2 mg/kg should be amended to exclude peaches.

A metalaxyl peach MRL higher than the current stone fruit MRL is proposed which therefore requires further consideration with respect to trade. This Trade Advice Notice considers the risk to trade in peaches.

## **Trade considerations**

### **Commodities exported**

Stone fruits, including peaches, are considered to be major export commodities<sup>1</sup>, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated stone fruits. Residues in these commodities resulting from the use of *Ridomil Gold 480 SL Systemic Fungicide* may have the potential to unduly prejudice trade.

The maximum livestock dietary burden for metalaxyl will not increase, noting peaches are not a significant feed for livestock and a grazing restraint of "DO NOT graze any treated area or cut for stockfood." is recommended. The current animal commodity MRLs for metalaxyl therefore remain appropriate. The risk to trade in animal commodities remains unchanged and does not require further consideration at this time.

## **Destination and value of exports**

According to the Australian Horticulture Statistics Handbook 2022–23, for the year ending June 2023, Australia exported 9,909 tonnes of nectarines/peaches valued at \$46.3m<sup>2</sup>.

#### Table 1: Key export markets for Australian nectarines/peaches

Сгор	Major destinations
Nectarines/Peaches	China, Singapore, Hong Kong, Malaysia and United Arab Emirates

<sup>&</sup>lt;sup>1</sup> APVMA Regulatory Guidelines – Agricultural Data Guidelines: <u>Overseas trade (Part 5B)</u>, accessed November 2024

<sup>&</sup>lt;sup>2</sup> Australian Horticulture Statistics Handbook 2022/23 - <u>All Fruit - Overview</u>, accessed November 2024

#### **Proposed Australian use pattern**

Table 2:	Proposed use pattern -	- Ridomil Gold 480 SL	Systemic	Fungicide (480 g/L metalaxyl-M)	

Crop	Pest	Rate	Critical comments	
Peaches 5 years or	Phytophthora Trunk Rot	5.2 mL/tree (2.5 g ai/tree)	Apply in the autumn after harvesting is completed and again in the spring when	
older	(Phytophthora	(	trees have good leaf cover. Apply RIDOMIL® Gold 480 SL fungicide evenly in	
Curative treatment	cactorum)		a shallow (5 cm) gutter dug around the base of the tree trunk.	
	Phytophthora Root Rot	5.2 mL/tree	Clear all weed growth from under tree	
	(P. cinnamomi)	(2.5 g ai/tree)	canopy. To ensure that the fungicide is carried into the feeder root zone of the tree, apply when rain is imminent or use irrigation as soon as practical. It is essential that good management practices including proper mulching, fertilisation, and irrigation, where required, be followed to allow satisfactory response to root rot control by RIDOMIL® Gold 480 SL fungicide.	

Harvest withholding period:

Peaches: DO NOT harvest for 21 days after application.

Grazing: DO NOT graze any treated area or cut for stockfood.

#### Results from residues trials presented to the APVMA

The proposed use for peaches 5 years or older is for an application in autumn after harvesting is completed followed by an application in spring when trees have good leaf cover, applied in a shallow gutter dug around the base of the tree trunk at a rate of 2.5 g ai/tree in conjunction with a harvest withholding period of 21 days. An alternative use pattern at the same rate does not specify application timing with the same harvest withholding period.

## Peaches

A total of 9 Spanish Good Laboratory Practice (GLP) trials on peaches (5 trials) and nectarines (4 trials) relevant to the proposed use have been provided.

Metalaxyl-M residues (whole fruit basis) on peach and nectarine fruits at 20–21 days after last application (DALA), following 2 soil applications (30–33 days apart) of metalaxyl-M soluble concentrate (SL) at BBCH<sup>3</sup> 71-85 at 558-592 g ai/ha (equivalent to ~0.74–1.34 g ai/tree or ~0.3-0.5 × proposed rate), were in ranked order:

- peach: < 0.01, 0.01, 0.02, 0.04 and 0.10 mg/kg (n=5)
- nectarine: < 0.01, 0.02 (2) and 0.07 mg/kg (n=4)

When scaled to the proposed rate, residues are expected to be in ranked order:

- peach: < 0.02, 0.02, 0.06, 0.11 and 0.32 mg/kg (n=5)
- nectarine: < 0.02, 0.04, 0.05 and 0.24 mg/kg (n=4)

The peaches and nectarine trials were combined to estimate an MRL. The combined dataset suitable for MRL estimation is, in ranked order: < 0.02 (2), 0.02, 0.04, 0.05, 0.06, 0.11, 0.24 and 0.32 mg/kg (n=9).

Based on the combined dataset which considered residues at 21 DALA, the Organisation for Economic Cooperation and Development (OECD) MRL Calculator recommends an MRL of 0.6 mg/kg. A metalaxyl MRL of 0.6 mg/kg for FS 0247 Peach is considered appropriate to support the proposed use on peaches in conjunction with a harvest withholding WHP of 21 days. The metalaxyl MRL for FS 0012 Stone fruits currently established at 0.2 mg/kg will be changed to exclude peach: FS 0012 Stone fruits {except Peach} at 0.2 mg/kg.

### **Codex Alimentarius Commission and overseas MRLs**

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. 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. Metalaxyl has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for metalaxyl.

<sup>&</sup>lt;sup>3</sup> <u>Biologische Bundesanstalt, Bundessortenamt and CHemical industry -</u> Growth stages of mono- and dicotyledonous plants, accessed November 2024

Commodity	Tolerance for residues arising from the use of metalaxyl (mg/kg)					
	Australia <sup>4</sup>	EU <sup>5</sup>	Japan <sup>6</sup>	Codex <sup>7</sup>	USA <sup>8</sup>	China <sup>9</sup>
Residue Definition	Metalaxyl (Residues arising from the use of Metalaxyl- M are covered by the MRLs for Metalaxyl)	Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))(R)	Metalaxyl and mefenoxam refer to metalaxyl ( include metalaxyl M)	Metalaxyl (sum of enantiomers)	Combined residues of the fungicide metalaxyl [N- (2,6- dmethylphyenyl)- N- (methoxyacetyl) alanine methylester] and its metabolites containing the 2,6- dimethylaniline moiety, and N- (2-hydroxy methyl-6- methylphenyl)-N- (methoxyacetyl)- alanine methyl ester, each expressed as metalaxyl equivalents,	Metalaxyl
Peach	0.2 (Stone Fruits - current) 0.6 (Peach – proposed)	*0.01 (Peaches)	0.2	-	1.0 (Fruit, stone, group 12)	1 (Deciduous fruits)

#### Table 3: Current Australian and overseas MRLs/tolerances for metalaxyl

<sup>4</sup> <u>Agricultural and Veterinary Chemicals Code (MRL Standard for Residues of Chemical Products) Instrument 2023</u>, accessed November 2024

<sup>5</sup> European Commission, <u>EU Pesticide residue(s) and maximum residue levels (mg/kg)</u>, European Commission website, accessed November 2024.

<sup>6</sup> The Japan Food Chemical Research Foundation, <u>Maximum Residue Limits (MRLs) List of Agricultural Chemicals in Foods</u>, The Japan Food Chemical Research Foundation website, accessed November 2024.

- <sup>7</sup> Food and Agriculture Organisation of the United Nations, <u>Codex Alimentarius, International Food Standards</u>, FAO website, accessed November 2024.
- <sup>8</sup> Electronic Code of Federal Regulations, <u>USA Electronic Code of Federal Regulations</u>, eCFR website, accessed November 2024.

<sup>9</sup> USDA Foreign Agricultural Service, <u>Translation of Maximum Residue Limits for Pesticides in Foods</u>, USDA website, accessed November 2024

## Current and proposed Australian MRLs for metalaxyl

#### Table 4: Current MRL Standard – Table 1

Compound F		Food	MRL (mg/kg)
Metal	axyl		
FS	0012	Stone fruits	0.2

#### Table 5: Proposed MRL Standard – Table1

Compound		Food	MRL (mg/kg)
Metal	axyl		
Delet	e:		
FS	0012	Stone fruits	0.2
Add:			
FS	0247	Peach	0.6
FS	0012	Stone fruits {except Peach}	0.2

### Potential risk to trade

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

The proposed peach MRL of 0.6 mg/kg is higher than the Japanese MRL of 0.2 mg/kg for peach. It is greater than the EU MRL of \*0.01 mg/kg for peaches and lower than the USA MRL of 1.0 mg/kg for fruit, stone, group 12 and the China MRL of 1 mg/kg for deciduous fruits. It is noted that a metalaxyl MRL for peach or any stone fruit is currently not established by Codex, but that in the available residue trials only 2 out of 9 results were above the previous Australian stone fruit MRL of 0.2 mg/kg.

# Conclusion

Syngenta Australia Pty Ltd has applied to vary the registration of Ridomil Gold 480 SL Systemic Fungicide containing metalaxyl-M to add a use on peaches.

Comment is sought on the potential for the use of Ridomil Gold 480 SL Systemic Fungicide on peaches to prejudice Australian trade when used according to the proposed label instructions.