



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



Trade Advice Notice

on mandipropamid and oxathiapiprolin in the product
KEYBRI® Ultra Fungicide for use on grapes

APVMA product number 92989

August 2023

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Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the [APVMA website](#).

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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.

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 APVMA is considering an application to register a new agricultural product.

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 register KEYBRI® Ultra 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 **15 September 2023** 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 [public consultation coversheet](#)).

Please lodge your submission using the [public consultation coversheet](#), 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 3262
Sydney NSW 2001

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: apvma.gov.au.

Introduction

The APVMA has before it an application from Syngenta Australia Pty Ltd to register KEYBRI® Ultra Fungicide for use on grapes. KEYBRI® Ultra Fungicide contains mandipropamid and oxathiapirolin as its active constituents.

Mandipropamid is registered for use in grapes under product Revus Fungicide (63052); however, oxathiapirolin has not been previously considered for use on grapes in Australia.

No changes are required to the current animal commodity MRLs for mandipropamid and oxathiapirolin from the proposed use on grapes. The risk to trade in animal commodities remains unchanged and does not require further consideration.

Trade considerations

Commodities exported

Grapes (including dried grapes) and wine are considered to be major export commodities¹. Residues in these commodities resulting from the use of KEYBRI® Ultra Fungicide may have the potential to unduly prejudice trade.

Destination and value of exports

In 2020–21 Australia exported approximately 121 kilo tonnes (kt) of table grapes worth \$461 million, 3.37 kt of dried vine fruit worth \$17.8 million and 637 mega litres of wine worth approximately \$2.2 billion². Major export markets for table grapes include China, Indonesia, Hong Kong, Japan and Philippines and major exports markets for wine include United States of America, United Kingdom, Hong Kong, Canada, Singapore, New Zealand, Malaysia, Netherlands, Japan, Denmark, China, Sweden, Germany and Italy³.

¹ Australian Pesticides and Veterinary Medicines Authority (APVMA), 2020. [Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade \(Part 5B\)](#), APVMA website, accessed 18 August 2023.

² Hort Innovation, 2021. [Australian Horticulture Statistics Handbook 2021/22](#), Hort Innovation website, accessed 17 July 2023.

³ Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES), 2023. [Agricultural commodities and trade data – Agricultural commodity statistics](#), ABARES website, accessed 23 May 2023.

Proposed Australian use pattern

KEYBRI® Ultra Fungicide (250 g/L mandipropamid and 30 g/L oxathiapiprolin)

Table 1: Proposed use pattern

Crop	Pest	Rate/concentration	Critical comments
Grapes	Downy mildew (<i>Plasmopara viticola</i>)	Dilute spraying 50 to 60 mL/100 L of water (12.5 to 15 g mandipropamid/100 L water + 1.5 to 1.8 g oxathiapiprolin/100 L water) Concentrate spraying Refer to the Application section	Apply KEYBRI® Ultra fungicide within a protectant fungicide program aimed at controlling downy mildew. DO NOT apply more than 2 applications of KEYBRI® Ultra fungicide per season. Use the lower rate when applying at 10-to-14-day intervals as part of a downy mildew control program before the first sign of infection. Use the higher rate when applying at 14-to-21-day intervals as part of a downy mildew control program or when disease pressure is expected to be higher. Apply by dilute or concentrate spraying equipment. Apply the same amount of product to the target whether applying this product by dilute or concentrate spraying methods. DO NOT make KEYBRI® Ultra fungicide the last spray of the season. KEYBRI® Ultra fungicide should not make up more than 33% of sprays targeting downy mildew. This use is subject to a CropLife Australia Fungicide Resistance Management strategy.

Withholding periods

Harvest

Do not harvest for 4 weeks after application.

Grazing

Do not cut treated vines for stockfood or graze treated vineyards.

Trade advice

Export of treated produce

Growers should note that appropriate MRLs or import tolerances may not be established in all markets for fruit harvested from KEYBRI® Ultra Fungicide treated plants. If you are growing grapes for export (either

fresh, dried or as wine), please check with your export agent (in regard to fresh and dried grapes), the Australian Wine Research Institute (in regard to wine) or Syngenta Australia for the latest information on MRLs and import tolerances before using KEYBRI® Ultra Fungicide.

Results from residues trials presented to the APVMA

The proposed use of KEYBRI® Ultra Fungicide involves a maximum of 2 applications at 12.5 to 15 g mandipropamid/100 L + 1.5 to 1.8 g oxathiapiprolin/100 L in a maximum spray volume of 3,000 L/ha water, at a re-treatment interval of 10 to 21 days in conjunction with a harvest withholding period of 4 weeks and a grazing restraint 'Do not cut treated vines for stockfood or graze treated vineyards.'

In support of the proposed use, the applicant has provided 13 grape residue trials conducted in Australia (6) and Brazil (7).

Mandipropamid

Grapes

In the 2021–22 Australian trials, highest mandipropamid residues in grapes following a foliar single application applied at berries beginning to soften to berries with intermediate sugar values (EL-34-36) at 45 g mandipropamid/100 L (3x concentrate spray) at 30 DAA or after one to 2 applications at longer intervals, were: 0.03, 0.04, 0.08, 0.09 (2) and 0.10 mg/kg (n=6).

In the 2015–17 Brazilian trials, mandipropamid residues in grapes following 2 foliar applications applied at 50% final size of fruit and 7 days before harvest (BBCH 75 to 85) at 250 g mandipropamid/ha (~0.55x proposed) at 21 days after last application (DALA), were: 0.08, 0.13, 0.14, 0.20, 0.37, 0.63 (2) mg/kg (n=7). Scaled to the proposed rate (assuming a maximum spray volume of 3,000 L/ha) residues would be expected to be: 0.14, 0.23, 0.25, 0.36, 0.67 and 1.1 (2) mg/kg (n=7). The supervised trials median residue (STMR) is 0.36 mg/kg.

The Brazilian trials with the same number of applications as proposed were considered suitable for MRL estimation. Based on the available data the existing mandipropamid MRL for Grapes at 0.3 mg/kg will be replaced by a recommended MRL at 2 mg/kg for [FB 0269] Grapes to cover mandipropamid residues arising in grapes from the proposed use in conjunction with the harvest withholding period of 4 weeks.

Wine and juice

In previously submitted processing studies, residues of mandipropamid were not observed to concentrate in wine or grape juice. Separate MRLs are therefore not required for wine or juice.

Raisins

In the previously submitted US processing studies, the highest processing factor for raisins was 8.8x (with a mean value of 4.82x and median value of 4.15x). Multiplying the highest processing factor (8.8x) by the grape highest residue (HR) of 1.1 mg/kg gives the highest residue in the processed commodity (HR-P) of 9.7 mg/kg. The supervised trials median residue in processed commodity (STMR-P) is 1.73 mg/kg.

Based on the available information, a mandipropamid MRL of 10 mg/kg for [DF 0269] Dried Grapes (= Currants, Raisins and Sultanas) is recommended to cover mandipropamid residues in dried grapes as a result of the proposed use. The recommended MRL will replace the existing mandipropamid MRL of 2 mg/kg for [DF 0296] dried grapes.

Grape pomace

In previously submitted Australian processing trials, the highest processing factor for dry pomace was 23x (with a mean value of 14x and median value of 13x). Multiplying the grape HR of 1.1 mg/kg by the highest processing factor of 23x gives an HR-P of 25.3 mg/kg for dry grape pomace. The STMR-P is 5.04 mg/kg.

Based on the calculated HR-P, a mandipropamid MRL of 30 mg/kg [AB 0269] grape pomace, dry is recommended to cover the proposed use of mandipropamid in grapes in conjunction with a harvest withholding period of 4 weeks. The recommended MRL will replace the existing MRL of 5 mg/kg for [AB 0269] grape pomace, dry.

Oxathiapiprolin

Grapes

In the 2021–22 Australian trials, highest oxathiapiprolin residues in grapes following a foliar single application applied at berries beginning to soften to berries with intermediate sugar values (EL-34-36) at 5.4 g oxathiapiprolin/100 L (3x concentrate spray) at 30 DAA or after one to 2 applications at longer intervals, were: <LOQ (2), 0.01 (2) and 0.02 (2) mg/kg (n=6).

In the 2015–17 Brazilian trials, oxathiapiprolin residues in grapes following 2 foliar applications applied at 50% final size of fruit and 7 days before harvest (BBCH 75 to 85) at 30 g oxathiapiprolin/ha (~0.55x proposed) at 21 days after last application (DALA), were: 0.01, 0.02 (2), 0.03, 0.04 and 0.08 (2) mg/kg (n=7). Scaled to the proposed rate (assuming a maximum spray volume of 3000 L/ha) residues would be expected to be: 0.02, 0.04 (2), 0.05, 0.07 and 0.14 (2) mg/kg (n=7). The supervised trials median residue (STMR) is 0.05 mg/kg.

The Brazilian trials with the same number of applications as proposed were considered suitable for MRL estimation. Based on the available data and noting some conservatism in the MRL estimation, an oxathiapiprolin MRL of 0.3 mg/kg for [FB 0269] Grapes is recommended to cover oxathiapiprolin residues arising in grapes as a result of the proposed use in conjunction with the proposed harvest withholding period of 4 weeks.

Wine

In the submitted grape processing study, oxathiapiprolin residues did not concentrate in wine. A separate wine MRL is not required, as residues in wine will not exceed the grape MRL as a result of the proposed use.

Raisins

In the processing study, the highest processing factor for raisins was 4.1x (with a mean value of 1.97x (median P_f = 1.45x). Multiplying the highest processing factor (4.1x) by the HR of 0.14 mg/kg gives an HR-P of 0.57 mg/kg. The STMR-P is 0.10 mg/kg.

Based on the available information, an oxathiapiprolin MRL of 1 mg/kg for [DF 0269] Dried Grapes (= Currants, Raisins and Sultanas) is recommended to cover oxathiapiprolin residues arising in dried grapes as a result of the proposed use.

Grape pomace

The highest processing factors for oxathiapiprolin residues in grape pomace was 16.7x (with a mean value of 12.18x median P_f = 14.25x). Multiplying the HR of 0.14 mg/kg by the highest processing factor (16.7x) gives an HR-P value of 2.34 mg/kg for dry grape pomace. The STMR-P is 0.71 mg/kg.

Based on the calculated HR-P, an MRL of 3 mg/kg is therefore recommended for oxathiapiprolin in AB 0269: grape pomace, dry.

Overseas registration and approved label instructions

The applicant indicated that KEYBRI® Ultra is registered in various countries globally including but not limited to Brazil, Canada, Greece, India, Japan, Portugal, Taiwan, United Arab Emirates, United States and Vietnam. Products containing mandipropamid and oxathiapiprolin, on their own and formulated with other active ingredients, are registered in Australia and internationally.

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. Mandipropamid and oxathiapiprolin have been considered by Codex. The following relevant Codex CXLs and/or international MRLs have been established for mandipropamid and oxathiapiprolin.

Table 2: Current and proposed Australian and overseas MRLs/tolerances for mandipropamid

Commodity	Tolerance for residues arising from the use of mandipropamid (mg/kg)							
	Australia ⁴	Codex ⁵	China ⁶	EU ⁷	Japan ⁸	Korea ⁹	Taiwan ¹⁰	USA ¹¹
Residue definition	Mandipropamid	Mandipropamid	Mandipropamid	Mandipropamid (any ratio of constituent isomer)	Mandipropamid	–	–	Mandipropamid
Grape	0.3 (current) 2 (proposed)	2	2	2	3	5	1.5	1.4 (subgroup 13–07F)
Grape, dried (= Currants, Raisins and Sultanas)	2 (current) 10 (proposed)	5	5 (Raisin)	–	–	–	5 (Raisin)	3 (Raisin)

⁴ Australian Government Federal Register of Legislation, 2019. [Agricultural and Veterinary Chemicals Code \(MRL Standard\) Instrument 2019](#), Federal Register of Legislation website, accessed 27 June 2023.

⁵ Food and Agriculture Organisation of the United Nations (FAO), 2023. [Codex Alimentarius – International Food Standards](#), FAO website, accessed 27 June 2023.

⁶ United States Department of Agriculture (USDA) Foreign Agricultural Service, 2021. [People's Republic of China – USFDA, Translation of MRLs of Pesticides in Foods](#), USDA website, accessed 27 June 2023.

⁷ European Commission, 2023. [European Commission – Pesticide residue\(s\) and maximum residue levels \(mg/kg\)](#), European Commission website, accessed 27 June 2023.

⁸ The Japan Food Chemical Research Foundation, (JFCRF), 2023. [Maximum Residue Limits \(MRLs\) List of Agricultural Chemicals in Foods](#), JFCRF website, accessed 27 June 2023.

⁹ Food Safety Korea, 2015. [Pesticide and Veterinary Drugs Information](#), FSK website, accessed 27 June 2023.

¹⁰ Food and Drug Authority, 2023. [Standards for Pesticide Residue Limits in Foods 2023/06/15](#) –, FDA website, accessed 27 June 2023.

¹¹ Electronic Code of Federal Regulations (eCFR), 2023. [USA Electronic Code of Federal Regulations](#), eCFR website, accessed 27 June 2023.

Table 3: Current and proposed Australian and overseas MRLs/tolerances for oxathiapiprolin.

Commodity	Tolerance for residues arising from the use of oxathiapiprolin (mg/kg)							
	Australia ¹²	Codex ¹³	China ¹⁴	EU ¹⁵	Japan ¹⁶	Korea ¹⁷	Taiwan ¹⁸	USA ¹⁹
Residue definition	Oxathiapiprolin	Oxathiapiprolin	Oxathiapiprolin	Oxathiapiprolin	Oxathiapiprolin	–	–	Oxathiapiprolin
Grape	0.3 (Proposed)	0.9	–	0.7	0.9	1.0	0.2	0.7
Grape, dried (= Currants, Raisins and Sultanas)	1 (Proposed)	1.3	1.3 (Raisin)	–	–	–	–	–

¹² Australian Government Federal Register of Legislation, 2019. [Agricultural and Veterinary Chemicals Code \(MRL Standard\) Instrument 2019](#), Federal Register of Legislation website, accessed 27 June 2023.

¹³ Food and Agriculture Organisation of the United Nations (FAO), 2023. [Codex Alimentarius – International Food Standards](#), FAO website, accessed 27 June 2023.

¹⁴ United States Department of Agriculture (USDA) Foreign Agricultural Service, 2021. [People's Republic of China – USFDA, Translation of MRLs of Pesticides in Foods](#), USDA website, accessed 27 June 2023.

¹⁵ European Commission, 2023. [European Commission – Pesticide residue\(s\) and maximum residue levels \(mg/kg\)](#) European Commission website, accessed 27 June 2023.

¹⁶ The Japan Food Chemical Research Foundation (JFCRF), 2023. [Maximum Residue Limits \(MRLs\) List of Agricultural Chemicals in Foods](#), JFCRF website, accessed 27 June 2023.

¹⁷ Food Safety Korea, 2015. [Pesticide and Veterinary Drugs Information](#), FSK website, accessed 27 June 2023.

¹⁸ Food and Drug Authority, 2023. [Standards for Pesticide Residue Limits in Foods 2023/06/15](#), FDA website, accessed 27 June 2023.

¹⁹ Electronic Code of Federal Regulations (eCFR), 2023. [USA Electronic Code of Federal Regulations](#), eCFR website, accessed 27 June 2023.

Current and proposed Australian MRLs for mandipropamid and oxathiapiprolin

Table 4: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Mandipropamid		
DF 0269	Dried grapes (= currants, raisins and sultanas)	2
MO 0105	Edible offal (mammalian)	*0.01
FB 0269	Grapes	0.3
MM 0095	Meat (mammalian) [in the fat]	*0.01
ML 0106	Milks	*0.01
Oxathiapiprolin		
MO 0105	Edible offal (mammalian)	*0.01
MM 0095	Meat (mammalian) [in the fat]	*0.01
ML 0106	Milks	*0.01

Table 5: Current MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Mandipropamid		
AB 0269	Grape pomace, dry	5

Table 6: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Mandipropamid		
Delete:		
DF 0269	Dried grapes (=current, raisins and sultanas)	2
FB 0269	Grapes	0.3
Add:		
DF 0269	Dried grapes (=current, raisins and sultanas)	10
FB 0269	Grapes	2
Oxathiapiprolin		

Compound	Food	MRL (mg/kg)
Add:		
DF 0269	Dried grapes (=current, raisins and sultanas)	1
FB 0269	Grapes	0.3

Table 7: Proposed MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Mandipropamid		
Delete:		
AB 0269	Grape pomace, dry	5
Add:		
AB 0269	Grape pomace, dry	30
Add:		
Oxathiapiprolin		
AB 0269	Grape pomace, dry	3

Potential risk to trade

Export of treated produce containing finite (measurable) residues of mandipropamid and oxathiapiprolin 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 applicant has proposed the following trade advice on the proposed label which is considered appropriate and acceptable.

Export of Treated Produce: Growers should note that appropriate MRLs or import tolerances may not be established in all markets for fruit harvested from KEYBRI® Ultra Fungicide treated plants. If you are growing grapes for export (either fresh, dried or as wine), please check with your export agent (in regard to fresh and dried grapes), the Australian Wine Research Institute (in regard to wine) or Syngenta Australia for the latest information on MRLs and import tolerances before using KEYBRI® Ultra Fungicide.

Mandipropamid and oxathiapiprolin residues do not concentrate in wine (mean $P_i = 0.13x$), therefore separate MRLs for wine are not required.

For mandipropamid, the proposed MRL for grapes is 2 mg/kg which is equivalent to the MRLs/Tolerances established by the EU, Codex and China. Korea has a mandipropamid MRL for grapes established at

5 mg/kg and Japan at 3 mg/kg, whereas Taiwan's mandipropamid MRL is lower than the proposed MRL at 1.5 mg/kg. The USA also has an MRL at 1.4 mg/kg.

The proposed mandipropamid MRL for Grapes, dried (= Currants, Raisins and Sultanas) is 10 mg/kg (STMR-P = 1.73 mg/kg). Codex has dried grapes MRL established at 5 mg/kg. China, Taiwan and the US have mandipropamid MRLs for raisins established at 5 mg/kg. Noting the STMR-P value of 1.73 mg/kg, and bulking and mixing of dried grapes during processing, poses a low risk to international trade to the countries where lower mandipropamid MRLs for dried grapes are established.

For oxathiapiprolin, MRLs/Tolerances are established by Codex, USA, Canada, Japan, Korea, the EU and Taiwan at levels ranging from 0.2 to 1 mg/kg. The risk of trade of grapes and wine is considered low to these markets noting the proposed Australian MRL is 0.3 mg/kg. Oxathiapiprolin has not been considered by China for fresh table grapes, and wine. These situations present a potential risk to international trade for exported grape products to these markets.

The proposed oxathiapiprolin MRL for Grapes, dried (=Currants, Raisins and Sultanas) is 1 mg/kg which is lower than 1.3 mg/kg established by the Codex and China (raisins only). The EU, Japan, Korea and Taiwan have not established a MRL for dried grapes for oxathiapiprolin.

Conclusion

Syngenta Australia Pty Ltd has applied for registration of a new product, KEYBRI® Ultra fungicide containing mandipropamid and oxathiapiprolin for use on grapes.

Comment is sought on the potential for the proposed use to cause undue risk to the Australian trade of grapes, dried grapes and wine and the ability of industry to manage any potential trade risk.