

Australian Government

Australian Pesticides and Veterinary Medicines Authority



Trade Advice Notice

on ipflufenoquin in the product Migiwa Kinoprol Active Fungicide for use on apples, pears and wine grapes

APVMA product number 91333

November 2023

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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 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 Migiwa Kinoprol Active 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 5 December 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 <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 and 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 AgNova Technologies Pty Ltd to vary the registration of Migiwa Kinoprol Active Fungicide to add uses on apples, pears and wine grapes. Migiwa Kinoprol Active Fungicide is a Suspension Concentrate (SC) formulation containing 218 g/L ipflufenoquin and is currently only registered for use on strawberries in Australia in both field and protected cropping situations.

Trade considerations

Commodities exported

Apples, pears and wine are considered to be major export commodities¹, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated apple and grape pomace. Residues in these commodities resulting from the use of Migiwa Kinoprol Active Fungicide may have the potential to unduly prejudice trade. As residues are not expected to occur in animal commodities (see Table 4), it is proposed that they do not require further consideration with respect to trade at this time.

Destination and value of exports

In 2021 Australia exported 2,147 t of fresh apples valued at \$5.9 million. Major export markets were Papua New Guinea (PNG), Italy, Hong Kong, Thailand and India. In 2021 Australia exported 8,229 t of fresh pears valued at \$13.5 million. Major export markets were New Zealand, Canada, Singapore, Indonesia and the United States of America (USA).²

Australian exports of wine totalled 637 mL (\$2,197 million) in 2021–22. The major export markets for wine in the year ending June 2021 included United States, United Kingdom, Hong Kong, Canada, Singapore, New Zealand, Netherlands, Japan, Denmark and China.³

The significant export markets for Australian beef, sheep, pig meat and offal are listed in the APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B).

Proposed Australian use pattern

Migiwa Kinoprol Active Fungicide (218 g/L ipflufenoquin).

¹ APVMA Regulatory Guidelines – Data Guidelines: Agricultural - <u>Overseas trade (Part 5B)</u>, last updated 20 July 2020, last reviewed 21 June 2023, accessed November 2023

² <u>Australian Horticulture Statistics Handbook</u>, 2020/21, Horticulture Innovation Australia Ltd, accessed November 2023.

³ Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES), <u>Agricultural Commodity Statistics</u> <u>2022</u>, Department of Agriculture, Fisheries and Forestry website, accessed November 2023.

Crop	Pest	Concentration	WHP	Critical comments
Wine grapes	Grey mould/Botrytis bunch rot <i>(Botrytis cinerea)</i>	Dilute spraying: 25 mL/100 L of water (5.45 g ai/	-	Apply preventatively when conditions (varietal and climatic) are conducive to disease development as part of a grey mould management spray program. Up to 2 applications of MIGIWA can be applied per season, with the final application no later than the growth stage E-L 29, berries peppercorn size (not > 4 mm in diameter).
		100 L)		Apply one application MIGIWA per season if a total of 2–3 fungicide applications are planned for grey mould management in a season. Two applications of MIGIWA can be made per season if ≥4 fungicide applications are planned for grey mould management in a season. Do not use MIGIWA in consecutive applications for grey mould management.
				Applications for the management of grey mould should focus on key growth stages and weather conditions. Applications of MIGIWA can be made between E-L 20 (10% capfall), and E-L 29 (berries pepper-corn size). Apply by dilute or concentrate spraying equipment. Apply in sufficient water volume to obtain thorough coverage of the crop, especially of flowers and fruit. As the crop grows, the required dilute spray volume will increase, and the sprayer setup and operation may also need to be changed. Refer to the section on concentrate spraying if low spray volumes are to be used. Apply the same amount of product per hectare to the target crop whether applying by dilute or concentrated spray volumes. Follow the CropLife Australia resistance management guidelines for grey mould in grapes.
Apples	Black spot/apple scab (Venturia inaequalis) Powdery mildew (Podosphaera leucotricha)	Dilute spraying: 15 mL/100 L of water (3.27 g ai/ 100 L)	uria spraying: weeks conducive to disease as part of a disease as part o	Apply before first sign of disease or when conditions are conducive to disease as part of a disease management program. Applications may commence at green tip or spur burst for black spot control, or at early pink stage for powdery mildew control. Applications for the control of Alternaria should begin after flowering (petal-fall) and during early fruit development.
	Alternaria (Alternaria spp.)			Apply sprays at 7- to-10-day intervals. Use the shorter intervals under conditions favouring disease infection or rapid crop growth.
Pears	Pears Black spot/pear scab (Venturia pirina)			As the crop grows, the required dilute spray volume to achieve complete coverage will change, and the sprayer setup and operation may also need to be changed.
				Refer to the section on concentrate spraying if low spray volumes are to be used.
				For resistance management: Do not apply more than 2 consecutive sprays of MIGIWA or apply more than 3 sprays per season.

Table 1: Proposed use pattern

Withholding periods:

Harvest:

Wine grapes: Not required when used as directed.

Apples, pears: Do not harvest for 6 weeks after application.

Grazing:

Do not graze livestock in treated vineyards or orchards.

Restraints:

DO NOT apply by aircraft.

Trade advice:

Growers should note that MRLs or import tolerances do not exist in all markets for fruit treated with MIGIWA Kinoprol Active Fungicide.

Pome fruit: Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. BEFORE using MIGIWA Kinoprol Active Fungicide, you are advised to contact AgNova Technologies and/or your industry body about any potential trade issues and their management.

Wine grapes: Contact your winery or the Australian Wine Research Institute (AWRI) at www.awri.com.au for the updated information on MRLs and overseas import tolerances BEFORE using MIGIWA Kinoprol Active Fungicide.

Results from residues trials presented to the APVMA

Apples, pears

The proposed use on apples and pears is for up to 3 applications, each at 3.27 g ai/100 L in conjunction with a 6-week harvest withholding period.

Australian residue trials conducted over 2 seasons under Good Laboratory Practice (GLP) on apples (5) and pears (3) have been provided.

Residues of ipflufenoquin in apples approximately 42 days after the last of 3 applications at 4.2 g ai/100 L (1.28× proposed) were <0.003 (2), <0.005, 0.006 and 0.007 mg/kg. Residues in pears were 0.008, 0.01 and 0.02 mg/kg. The combined dataset for MRL recommendation is <0.003 (2), <0.005, 0.006, 0.007, 0.008, 0.01 and 0.02 mg/kg. The Organisation for Economic Cooperation and Development (OECD) Maximum Residue Limit (MRL) Calculator recommends an MRL of 0.03 mg/kg (Supervised Trial Median Residue (STMR) = 0.007 mg/kg, n = 8). Given a High Residue (HR) of 0.02 mg/kg, an MRL of 0.05 mg/kg is recommended for ipflufenoquin on FP 0009 Pome fruits in conjunction with the proposed 6-week harvest withholding period.

In an apple processing study, residues did not concentrate on processing to juice or canned apple sauce. Residues in these commodities should be covered by the proposed pome fruit MRL. Residues did concentrate on processing to dried apples (processing factors 3.77×, 4.18×, 1.32× and 1.18×). Applying the highest processing factor for dried apples to the apple HR (0.007 mg/kg) gives an HR-P for dried apples of 0.029 mg/kg which is still within the proposed ipflufenoquin pome fruit MRL of 0.05 mg/kg.

Processing factors to wet pomace were 2.55×, 5.53×, 3.58× and 1.23×. The OECD Livestock Feed Calculator indicates that wet apple pomace contains 40% dry matter. The highest processing factor on a dry weight basis is therefore 13.8× giving an HR-P in dry apple pomace of 0.28 mg/kg (13.8 × 0.02). An MRL of 0.5 mg/kg is recommended for ipflufenoquin on AB 0226 Apple pomace, dry in conjunction with the proposed 6-week harvest withholding period. The STMR-P for dry apple pomace for calculation of the livestock dietary burden is 0.10 mg/kg (13.8 × 0.007).

Wine grapes

The proposed use of ipflufenoquin on wine grapes is for up to 2 applications at 5.45 g ai/100 L, with the final application no later than the growth stage E-L 29, berries peppercorn size (not > 4 mm in diameter).

Australian GLP residue trials on wine grapes over 2 seasons (2 + 6 trials) have been provided.

Grapes

Residues in wine grapes from the Australian trials after 2 applications at 7.7 to 7.9 g ai/100 L (~1.4× proposed) with the last application at E-L 29⁴ were <0.005, <0.005, 0.007, 0.008, 0.009, 0.011, 0.027 and 0.035 mg/kg. Scaled for application rate residues were <0.005, <0.005, 0.005, 0.006, 0.006, 0.008, 0.019 and 0.025 mg/kg. The OECD MRL Calculator recommends an MRL of 0.04 mg/kg (STMR = 0.006 mg/kg, n = 8).

An MRL of 0.04 mg/kg is recommended for ipflufenoquin on FB 1236 Wine grapes in conjunction with the proposed withholding period of 'Not required when used as directed'.

Wine

Residues in wine from the Australian trials after 2 applications at 7.7 to 7.9 g ai/100 L (\sim 1.4× proposed) with the last application at E-L 29 were <0.003 (7) and 0.008 mg/kg. Scaled for application rate residues were <0.003 (7) and 0.006 mg/kg.

Estimated residues in wine were generally below method LOQs. A separate MRL is not required for wine as residues did not concentrate in this commodity and will be covered by the wine grape MRL recommended above.

⁴ E-L is a numbering system for identifying major and intermediate grapevine growth stages.

Pomace

Residues in grape pomace from the Australian trials after 2 applications at 7.7 to 7.9 g ai/100 L (~1.4× proposed) with the last application at E-L 29 were 0.039, 0.047, 0.048, 0.064, 0.087, 0.090, 0.130 and 0.135 mg/kg on a dry weight basis. Scaled for application rate residues were 0.027, 0.032, 0.033, 0.045, 0.061, 0.062, 0.090 and 0.096 mg/kg on a dry weight basis. The OECD MRL Calculator recommends an MRL of 0.2 mg/kg (STMR = 0.053 mg/kg, n = 8).

An MRL of 0.2 mg/kg is recommended for ipflufenoquin on AB 0269 Grape pomace, dry in conjunction with the proposed withholding period of 'Not required when used as directed'.

Animal commodities

There is a restraint against allowing livestock to graze treated orchards or vineyards. Apple and grape pomace are feeds for cattle in Australia. The estimated dietary burdens for beef and dairy cattle from the OECD Livestock Feed Calculator are summarised in Table 2 and Table 3.

Beef cattle- for MRLs							
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	AU diet content (%)	AU residue contribution (pmm)
						AU	AU
Apple pomace, wet	AB	0.1	STMR	100	0.1	20	0.02
Total						20	0.02

Table 2: Estimated livestock dietary burden for beef cattle

Table 3: Estimated livestock dietary burden for dairy cattle

Dairy cattle – for MRLs							
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	AU diet content (%)	AU residue contribution (pmm)
						AU	AU
Apple pomace, wet	AB	0.1	STMR	100	0.1	10	0.01
Grape pomace, wet	AB	0.053	STMR	100	0.1	10	0.01
Total						20	0.02

Estimated residues in tissues and milk and required MRLs are summarised in Table 4.

	Milk	Muscle	Liver	Kidney	Fat			
Feeding level (ppm)	Parent ipflufenoquin residue (total residue for risk assessment) (mg/kg)							
2.5 (feeding study)	<0.01	<0.01	<0.01	<0.01	<0.01			
	(<0.024)	(<0.024)	(0.049)	(0.03)	(<0.024)			
0.02 – beef, estimated burden	_	<0.01	<0.01	<0.01	<0.01			
		(<0.024)	(<0.024)	(<0.024)	(<0.024)			
0.02 – dairy, estimated burden	<0.01	_	_	_	_			
	(<0.024)							
Established MRLs	*0.01 (milks)	*0.01 (meat in fat)		*0.01 (offal)	_			
Recommended MRLs	No change	No change		No change	_			

Table 4: Estimated residues in tissues and milk and required mammalian commodity MRLs

No changes are required to the current mammalian commodity MRLs for ipflufenoquin established at the method LOQ. Quantifiable residues according to the risk assessment definition are also not expected to occur.

Poultry

Apple and grape pomace are not considered to be common feeds for poultry in Australia. Current poultry MRLs for ipflufenoquin established at the method LOQ should remain appropriate.

Overseas registration and approved label instructions

The applicant indicated that ipflufenoquin products are registered for use on apples, pears and grapes in Japan, on pome fruit in the USA and on apples and pears in Korea.

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. Ipflufenoquin has not been considered by Codex. The following relevant international MRLs have been established for ipflufenoquin.

Commonditur	Tolerance for residues arising from the use of ipflufenoquin (mg/kg)							
Commodity	Australia	Codex₅	EU٩	Japan ⁷	Korea ^s	Taiwan [。]	USA10	
Residue definition	lpflufenoquin	-	-	Ipflufenoquin	-	-	Ipflufenoquin	
Pome fruit	0.05	-	_	2 (apple, pear)	0.3 (apple, pear)	_	0.15	
Wine grapes	0.04	_	_	6 (grape)	3.0 (grapes)	_	_	

Table 5: International MRLs established for ipflufenoquin

Current and proposed Australian MRLs for ipflufenoquin

Table 6: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Ipflufenoquin		
MO 0105	Edible offal (mammalian)	*0.01
PE 0112	Eggs	*0.01
MM 0095	Meat (mammalian) [in the fat]	*0.01
ML 0106	Milks	*0.01
PM 0110	Poultry meat [in the fat]	*0.01
PO 0111	Poultry, edible offal of	*0.01

⁷ Japanese Food Chemistry Research Foundation, <u>Table of MRLs for Agricultural Chemicals</u>, JFCRPF website, accessed November 2023.

⁹ Laws & Regulations Database of the Republic of China (Taiwan), <u>Standards for Pesticide Residue Limits in Foods</u>, accessed November 2023.

⁵ Food and Agriculture Organization of the United Nations, <u>Codex Alimentarius, International Food Standards</u>, FAO website, accessed November 2023.

⁶ European Commission, <u>EU Pesticide residue(s) and maximum residue levels (mg/kg)</u>, European Commission website, accessed November 2023.

⁸ Ministry of Food and Drug Safety, Korea, <u>MRLs in Pesticides</u>, accessed November 2023.

¹⁰ Electronic Code of Federal Regulations, <u>USA Electronic Code of Federal Regulations</u>, eCFR website, accessed November 2023.

Table 7: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Ipflufenoquin		
Add:		
FP 0009	Pome fruits	0.05
FB 1236	Wine grapes	0.04

Table 8: Proposed MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Add:		
lpflufenoquin		
AB 0226	Apple pomace, dry	0.5
AB 0226	Grape pomace, dry	0.2

Potential risk to trade

Export of treated produce containing finite (measurable) residues of ipflufenoquin 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 Australian pome fruit MRL is lower than the relevant MRLs established in Japan, Korea and the USA. In the available residue trials, residues in apples and pears were <0.01 mg/kg by 8 weeks after treatment (although there were some detections above the LOQ of 0.005 mg/kg).

The proposed Australian wine grapes MRL is lower than the grapes MRLs established in Japan and Korea, noting also that estimated residues in wine were generally below the method LOD (0.003 mg/kg) in the available residue trials.

The following export advice has been proposed to manage any potential risks to trade:

EXPORT OF TREATED PRODUCE

Growers should note that MRLs or import tolerances do not exist in all markets for fruit treated with MIGIWA Kinoprol Active Fungicide.

Pome fruit: Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. BEFORE using MIGIWA Kinoprol Active Fungicide, you are advised to contact AgNova Technologies and/or your industry body about any potential trade issues and their management.

Wine grapes: Contact your winery or the Australian Wine Research Institute (AWRI) at www.awri.com.au for the updated information on MRLs and overseas import tolerances BEFORE using MIGIWA Kinoprol Active Fungicide.

Given the low residues (<0.01 mg/kg) observed in wine and also in apples and pears if an 8-week export interval is observed, it is proposed that the risk to trade is low and should be manageable by industry systems.

Conclusion

AgNova Technologies Pty Ltd have applied to vary the registration of Migiwa Kinoprol Active Fungicide to add uses on apples, pears and wine grapes. Comment is sought on the potential for the proposed uses to pose a risk to Australian trade.