



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



Trade Advice Notice

on pyraclostrobin and fluxapyroxad in the product
Merivon Fungicide for use on lemon and tangelo

APVMA product number 85698

June 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 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 Merivon 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 30 June 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:

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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](#).

Introduction

The APVMA has before it an application from BASF Australia Ltd to vary the registration of Merivon Fungicide containing pyraclostrobin and fluxapyroxad to add uses on lemon and tangelo.

Pyraclostrobin and fluxapyroxad together are registered for the control of various diseases in macadamia, almond and cherries (Merivon Fungicide, P85698). There are currently no registered or permitted uses of pyraclostrobin and fluxapyroxad on lemon and tangelo.

Trade considerations

Commodities exported

Citrus fruits 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 citrus fruits. Residues in these commodities resulting from the use of Merivon Fungicide may have the potential to unduly prejudice trade. As the maximum livestock dietary burden for pyraclostrobin and fluxapyroxad will not increase from the proposed use, noting the existing animal feed commodity Maximum Residue Limits (MRLs) listed in Table 6, the risk to trade in animal commodities remains unchanged and does not require further consideration.

Destination and value of exports

Australia exported 238,576 to 284,667 tonnes of fresh citrus (grapefruit, lemons/limes, mandarins and oranges) annually from 2017–22². For the year ending June 2022, Australia exported 4,678 tonnes (\$8.2 million) of lemons/limes. The export value for tangelos is not known but not expected to be significant.

Table 1: Major destinations for Australian lemons/limes² (year ending June 2022)

Crop	Major destinations
Lemons/limes	Indonesia, Japan, Malaysia, Canada and USA

Proposed Australian use pattern

Table 2: Proposed use pattern – Merivon Fungicide (250 g/L pyraclostrobin+ 250 g/L fluxapyroxad)

Crop	Disease	Rate/concentration	Critical comments
Lemon and Tangelo	Emperor brown spot (<i>Alternaria alternata</i>) and Blossom blight/mould (<i>Botrytis cinerea</i>)	25 mL/100 L (6.25 g ai/100 L pyraclostrobin+ 6.25 g ai/100 L fluxapyroxad)	<p>Use Merivon in a preventative fungicide program with spray intervals of 7 to 14 days.</p> <p>Apply a maximum of 3 applications of MERIVON a year, and no more than 2 consecutive applications per year.</p> <p>Apply as a dilute spray up to the point of runoff, to a maximum volume of 2000 L/ha.</p> <p>Ensure that fungicides from an alternative chemical group are included in the spray program each season.</p>

¹ Australian Pesticides and Veterinary Medicines Authority, [APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade \(Part 5B\)](#), APVMA website, 20 July 2020, accessed May 2023.

² Hort Innovation, [Australian Horticulture Statistics Handbook 2021–22 – Fruit](#), Hort Innovation website, accessed May 2023.

Withholding periods

Harvest

Nil

Restrictions

DO NOT apply with aircraft.

Results from residues trials presented to the APVMA

The proposed use in lemon and tangelo allows a maximum of 3 applications of pyraclostrobin and fluxapyroxad (7 to 14 days apart) a year, applied as a preventative application at a concentration of 6.25 g ai/100 L pyraclostrobin and 6.25 g ai/100 L fluxapyroxad in conjunction with a harvest withholding period (WHP) of *Nil* (equal to zero days).

Australian residue trials on lemon and tangelo are supported by Brazilian residue trials on lemons.

In the 7 Australian trials on lemon (3) and tangelo (4), 3 foliar applications of pyraclostrobin and fluxapyroxad were made between BBCH³ 60 to 89, with a re-treatment interval (RTI) of 14 days, at a nominal concentration of 6.25 g ai/100 L pyraclostrobin+ 6.25 g ai/100 L fluxapyroxad (1× the proposed concentration). Pyraclostrobin and fluxapyroxad residues were determined in lemon and tangelo fruits taken at 0, 7±1, 14±1 and 21±1 days after last application (DALA).

In the 2 Brazilian trials on lemon, 3 foliar applications of pyraclostrobin and fluxapyroxad plus an adjuvant were made at BBCH 73 to 89, with an RTI of 27 to 29 days, at a nominal rate of 99.9 g ai/ha pyraclostrobin+ 50.1 g ai/ha fluxapyroxad (equivalent to ~0.8× and ~0.4× the proposed maximum rate, respectively). Pyraclostrobin and fluxapyroxad residues were determined in lemon fruits taken at 0, 7, 14, 21 and 28 DALA.

Lemon fruit

Pyraclostrobin

The Australian and Brazilian trials were combined to estimate an MRL. The combined dataset suitable for MRL estimation is, in ranked order: 0.08, 0.10, 0.20, 0.25 and 0.32 mg/kg (n=5). The Supervised Trials Median Residue (STMR) is 0.2 mg/kg. The Organisation for Economic Co-operation and Development (OECD) MRL calculator estimates an MRL of 0.6 mg/kg, noting the uncertainty due to the small dataset.

A pyraclostrobin MRL of 0.7 mg/kg for FC 0204 Lemon is considered appropriate for the proposed use of pyraclostrobin on lemon in conjunction with a harvest WHP of *Nil*.

³ BBCH is a system for a uniform coding of phenologically similar growth stages of all mono- and dicotyledonous plant species.

Fluxapyroxad

The results of the Brazilian trials were scaled to the proposed concentration and were combined with the Australian trials to estimate an MRL. The combined dataset suitable for MRL estimation is, in ranked order: 0.15, 0.25, 0.26, 0.38 and 0.42 mg/kg (n=5). The STMR is 0.26 mg/kg. The OECD MRL calculator estimates an MRL of 0.9 mg/kg, noting the uncertainty due to the small dataset.

A fluxapyroxad MRL of 1 mg/kg for FC 0204 Lemon is considered appropriate for the proposed use of fluxapyroxad on lemon in conjunction with a harvest WHP of *Nil*.

Tangelo fruit

Pyraclostrobin

Based on the Australian trials, the dataset suitable for MRL estimation is, in ranked order: 0.14, 0.19, 0.21 and 0.42 mg/kg (n=4). The STMR is 0.20 mg/kg. The OECD MRL calculator estimates an MRL of 0.8 mg/kg, noting the uncertainty due to the small dataset.

Pyraclostrobin MRLs of 1 mg/kg for FC 4029 Tangelo, large-sized cultivars and FC 4031 Tangelo, small and medium sized cultivars are considered appropriate for the proposed use of pyraclostrobin on tangelo in conjunction with a harvest WHP of *Nil*.

Fluxapyroxad

Based on the Australian trials, the dataset suitable for MRL estimation is, in ranked order: 0.15, 0.18, 0.22 and 0.62 mg/kg (n=4). The STMR is 0.20 mg/kg. The OECD MRL calculator estimates an MRL of 1.5 mg/kg, noting the uncertainty due to the small dataset.

Fluxapyroxad MRLs of 1.5 mg/kg for FC 4029 Tangelo, large-sized cultivars and FC 4031 Tangelo, small and medium sized cultivars are considered appropriate for the proposed use of fluxapyroxad on tangelo in conjunction with a harvest WHP of *Nil*.

Processing

In a pyraclostrobin processing study conducted in oranges in the USA, oranges collected from one site were processed to produce washed oranges, pulp (dried), oil and juice. Pyraclostrobin residues were determined in unwashed oranges and in the processed orange commodities and a mean processing factor of 8.9× for pulp (dry) was calculated.

In a fluxapyroxad processing study conducted in oranges in the USA, oranges collected from 2 sites were processed to produce wet pomace, dried pulp, peel, juice, marmalade and oil. Fluxapyroxad residues were determined in unwashed oranges and in the processed orange commodities and a mean processing factor of 4.8× for pulp (dry) was calculated.

Animal feeds

Pyraclostrobin

Based on the combined dataset (lemon+ tangelo) used to estimate pyraclostrobin MRLs for lemon and tangelo and using a mean processing factor of 8.9 for pulp (dry), the Highest Residues-Processed (HR-P) and STMR-P in citrus pulp (dry) are estimated to be 3.76 mg/kg and 1.81 mg/kg, respectively. A pyraclostrobin MRL of 5 mg/kg for AB 0001 Citrus pulp, dry is considered appropriate for the proposed use of pyraclostrobin on lemon and tangelo in conjunction with a harvest WHP of *Nil*.

Fluxapyroxad

Based on the combined dataset (lemon+ tangelo) used to estimate fluxapyroxad MRLs for lemon and tangelo and using a mean processing factor of 4.8 for pulp (dry), the HR-P and STMR-P in citrus pulp (dry) are estimated to be 2.98 mg/kg and 1.20 mg/kg, respectively. A fluxapyroxad MRL of 4 mg/kg for AB 0001 Citrus pulp, dry is considered appropriate for the proposed use of fluxapyroxad on lemon and tangelo in conjunction with a harvest WHP of *Nil*.

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. Pyraclostrobin and fluxapyroxad have been considered by Codex. The following relevant Codex CXLs/overseas MRLs have been established for pyraclostrobin and fluxapyroxad.

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

Commodity	Tolerance for residues arising from the use of pyraclostrobin (mg/kg)					
	Australia	EU ⁴	Japan ⁵	Codex ⁶	Canada ⁷	USA ⁸
Residue definition	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin+ the metabolite 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl] carbamate	Pyraclostrobin+ its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]carbamate)
Citrus fruits	–	2 (Citrus fruits, Grapefruits, Oranges)	2 (Citrus NATSUDAIDAI, (whole), Orange (including navel orange), Grapefruit, Other citrus fruits)	2 (Citrus fruits (group), Citrus oil, edible)	2 (Citrus hybrids, Citrus oil, Citrus citrons, Calamondins, Grapefruits, Kumquats, Oranges)	2.0 (Fruit, citrus, group 10-10)
Lemon	0.7 (Lemon – proposed)	2 (Lemons, Limes)	2 (Lime)	–	2 (Lemons, Limes)	–

⁴ European Commission, [EU Pesticide residue\(s\) and maximum residue levels \(mg/kg\)](#), European Commission website, accessed May 2023.

⁵ Japanese Food Chemistry Research Foundation, [Table of MRLs for Agricultural Chemicals](#), JFCRPF website, accessed May 2023.

⁶ Food and Agriculture Organisation of the United Nations, [Codex Alimentarius, International Food Standards](#), FAO website, accessed May 2023.

⁷ Health Canada, [Maximum Residue Limits for Pesticides](#), Health Canada website, accessed May 2023.

⁸ Electronic Code of Federal Regulations, [USA Electronic Code of Federal Regulations](#), eCFR website, accessed May 2023.

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Commodity	Tolerance for residues arising from the use of pyraclostrobin (mg/kg)					
	Australia	EU ⁴	Japan ⁵	Codex ⁶	Canada ⁷	USA ⁸
Tangelo	1	2	–	–	2	–
	(Tangelo, large-sized cultivars; Tangelo, small and medium-sized cultivars – proposed)	(Mandarins, Others)			(Pummelos, Tangerines, Satsuma mandarins)	

Table 4: Current and proposed Australian and overseas MRLs/tolerances for fluxapyroxad

Commodity	Tolerance for residues arising from the use of fluxapyroxad (mg/kg)							
	Australia		EU ⁴	Japan ⁵	Codex ⁶	Canada ⁷	USA ⁸	
Residue definition	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	
Citrus fruits	–	0.6 (Grapefruits), 1.5 (Oranges)	(Citrus NATSUDAIDAI, whole; Orange (including navel orange), Grapefruit, Other citrus fruits)	1	(Oranges, sweet, sour (including Orange-like hybrids) (subgroup))	1.5	1	1.0
						(Grapefruits, Calamondins, Oranges, Japanese summer grapefruits, Tachibana oranges, Citrus citrons, Citrus hybrids, Uniq fruits, Kumquats)	(Fruit, citrus, group 10-10)	
Lemon	1	1	1	1	1	1	–	
	(Lemon – proposed)	(Lemons, Limes)	(Lemon, Lime)	Lemons and limes (including citron)(subgroup))	(Lemons, Limes)			

Commodity	Tolerance for residues arising from the use of fluxapyroxad (mg/kg)					
	Australia	EU ⁴	Japan ⁵	Codex ⁶	Canada ⁷	USA ⁸
Tangelo	1.5 (Tangelo, large-sized cultivars; Tangelo, small and medium-sized cultivars – proposed)	1 (Mandarins), *0.01 (Others)	–	1 (Mandarins (including mandarin-like hybrids (subgroup)), 0.6 (Pummelo and grapefruits (including Shaddock-like hybrids, among others Grapefruit) (subgroup))	1 (Tangelos, Tangerines, Tangors, Pummelos, Mediterranean mandarins, Satsuma mandarins)	–

Current and proposed Australian MRLs for pyraclostrobin and fluxapyroxad

Table 5: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Fluxapyroxad		
Add:		
FC 0204	Lemon	1
FC 4029	Tangelo, large-sized cultivars	1.5
FC 4031	Tangelo, small and medium sized cultivars	1.5
Pyraclostrobin		
Add:		
FC 0204	Lemon	0.7
FC 4029	Tangelo, large-sized cultivars	1
FC 4031	Tangelo, small and medium sized cultivars	1

Table 6: Current MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Fluxapyroxad		
AB 0226	Apple pomace, dry	5
	Forage and fodder of cereal grains	20
	Primary feed commodities {except Forage and fodder of cereal grains}	1
Pyraclostrobin		
AB 0226	Apple pomace, dry	25
	Cereal forage, green	5
AB 0269	Grape pomace, dry	10
AS 0081	Straw and fodder (dry) of cereal grains	0.5

Table 7: Proposed MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Fluxapyroxad		
Add:		
AB 0001	Citrus pulp, dry	4
Pyraclostrobin		
Add:		
AB 0001	Citrus pulp, dry	5

Potential risk to trade

Export of treated produce containing finite (measurable) residues of pyraclostrobin and fluxapyroxad 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 recommended MRLs of 0.7 mg/kg for pyraclostrobin and 1 mg/kg for fluxapyroxad on lemon and 1 mg/kg for pyraclostrobin on tangelos are no greater than those established internationally. Whilst the recommended MRL of 1.5 mg/kg for fluxapyroxad on tangelo is higher than those established internationally for tangelos (USA and Canada only) and similar citrus fruits (i.e. mandarins and pummelos), tangelos are not generally considered to be a major export commodity.

Conclusion

BASF Australia Ltd has applied to vary the registration of Merivon Fungicide containing pyraclostrobin and fluxapyroxad to add uses on lemon and tangelo.

Comment is sought on the potential for the use of Merivon Fungicide on lemon and tangelo to prejudice Australian trade when used according to the proposed label instructions.