



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



Trade Advice Notice

on mefentrifluconazole in the product Belanty[®] Fungicide for use on cotton

APVMA product number 84344

January 2024

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ISSN 2200-3894 (electronic)

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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 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 for emergency use of Belanty® 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 19 January 2024 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 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 Cotton Australian Limited for an emergency permit for the use of Belanty® Fungicide containing 75 g/L mefentrifluconazole on cotton.

Trade considerations

Commodities exported

Cotton seed and its derived oils and meals 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 forages and fodders. Residues in these commodities resulting from the use of Belanty® Fungicide may have the potential to unduly prejudice trade.

Destination and value of exports

Australia exported an estimated 550 kt of total oilseeds worth AUD\$5967 million in the fiscal year 2021–222. Australian exports of cottonseed comprised of approximately 306 kt.

The major export markets for cottonseed in 2021–22 were China, Korea and Japan⁶.

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). However, no changes are required to the current animal commodity MRLs, and an ESI is not required for the use considered here.

Proposed Australian use pattern

Table 1: Proposed use pattern

Crop	Pest	Rate/concentration	Critical comments
Cotton (field)	<i>Ramularia</i> Leaf spot	1.25 L/ha (93.75 g ai/ha)	Apply BELANTY prior to an infection period when conditions favour the development of disease.
Incl. genetically modified crops			Apply by aircraft in a minimum spray volume of 30 L/ha. Apply by boom sprayer in spray volumes of 70–100 L/ha.

Restrictions

DO NOT apply if heavy rains or storms are forecast within 3 days.

DO NOT apply more than 3 applications per crop.

¹ APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B)

² Australian Bureau of Agricultural and Resource Economics – [Agricultural Commodity Statistics](#), website accessed 5 December 2023.

DO NOT apply less than 15-day intervals between applications.

DO NOT irrigate to the point of field runoff for at least 3 days after application.

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature inversion conditions exist most evenings one to 2 hours before sunset and persist until one to 2 hours after sunrise.

BELANTY is not compatible with Dithane Rainshield Neo Tech 750 WG.

Withholding periods

Harvest

Do not harvest for 30 days after the last application.

Grazing

DO NOT feed cotton fodder, stubble or trash to livestock.

Results from residues trials presented to the APVMA

Mefentrifluconazole residues in undelinted cottonseed following 3 applications at ~1.6× the proposed rate, at a re-treatment interval of 6–9 days, at 29–31 days PHI, in rank order, were: <0.01, 0.01, 0.03 (2), 0.05, 0.06 (2), 0.07 (2), 0.10, 0.12 and 0.16 mg/kg (n=12). Scaling down to the proposed rate, mefentrifluconazole residues in undelinted cottonseeds were: <0.01 (2), 0.02 (2), 0.03, 0.04 (4), 0.06, 0.08 and 0.10 mg/kg (n=12).

The OECD MRL calculator estimates an MRL of 0.15 mg/kg. The STMR was 0.04 mg/kg.

Based on the available information and noting a re-treatment interval of 6–9 days in the submitted trials compared with a re-treatment interval of 15 days, a mefentrifluconazole MRL of 0.2 mg/kg for (SO 0691) Cotton seed is recommended to cover mefentrifluconazole residues arising in cottonseed as a result of the proposed use in conjunction with a harvest withholding period of 30 days.

Cotton gin-byproducts

Mefentrifluconazole residues in cotton trash following 3 applications at ~1.6× the proposed rate, at a re-treatment interval of 6–9 days, at 29–31 days PHI, in rank order, were: 1.64, 3.80 and 4.14 mg/kg. Scaling down to the proposed rate, mefentrifluconazole residues in cotton trash were: 1.03, 2.38 and 2.59 mg/kg (n=3).

Cotton forage and fodder data was not provided. It is not considered good practice to feed cotton fodder, stubble or trash to livestock. 'Table 4 – Animal Feed Commodities' entries for the MRL Standard will not be established for these commodities at this time (an MRL of T5 mg/kg would be required for mefentrifluconazole on cotton trash should this practice be changed in the future). It is recommended that the following restraint be included on the permit: 'DO NOT feed cotton fodder, stubble or trash to livestock'.

Processing studies

Processing studies have not been provided. The highest scaled residue in cotton seed is at the 0.1 mg/kg threshold for requirement of a processing study. However, the STMR is significantly lower. Processing factors reported by the 2022 JMPR for cotton hulls, meal and refined oil were all <1.

Overseas registration and approved label instructions

The applicant indicated that Belanty[®] Fungicide is registered for use on rice, banana, tomato, soy and grapes in Brazil.

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. Mefentrifluconazole MRLs recommended by the 2022 JMPR are being considered by Codex. The following relevant Codex CXLs have been established for mefentrifluconazole.

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

Commodity	Tolerance for residues arising from the use of mefentrifluconazole (mg/kg)					
	Australia	China ³	Codex	EU ⁴	Japan ⁵	Korea ⁶
Residue definition	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole ⁷	Mefentrifluconazole	Mefentrifluconazole	–
Cotton seed	T0.2 (PROPOSED)		0.2 (proposed by 2022 JMPR, based on same dataset considered here, but different GAP)	*0.01	0.2	–

³ United States Department of Agriculture (USDA) 2023, [National Food Safety Standard for Maximum Residue Limits of 112 Pesticides in Foods Released](#), accessed 5 December 2023.

⁴ European Commission – [Pesticide residues and maximum residues levels](#), website accessed 5 December 2023.

⁵ The Japan Food Chemical Research Foundation – [Pesticides Database](#), website accessed 5 December 2023.

⁶ Food Safety Korea – [Pesticides and Veterinary Drugs Information](#), website accessed 5 December 2023.

⁷ World Health Organization (WHO) – [FAO Plant Production and Protection Paper series](#), website accessed 5 December 2023.

Current and proposed Australian MRLs for mefentrifluconazole

Table 3: Current MRL Standard – Table1

Compound	Food	MRL (mg/kg)
Mefentrifluconazole		
SO 0495	Rape seed (canola)	T0.05

Table 4: Proposed MRL Standard – Table1

Compound	Food	MRL (mg/kg)
Mefentrifluconazole		
Add:		
SO 0691	Cotton seed	T0.2

Potential risk to trade

Export of treated produce containing finite (measurable) residues of mefentrifluconazole may pose a risk to Australian trade in situations where:

- no residue tolerance (import tolerance) is established in the importing country
- residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

The overall risk to export trade in animal commodities is considered to be unaffected by the proposed use in cotton seed. Therefore, no changes are required to the current animal commodity MRLs, and an ESI is not required.

The EU has established a cotton seed MRL for mefentrifluconazole at *0.01 mg/kg. Japan is one of the major export markets for Australian cotton seed. The Japanese cotton seed MRL is currently established at 0.2 mg/kg, which is the same as the proposed Australian MRL. It is noted that the other 2 important export markets, China, and Korea, have not established a cotton seed MRL for mefentrifluconazole. An MRL of 0.2 mg/kg for cotton seed has been proposed by the 2022 JMPR and is being considered by Codex.

The applicant has requested aerial application. None of the registered mefentrifluconazole products are approved for application by air. However, there are buffer zones for ground application in place for the protection of international trade.

For residues of parent to be at the LOQ (0.01 mg/kg), the maximum feeding level is 0.46 ppm. If the RAL for mefentrifluconazole is used in the APVMA Spray Drift Risk Assessment tool, the following label statements are required for protection of international trade, assuming droplets are not smaller than medium.

The following advice in relation to spray drift and protection of international trade should be added to the permit:

SPRAY DRIFT RESTRAINTS		
Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift		
DO NOT allow bystanders to come into contact with the spray cloud.		
DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The advisory buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.		
DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.		
DO NOT apply if there are surface temperature inversion conditions present at the application site during the time of application. These conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.		
DO NOT apply by a boom sprayer unless the following requirements are met:		
<ul style="list-style-type: none"> - spray droplets not smaller than a MEDIUM spray droplet size category - minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed. 		
Buffer zones for boom sprayers		
Application rate	Boom height above the target canopy	Livestock areas
Up to maximum label rate	0.5 m or lower	Not required
	1.0 m or lower	30 metres
DO NOT apply by a vertical sprayer.		
DO NOT apply by aircraft unless the following requirements are met:		
<ul style="list-style-type: none"> - spray droplets not smaller than a MEDIUM spray droplet size category - for maximum release heights above the target canopy of 3m or 25% of wingspan or 25% of rotor diameter whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for aircraft') are observed. 		
Buffer zones for aircraft		
Type of aircraft	Livestock areas	
Fixed wing	220 metres	
Helicopter	140 metres	

Conclusion

Cotton Australian Limited has applied for an emergency permit for the use of Belanty® Fungicide containing 75 g/L mefentrifluconazole on cotton. Comment is sought on the potential for the proposed use to pose a risk to Australian trade.