Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on isocycloseram in the product Vertento Insecticide for use on citrus

APVMA product number 93995

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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 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 register Vertento Insecticide 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 **Friday 10 May 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 Syngenta Australia Pty Ltd to register Vertento Insecticide, a Suspension Concentrate (SC) formulation containing 400 g/L isocycloseram. The product is proposed for use on almonds, macadamias, citrus and various tropical and subtropical fruit with inedible peel. This Trade Advice Notice relates only to the use on citrus, which are the only one of the requested commodities currently considered to be a major export commodity.

It is noted that the submitted residue trials indicate that quantifiable residues of isocycloseram are not expected to occur in almond and macadamia kernels or in avocado or mango whole fruit from the other uses not discussed further in this Trade Advice Notice.

Trade considerations

Commodities exported

Almonds, macadamias and assorted tropical and sub-tropical fruit – inedible peel are not currently considered to be major export commodities and do not require further consideration with respect to trade in this notice.

Citrus fruit are considered to be major export commodities[1], 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 pulp or almond hulls. Residues in these commodities resulting from the use of Vertento Insecticide may have the potential to unduly prejudice trade. As no changes are required to the current animal commodity Maximum Residue Limits (MRLs) for isocycloseram which are established at the Limit of Quantification (LOQ) for the analytical method they do not require further consideration with respect to trade at this time.

Destination and value of exports

In 2021–22 Australia exported 243,436 tonnes of fresh citrus fruits valued at $451.2 million.[2] Major export markets for grapefruit were Japan, Canada, Hong Kong, China and United States. Major export markets for lemons/limes were Indonesia, Japan, Canada, Malaysia and United States. Major export markets for mandarins were China, Thailand, Philippines, New Zealand and Indonesia. Major export markets for oranges were Japan, Hong Kong, China, Singapore and Malaysia.

[1] APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B), last updated 20 July 2020, last reviewed 21 June 2023, APVMA website, accessed April 2024

[2] Hort Innovation, *Australian Horticulture Statistics Handbook 2021/22 - Fruit*, Hort Innovation website, accessed April 2024.

Proposed Australian use pattern

Vertento Insecticide (400 g/L Isocycloseram).

Table 1: Proposed use pattern

Crop	Pest	Concentration	Critical comments
Citrus	Banana spotting bug (*Amblypelta lutescens*) Fruit spotting bug (*Amblypelta nitida*) Fuller's rose weevil (*Naupactus godmanni*) Kelly's citrus thrips (*Pezothrips kellyanus*) Light brown apple moth (*Epiphyas postvittana*)	Dilute spraying 5 mL/100 L plus adjuvant[Δ] (2 g ai/100 L)	**Kelly's citrus thrips**: Monitor orchard and commence VERTENTO® insecticide applications after flowering when local economic spray thresholds are reached and prior to calyx closure. A single application may be suitable where pest pressure is low. Under high thrips insect pressure, apply a second spray application prior to calyx closure no less than 14 days after the first VERTENTO® insecticide spray. **Fuller's rose weevil**: Monitor crops for weevil emergence. Apply VERTENTO® insecticide prior to the start of egg lay which usually occurs in late summer and through autumn. **Spotting bug and light brown apple moth**: Monitor orchards for insect presence and apply VERTENTO® insecticide when local economic spray thresholds are reached. Continue to monitor crops and where pest pressure continues apply a second application no less than 14 days after the first VERTENTO® insecticide spray. **DO NOT apply more than 2 applications per cropping season.** **DO NOT exceed 200 mL of VERTENTO® per hectare per spray application.** **Concentrate spraying is not recommended for this use pattern**. Ensure thorough coverage of the target crop – refer to the Application section in General Instructions. [Δ] Always add a specified adjuvant – refer to the Adjuvant section in General Instructions.

Withholding periods

Harvest: **DO NOT** harvest for 14 days after application.

Grazing: **DO NOT** graze treated orchards

Trade advice

EXPORT OF TREATED PRODUCE

Crops treated with VERTENTO® insecticide may contain finite (measurable) residues of isocycloseram and may pose a risk to trade in situations where no residue tolerance (import tolerance) is established in the importing country or where residues in Australian commodities are likely to exceed a residue tolerance (import tolerance) established in the importing country. For further information, please contact your export organisation or Syngenta Australia for the latest information on MRLs and import tolerances before using VERTENTO®.

Results from residues trials presented to the APVMA

The proposed use on citrus is for up to 2 applications at 2 g ai/100 L to a maximum of 80 g ai/ha for each application. The proposed minimum re-treatment interval is 14 days. The proposed harvest withholding period is 14 days and treated orchards will not be grazed.

Australian citrus residue trials used a Dispersible Concentrate (DC) formulation of isocycloseram as for the product Simodis Plinazolin technology Insecticide (P89460). A North American bridging study has been provided to show that residues in citrus resulting from the application of a DC formulation like Simodis are equivalent to those resulting from the application of an SC formulation, such as Vertento.

Residues of parent isocycloseram in citrus whole fruit from Australian trials at 14 days after the last application of a DC formulation at 2 g ai/100 L (1× proposed) were 0.02, 0.03, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.05 and 0.08 mg/kg.

The APVMA crop group guidelines indicate that the representative crops for citrus are lemon and orange.[3] APVMA residue guidelines indicate that 6 orange, 4 lemon and 4 mandarin trials are normally sufficient to set a group citrus MRL.[4] The available relevant Australian trials are 6 orange, 2 lemon and 2 mandarin. However, residues were considered similar in oranges, lemons and mandarins with a High Residue (HR) in oranges of 0.08 mg/kg, 0.05 mg/kg in lemons and 0.05 mg/kg in mandarins. The combined dataset suitable for MRL recommendation is 0.02, 0.03, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.05 and 0.08 mg/kg. The Organisation for Economic Cooperation and Development (OECD) MRL calculator recommends an MRL of 0.15 mg/kg (Supervised Trial Median Residue (STMR) = 0.042 mg/kg (unrounded), n = 10). An MRL of 0.2 mg/kg is recommended for isocycloseram on FC 0001 Citrus fruits in conjunction with a 14 day withholding period.

Citrus pulp is a feed for livestock in Australia. Processing factors to dried citrus pulp in North American trials were 4.4× and 8.5×. Applying the highest processing factor to the highest residue of 0.08 mg/kg in the Australian trials gives a HR-P of 0.68 mg/kg. An MRL of 1 mg/kg is recommended for isocycloseram on AB 0001 Citrus pulp, dry.

Applying the average processing factor of 6.5× to the unrounded citrus STMR of 0.042 mg/kg gives an STMR-P for calculation of livestock dietary burden of 0.27 mg/kg.

[3] APVMA Crop Group Guidelines, Crop Group 001: Citrus Fruits, APVMA website, accessed April 2024

[4] APVMA Data Guidelines, Residue trials to obtain permanent maximum residue limits for crops (Residues), APVMA website, accessed April 2024

Animal commodities

Citrus pulp and almond hulls are feeds for beef and dairy cattle in Australia, along with tomato pomace from currently registered uses. It is noted that detectable residues are not expected to occur in rape seed [canola] forage and fodder from the registered seed treatment use. The estimated livestock dietary burdens for beef and dairy cattle are calculated below in Table 2 and Table 3 using the OECD Livestock Feed Calculator:

Table 2: Calculation of dietary burden for beef cattle

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	AU Diet content (%)	AU Residue Contribution (ppm)
Almond hulls	AM/AV	0.93	STMR	100	0.9	10	0.09
Tomato pomace, wet	AB	0.4	STMR	100	0.4	10	0.04
Citrus dried pulp	AB	0.27	STMR	91	0.3	20	0.06
Total						40	0.2

Table 3: Calculation of dietary burden for dairy cattle

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	AU Diet content (%)	AU Residue Contribution (ppm)
Almond hulls	AM/AV	0.93	STMR	100	0.9	10	0.09
Tomato pomace, wet	AB	0.4	STMR	100	0.4	10	0.04
Citrus dried pulp	AB	0.27	STMR	91	0.3	20	0.06
Total						40	0.2

Estimated parent isocycloseram residues (the residue definition for enforcement) in tissues and milk for the calculated maximum livestock dietary burden of 0.2 ppm for beef and dairy cattle are summarised below in Table 4.

Table 4: Estimated residues in animal tissues and milk and required MRLs

Feeding level (ppm)	Milk	Muscle	Liver	Kidney	Fat
	Parent isocycloseram residue (mg/kg)				
4.40 (feeding study)	0.0181	<0.01	0.0257	<0.01	0.0575
0.2 – beef, estimated burden	-	<0.01	<0.01	<0.01	<0.01
0.2 – dairy, estimated burden	<0.01	-	-	-	-
Current MRLs	*0.01 (milks)	*0.01 (meat - in fat)		*0.01 (offal)	-
MRL recommendations	No change	No change		No change	No change

No changes are required to the current animal commodity MRLs for isocycloseram which are established at the LOQ for the analytical method. It is also noted that estimated residues of all metabolites reported in the dairy cattle transfer study would also be <0.01 mg/kg in all tissues and milk for a dietary burden of 0.2 ppm.

Overseas registration and approved label instructions

The applicant indicated that isocycloseram products are registered in Argentina, South Korea, Pakistan and Vietnam, including a use on mandarin in South 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. Isocycloseram has not been considered by Codex. The following relevant International MRLs in Table 5 have been established for isocycloseram.

Table 5: Relevant International MRLs for isocycloseram

Commodity	Tolerance for residues arising from the use of isocycloseram (mg/kg)							
	Australia	Canada[5]	Codex[6]	EU[7]	Japan[8]	Korea[9]	Taiwan[10]	USA[11]
Residue Definition	Isocycloseram	–	–	–	–	–	–	–
Citrus	0.2 (proposed)	–	–	–	–	0.7 (mandarin)	–	–

Note: Details of overseas MRLs supplied by the applicant reflected the default MRLs of 0.1 mg/kg in Canada and 0.01 mg/kg in Japan.

Current and proposed Australian MRLs for isocycloseram

Table 6: Current MRL Standard – Table1

Compound	Food	MRL (mg/kg)
Isocycloseram		
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

[5] Health Canada website, Maximum Residue Limits Database, accessed March 2024

[6] Food and Agriculture Organisation of the United Nations, *Codex Alimentarius, International Food Standards*, FAO website, accessed March 2024.

[7] European Commission, *EU Pesticide residue(s) and maximum residue levels (mg/kg)*, European Commission website, accessed March 2024.

[8] Japanese Food Chemistry Research Foundation, *Table of MRLs for Agricultural Chemicals*, JFCRPF website, accessed March 2024.

[9] Ministry of Food and Drug Safety, Korea, MRLs in Pesticides, accessed March 2024.

[10] Laws & Regulations Database of the Republic of China (Taiwan), Standards for Pesticide Residue Limits in Foods, accessed March 2024.

[11] Electronic Code of Federal Regulations, *USA Electronic Code of Federal Regulations*, eCFR website, accessed March 2024.

Table 7: Proposed MRL Standard – Table1

Compound	Food	MRL (mg/kg)
Isocycloseram		
Add:		
FC 0001	Citrus fruits	0.2

Potential risk to trade

An MRL of 0.2 mg/kg is proposed for citrus and appropriate MRLs have yet to be established overseas, with the exception of an MRL for mandarins in Korea which is higher than the proposed Australian citrus MRL. It is noted that the HR in citrus in the available trials was lower than the default Canadian MRL or 0.1 mg/kg. The draft label includes the following trade advice statement:

EXPORT OF TREATED PRODUCE

Crops treated with VERTENTO® insecticide may contain finite (measurable) residues of isocycloseram and may pose a risk to trade in situations where no residue tolerance (import tolerance) is established in the importing country or where residues in Australian commodities are likely to exceed a residue tolerance (import tolerance) established in the importing country. For further information, please contact your export organisation or Syngenta Australia for the latest information on MRLs and import tolerances before using VERTENTO®.

Conclusion

Syngenta Australia Pty Ltd have applied to register Vertento Insecticide containing isocycloseram for use on citrus. Comment is sought on the potential risk to Australian trade when Vertento Insecticide is used on citrus as proposed.