



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



Trade advice notice

On indoxacarb in the product Avatar eVo Insecticide for use on cherries and
sweet corn

APVMA product number 86106

JUNE 2019

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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 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 to vary the registration of **Avatar eVo Insecticide**. 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 **Monday, 15 July 2019** 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 group name (if relevant)
- postal address
- email address (if available)

- submission date.

All personal and *confidential commercial information (CCI)*¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the **grounds for registration** should be addressed in writing to:

Residues and Trade
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Phone: +61 2 6210 4701

Email: enquiries@apvma.gov.au.

Further information

Further information can be obtained via the contact details provided above.

Further information on public release summaries can be found on the [APVMA website](#).

¹ A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from FMC Australasia Pty Limited, to register a new product Avatar eVo Insecticide containing 300 g/kg indoxacarb for use on cherries and sweet corn.

The use of indoxacarb on cherries is currently allowed under PER11002 (14 May 2009 to 31 March 2020) with a use pattern involving two applications at 17 g/100L (5.1 g ai/100L) with a 14 day withholding period. There is an established temporary indoxacarb MRL for cherries at T2 mg/kg. An equivalent use pattern as is proposed for cherries is currently registered for stone fruit (except cherries).

The use of indoxacarb on sweet corn has not been previously considered. Sweet corn forage and fodder are significant animal feeds and the proposed use will require increases in MRLs for mammalian meat (in the fat), offal and milk fats.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Cherries are considered to be a major export commodity².

Sweet corn is not considered to be a major export commodity. However, commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed on treated sweet corn forage and fodder, are major export commodities. Residues in these commodities resulting from the use of Avatar eVo Insecticide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Australian exports of cherries totalled 4.1 kt (value \$62.2 m) in 2017–18. This represents 26 per cent of Australia's cherry production. The major export markets for cherries in 2017–18 included Hong Kong (30 per cent), China (16 per cent), Singapore (12 per cent), Vietnam (10 per cent) and Taiwan (6 per cent)³.

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

2.3 Proposed Australian use-pattern

Table 1: Proposed use pattern, Avatar eVo Insecticide (300 g/kg indoxacarb)

Crop	Pest	Rate	Critical comments
Stone fruits including: apricot cherries nectarine peaches plums	Budworms (<i>Helicoverpa</i> spp.)	25 g/100 L (7.5 g ai/100L)	Target sprays against eggs and newly hatched larvae before they become entrenched. A maximum of 3 applications of Avatar® eVo is to be applied at 10 day intervals to each crop. Further treatments should be made with alternative mode of action insecticides (non-Group 22A). Thorough coverage is essential. Best results are obtained when Avatar® eVo treatments are applied consecutively.
	European earwig (<i>Forficula auriculari</i>) (suppression only)		Spray when local thresholds have been reached and damage is being observed. DO NOT retreat within ten (10) days. Apply a maximum of two (2) applications per season.
	Oriental fruit moth (<i>Grapholita molesta</i>)		Thorough coverage is essential. When treating the first generation, apply the initial treatment before 110 Degree Days after Oriental fruit moths are detected in traps. A maximum of 3 applications of Avatar® eVo is to be applied at 10 day intervals to each crop. Target sprays against eggs and newly hatched larvae before they become entrenched.

² APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

³ Australian Horticulture Statistics Handbook 2017/18, <https://www.horticulture.com.au>

Crop	Pest	Rate	Critical comments
			Best results are obtained when Avatar® eVo treatments are applied consecutively. Further treatments should be made with alternative mode of action insecticides.
	Inland katydid (<i>Caedicia simplex</i>)		Spray when local thresholds have been reached. Thorough coverage is essential.
	Lightbrown apple moth (<i>E. postvittana</i>)		Thorough fruit coverage is essential. A maximum of 3 applications of Avatar® eVo are to be applied at 14 day intervals commencing at 140 Degree Days after lightbrown apple moths are detected in traps. Best results are obtained when Avatar® eVo treatments are applied consecutively. Further treatments should be made with alternative mode of action insecticides.
	Pear and Cherry Slug (<i>Caliroa cerasai</i>)	12.5 g/100L (3.75 g ai/100L)	Spray when local thresholds have been reached and damage is being observed. DO NOT retreat within ten (10) days.
	Weevils: Apple weevil (<i>Otiorhynchus cribricollis</i>) Fuller's rose weevil (<i>Asynonychus cervinus</i>) Garden weevil (<i>Phlyctinus callosus</i>)		Monitor weevil emergence. Garden weevil usually emerges late October to late November. Apple weevil and Fuller's Rose weevil usually emerge late November to late December. Garden weevil and Apple weevil: Prevent damage by treating early in the stages of emergence. Fuller's Rose weevil: Spray after peak weevil emergence when leaf damage is obvious. Thorough coverage is essential. Continue monitoring after spraying. For weevils there is a maximum of 2 applications per season. Do not retreat within ten (10) days. DO NOT use for more than 2 consecutive seasons.
	Wingless grasshopper (<i>Phaulacridium vittatum</i>)	25 g/100L (7.5 g ai/100L)	Spray when local thresholds have been reached and damage is being observed. Thorough coverage is essential. DO NOT retreat within ten (10) days.
Sweet corn	Corn earworm or Cotton bollworm (<i>Helicoverpa armigera</i>)	170 g/ha or 250 g/ha (51 g ai/ha or 75 g ai/ha)	Regularly scout crops to monitor for eggs and larvae. Target sprays against eggs and newly hatched larvae before they become entrenched. Best results are achieved when Avatar® eVo is used prior to the start of silking (vegetative—early tasselling). Larvae present within the silks or cob at the time of spraying will not be controlled. Thorough spray coverage is critical. Use enough water to ensure thorough coverage of the crop. Refer to Surfactant/Wetting agent section. Apply a maximum of 3 applications to any one crop. DO NOT retreat within seven (7) days. Further treatments should be made with alternative mode of action insecticides. Where more than one crop is grown per year do not apply more than three sprays per year.

Crop	Pest	Rate	Critical comments
			<p>As part of an Insecticide Resistance Management programme for cotton bollworm, it is important to pupae bust immediately after harvest.</p> <p>Use 250 g/ha during periods of moderate or heavy pressures.</p>

Restraint:

For cherries, DO NOT apply in a spray volume exceeding 2000L/ha

Withholding periods:

Harvest: Cherries DO NOT apply later than 14 days before harvest.

Harvest: Sweet corn DO NOT apply later than three days before harvest.

Grazing: Sweet corn DO NOT graze or cut for stock food for three days after application.

LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, that the Export Slaughter Interval is observed before stock are sold or slaughtered.

EXPORT SLAUGHTER INTERVAL (ESI)

49 days: After observing the grazing withholding period, livestock that has been grazed on or fed treated sweet corn forage and/or fodder should be placed on clean feed for 49 days (seven weeks) prior to slaughter.

When Avatar® eVo is used as directed and the above withholding periods and/or export intervals are observed, livestock are considered acceptable for export slaughter. However, export requirements are subject to change. Consult your exporter for updated information about specific market requirements.

TRADE ADVICE EXPORT STATEMENT

Suitable Maximum Residue Limits (MRLs) or Import tolerances for produce treated with Avatar® eVo insecticide may not be established in some countries. Consult with your exporter or FMC before applying Avatar® eVo insecticide to crops from which produce is to be exported.

2.4 Results from residues trials presented to the APVMA

Indoxacarb in cherries

The proposed use pattern for cherries is for up to three foliar applications at 3.75–7.5 g ai/100L with a harvest withholding period of 14 days. The proposed maximum spray volume is 2000L/ha, so the maximum application rate is 150 g ai/ha.

15 relevant indoxacarb GLP residue trials for cherries from the US and Canada were provided that involved four applications at 168 g ai/ha (~1.1× maximum proposed rate) at 12 to 14 days after last application. Indoxacarb residues in cherries were; 0.07 (2), 0.13, 0.15 (3), 0.16, 0.19, 0.22, 0.26, 0.28, 0.32 (2), 0.51 and 0.64 mg/kg (n=15). The STMR was 0.19 mg/kg. The OECD MRL calculator estimates an MRL of 0.9 mg/kg.

Based on the available information, an indoxacarb MRL of 1 mg/kg for FS 0013 cherries will cover indoxacarb residues arising in cherries as a result of the proposed use in conjunction with a harvest withholding period of 14 days.

Indoxacarb in sweet corn forage and fodder

The proposed use pattern for sweet corn is for up to three foliar applications per crop at 51 or 75 g ai/ha with harvest and grazing withholding periods of three days after last application.

Forage

17 relevant indoxacarb GLP residue trials for sweet corn forage from the US were provided that involved four applications at 100–150 g ai/ha (~1.3–2 × maximum proposed rate) with a three day PHI. After scaling the data to the proposed rate of 75 g ai/ha, the combined dataset suitable for MRL estimation for sweet corn forage is, 2.7, 6.3, 6.8, 12, 16 (2), 17 (4), 18 (2) 20, 22, 25, 27 and 30 mg/kg (n=17). The STMR was 17.1 mg/kg. An indoxacarb MRL of 50 mg/kg for sweet corn forage is considered appropriate for the proposed use in conjunction with a three day grazing withholding period.

Stover

Eight relevant indoxacarb GLP residue trials for sweet corn stover from the US were provided that involved four applications at 100–150 g ai/ha (~1.3–2 × maximum proposed rate) three days prior to harvest. After scaling the data to the proposed rate, the combined dataset, for sweet corn stover, suitable for MRL estimation is, in rank order, 0.60, 1.8, 4.7, 5.8, 6.1, 7.3, 8.8 and 15 mg/kg (n=8). The STMR was 5.95 mg/kg. An indoxacarb MRL of 30 mg/kg for sweet corn fodder is considered appropriate for the proposed use.

Indoxacarb in Animal commodities

Sweet corn forage, fodder and cannery waste can comprise 80 per cent, 40 per cent and 30 per cent of the daily feed intake respectively for beef cattle and 40 per cent, 20 per cent and 10 per cent respectively for dairy cattle⁴. Pulse forage (current MRL of 10 mg/kg for legume animal feeds) can comprise 100 per cent and 40 per cent of the daily feed intake for beef and dairy cattle respectively. The anticipated maximum livestock dietary burden, from proposed and existing uses, is 26 ppm for beef cattle and 19ppm for dairy cattle.

Animal transfer studies were considered involving dosing of indoxacarb at a ratio approximating that present in animal feeds for 28 days for lactating cattle and 14 days for beef cattle. Observed residues from the available transfer studies and estimated residues in tissues and milk as a result of feeding livestock on sweet corn forage and fodder are calculated below along with the required animal commodity MRLs:

⁴ OECD table of feedstuffs derived from field crops

Table 2: Cattle—estimated indoxacarb residues in tissues and milk

Feeding level (mg/kg)	Milk	Cream	Milks fats	Muscle	Liver	Kidney	Fat
Indoxacarb residue (mg/kg)							
75—beef cattle	-	-	-	0.054	0.037	0.78	6.6
23—dairy cattle	0.053	0.58	-	0.01	0.013	0.02	0.54
26—beef, estimated burden	-	-	-	0.019	0.013	0.27	2.28
19—dairy, estimated burden	0.0445	0.49	0.97	<0.01	0.011	0.017	0.45
Established MRLs (mg/kg)	0.1	-	1	1 (in the fat)-	*0.01 (offal except kidney)	0.2	-
Recommended MRLs (mg/kg)	-	-	2	3 (in the fat)	0.02 (offal except kidney)	0.5	-

Based on the expected indoxacarb residue in the fat at ~2.28 mg/kg and the longest half-life seen in subcutaneous back fat (6.2 days), residues in all tissues are expected below the LOQ of 0.01 mg/kg after 49 days on clean feed. An ESI of 49 days (seven weeks) is therefore considered appropriate for the proposed grazing of treated sweet corn forage and fodder.

2.5 Overseas registration and approved label instructions

The applicant has not provided details of overseas registrations of indoxacarb products, but has noted MRLs are established in a number of markets.

2.6 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. Indoxacarb has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for indoxacarb:

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

Commodity	Tolerance for residues arising from the use of indoxacarb (mg/kg)							
	Australia ⁵	Codex ⁶	EU ⁷	USA ⁸	Japan ⁹	Korea ¹⁰	Taiwan ¹¹	
Residue definition	Sum of Indoxacarb and its R-isomer.	Plant commodities—Sum of indoxacarb and its R enantiomer Animal commodities—sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb	Sum of indoxacarb and its R enantiomer	Indoxacarb including its metabolites and degradates., indoxacarb, (S)-methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, and its R-enantiomer, (R)-methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate		Sum of indoxacarb (S-enantiomer) and R-enantiomer of indoxacarb	Plant commodities—Sum of indoxacarb Animal commodities—Sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb	-
Cherries	T2 (1 proposed)	-	1	-	0.9	0.9	0.5	
Stone fruits	2	1	1	0.9	-	-	-	

⁵ www.legislation.gov.au/Details/F2018C00574

⁶ www.codexalimentarius.net

⁷ ec.europa.eu

⁸ www.ecfr.gov

⁹ db.ffcr.or.jp/front/

¹⁰ www.foodsafetykorea.go.kr/residue/main.do

¹¹ www.fda.gov.tw/EN/law.aspx?cid=16&key=residue%20limits%20

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Commodity	Tolerance for residues arising from the use of indoxacarb (mg/kg)						
	Australia ⁵	Codex ⁶	EU ⁷	USA ⁸	Japan ⁹	Korea ¹⁰	Taiwan ¹¹
Edible offal (mammalian) (except kidney)	*0.01 (0.02 proposed)	0.05 (edible offal (mammalian))	0.05 (edible offal other than liver or kidney) 0.05 (Liver)	0.03 (meat by products)	0.5	-	-
Kidney (mammalian)	0.2 (0.5 proposed)	-	0.05	-	0.5	-	-
Meat (mammalian) (in the fat)	1 (3 proposed)	2 Meat (from mammals other than marine mammals) (fat)	2 (muscle and fat)	0.05 (meat) 1.5 (fat)	1 (muscle and fat)	-	-
Milks	0.1	0.1	0.1	0.15	0.1	-	-
Milk fats	1 (2 proposed)	2	-	4.0	-	-	-

2.7 Current and proposed Australian MRLs for indoxacarb

Table 4: Current MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
INDOXACARB		
FS 0013	Cherries	T2
MO 0105	Edible offal (mammalian) (except kidney)	*0.01
	Kidney (mammalian)	0.2
MM 0095	Meat (mammalian) (in the fat)	1
ML 0106	Milks	0.1
FM 0183	Milk fats	1
FS 0012	Stone fruits (except cherries)	2

Table 5: Proposed changes to MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
INDOXACARB		
DELETE:		
FS 0013	Cherries	T2
MO 0105	Edible offal (mammalian) (except kidney)	*0.01
	Kidney (mammalian)	0.2
MM 0095	Meat (mammalian) (in the fat)	1
FM 0183	Milk fats	1
ADD:		
FS 0013	Cherries	1
MO 0105	Edible offal (mammalian) (except kidney)	0.02
	Kidney (mammalian)	0.5
MM 0095	Meat (mammalian) (in the fat)	3
FM 0183	Milk fats	2

Table 6: Proposed changes to MRL Standard—Table 4

COMPOUND	FOOD	MRL (mg/kg)
INDOXACARB		
ADD:		
	Sweet corn fodder	30
	Sweet corn forage	50

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of indoxacarb 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 indoxacarb MRL at 1 mg/kg for cherries is equivalent to that established by the EU for cherries and Codex for stone fruits and higher than other international cherry or stone fruit MRLs (0.9 mg/kg in the US, Japan and Korea and 0.5 mg/kg in Taiwan), noting the HR for cherries of 0.64 mg/kg observed in the trials is below international MRLs except for Taiwan. Industry will need to ensure that effective and manageable strategies are in place to mitigate the potential risk to Australian trade.

Residues may be expected in the fat, kidney, liver, muscle and milk from the proposed uses and lower tolerances are established in most markets or not established in some markets for Australian animal commodities. However the calculated 49 day (seven week) ESI will ensure there are no detectable residues in animal commodities for export.

3 CONCLUSION

The risk to trade from the proposed uses on cherries and sweet corn (animal feeds) is not considered to be undue, however comment is sought from industry stakeholders on the potential risk to trade.