



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



Trade Advice Notice

on acetamiprid and emamectin in the product
Skope Insecticide for use on pulses

APVMA product number 81486

August 2020

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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 Skope 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 18 September 2020 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
Scientific Assessment and Chemical Review
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 public release summaries can be found on the APVMA website: apvma.gov.au.

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 Adama Australia Pty Limited for registration of Skope Insecticide, containing acetamiprid and emamectin, for use on summer and winter pulses (except field peas and lupins).

Acetamiprid is currently not approved in Australia for use in pulses. Emamectin is registered for use in summer and winter pulse crops at rates up to 5.1 g ai/ha with a 21 day harvest withholding period.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Specified pulses (including chickpeas, faba beans, navy beans and mung beans) are considered to be major export commodities², as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated pulses. Residues in these commodities resulting from the use of Skope Insecticide may have the potential to unduly prejudice trade.

No changes are required to the current animal commodity MRLs for acetamiprid and emamectin as the maximum dietary burden remains unchanged when compared to currently registered uses. The risk to trade in animal commodities is unchanged and will not be considered further.

2.2 Destination and value of exports

The main export markets for Australian pulses include Asia, North Africa, Middle East and the Indian sub-continent³. The total volume and value of pulse exports in 2017–18 was 2730kt and \$1.9 billion⁴.

2.3 Proposed Australian use-pattern

Skope Insecticide (218 g/L acetamiprid and 32.5 g/L emamectin present as emamectin benzoate).

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

³ pulseaus.com.au/growing-pulses/publications/marketing-pulses

⁴ agriculture.gov.au/abares/research-topics/agricultural-outlook/ACS2019_PulsesTables_v1.0.0

Table 1: Proposed use pattern

Crop	Insect	Rate/ha	Critical comments
Summer and winter pulses (except field peas and lupins): Adzuki beans, chickpeas, faba beans, lentils, mung beans, navy beans, pigeon peas and soybeans.	Silverleaf whitefly (<i>Bemisia tabaci</i> biotype B)	320 mL (69.8g ai/ha acetamiprid and 10.4g ai/ha emamectin	Skope® has activity primarily on whitefly nymphs and evidence of activity will be slower than typical contact insecticides. Apply Skope® when whitefly first appears and prior to heavy populations becoming established in the crop. Use the higher rate when conditions favour a rapid increase in the whitefly population, for longer residual control, during periods of rapid crop growth or when crops are well advanced. After application, continue to monitor the crop and if a second spray is required, apply an insecticide from a different mode of action group before applying a second application of Skope®. Adjuvant When silverleaf whitefly is the primary target insect, apply Skope® with Hasten† or Canopy† at 1 L/ha.
	Jassids (<i>Amrasca terraereginae</i>)		Apply Skope® when jassid numbers reach action thresholds. Treated insects may still be on the plant for 2 or 3 days after application but will have stopped feeding. Adjuvant Apply with an organosilicone adjuvant such as Pulse† Penetrant at 0.2% v/v.
	Two-spotted mite (<i>Tetranychus urticae</i>) Suppression only		Apply to actively growing crops, ensuring thorough coverage. Monitor crops regularly and apply when mite numbers reach action thresholds. Best results will be obtained when applied to low mite populations. Do not apply to high populations as Skope® may not provide a sufficient reduction in mite density. Adjuvant Apply with a non-ionic surfactant at the recommended label rate.

Crop	Insect	Rate/ha	Critical comments
	Green mirid (<i>Creontiades dilutus</i>) Rutherglen bug (<i>Nysius vinitor</i>)	160 to 320 mL	<p>Apply Skope® when pest numbers reach action thresholds. Use the higher rate on heavier populations, for faster knockdown and for longer residual control. Treated insects may still be on the plant for 2 or 3 days after application but will have stopped feeding.</p> <p>If additional sprays are required, apply an insecticide from a different mode of action group before applying a second application of Skope.</p> <p>Green mirid</p> <p>Apply Skope® when green mirid numbers reach action thresholds. Skope® applications should be targeted at green mirid populations dominated by nymphs. Skope® may not provide adequate control of high populations of green mirid dominated by adults.</p> <p>Rutherglen bug</p> <p>Apply Skope® when Rutherglen bug numbers reach action thresholds.</p> <p>Adjuvant</p> <p>Apply with a non-ionic surfactant at the recommended label rate or an organosilicone adjuvant such as Pulse† Penetrant at 0.2% v/v. If high levels of Rutherglen bug are present, apply Skope® with Canopy at 1 L/ha.</p>
	Green vegetable bug (<i>Nezara viridula</i>) Red banded shield bug (<i>Piezodorus hybneri</i>)		<p>Under heavy/sustained pest pressure, Skope® may only provide knockdown and residual control for 7 days. A second application with an insecticide from a different mode of action group may be required if pest populations recover rapidly and numbers approach the action threshold.</p> <p>Adjuvant</p> <p>When targeting green vegetable bug, apply Skope with an organosilicone adjuvant such as Pulse Penetrant at 0.2% v/v. On red banded shield bug, a non-ionic surfactant can be used as an alternative adjuvant.</p>
	Cotton bollworm (<i>Helicoverpa armigera</i>) Native budworm (<i>Helicoverpa punctigera</i>)	80 to 320 mL	<p>Regularly scout crops and target sprays at or just prior to the anticipated time of hatching of eggs. Larvae must feed on treated areas in order to achieve effective control. As earlier larval stages are easier to control, DO NOT target larvae larger than 5 mm (very small to small). Large larvae and larvae entrenched within feeding sites may not be controlled.</p>

Crop	Insect	Rate/ha	Critical comments
	Soybean looper (<i>Pseudoplusia includens</i>) Cluster caterpillar (<i>Spodoptera litura</i>) suppression only	160 to 320 mL	After application, continue to monitor the crop and if a second spray is required, apply an insecticide from a different mode of action group before applying a second application of Skope®. Use Skope at the lower end of the recommended rate range for the target pest species on light infestations. Use higher rates where high insect pressure is present, where conditions favour rapid population development and when targeting mixed pest populations Adjuvant <i>Helicoverpa</i> spp: apply with Canopy at 2 L/ha or with a non-ionic surfactant at the label rate. Soybean looper: apply with a non-ionic surfactant at the label rate or with Canopy at 2 L/ha. Cluster caterpillar: apply with Canopy at 2 L/ha.
	Bean pod borer (<i>Maruca vitrata</i>)		Timing is important, as earlier larval stages are easier to control. For best results, apply at or just prior to the anticipated time of egg hatch, as indicated by egg levels or scouting. After application, continue to monitor the crop and if a second spray is required, apply an insecticide from a different mode of action group before applying a second application of Skope®. Adjuvant Apply with a non-ionic surfactant at the recommended label rate.

RESTRAINTS

DO NOT apply to crops under visible stress.

DO NOT spray crops while bees are actively foraging.

DO NOT apply more than two applications of Skope per crop.

WITHHOLDING PERIOD

Harvest: Mung beans: DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION

Pulses (except Mung beans): DO NOT HARVEST FOR 6 WEEKS AFTER APPLICATION

Grazing: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 6 WEEKS AFTER APPLICATION

EXPORT OF TREATED PRODUCE

MRLs or import tolerances do not exist in all markets for produce treated with Skope®. If you are growing produce destined for export, please consult with ADAMA Australia for the latest information on MRLs and import tolerances before using Skope®.

2.4 Results from residues trials presented to the APVMA

Acetamiprid

Grain

The proposed use of acetamiprid in pulses (except field peas and lupins) involves two foliar applications at a maximum rate of 69.8 g ai/ha with four weeks harvest withholding period for mung beans and six weeks harvest withholding period for other pulses. A grazing WHP of six weeks is proposed.

In two Australian mung bean trials at the proposed GAP, residues in grains at four weeks pre-harvest interval (PHI) were 0.02 and 0.07 mg/kg. In other pulses (soybean, navy bean, faba bean and chickpeas), residues were <0.01 (n=3), 0.03 and 0.04 mg/kg at four weeks PHI. Residues of acetamiprid in Brazilian soybean trials (~1-1.6X the maximum proposed rate) were <0.01 mg/kg (n=4) at a PHI of four weeks. Based on the available data on pulses at four weeks PHI, the OECD calculator estimates an MRL of 0.1 mg/kg (STMR 0.01 mg/kg).

At a PHI of six weeks, residues of acetamiprid on pulse grains (chickpeas (two), mung bean (two) soybean, navy bean and faba bean) were <0.01 (n=4), 0.02 and 0.04 (n=2) mg/kg. Based on the available data on pulses at a six week PHI, the OECD calculator estimates an MRL of 0.09 mg/kg (STMR 0.01 mg/kg).

Based on the available information, an MRL of 0.1 mg/kg for pulses {except field pea (dry); lupin (dry)} is recommended for the proposed use in conjunction with four weeks harvest withholding period for mung beans and 6 weeks withholding period for other pulses.

Straw/stubble and forage

At a PHI of six weeks, residues of acetamiprid in pulse straw/stubble on a dry weight basis were <LOQ (3), 0.03, 0.04, 0.19, 0.26 and 0.69 mg/kg. In pulse forage, residues on a dry weight basis were <LOQ (3), 0.02, 0.39, 0.41, 0.62 and 0.71 mg/kg. A Table 4 MRL of 2 mg/kg for pulse forage and fodder for acetamiprid is considered appropriate for the proposed use in conjunction with a grazing WHP of six weeks.

Emamectin

Grain

The residues of emamectin on pulses (chickpeas (two), mung bean (two) soybean, navy bean and faba bean) at four and six weeks PHI's were <LOD (0.005 mg/kg). Based on the available information, the current emamectin MRL for pulses established at *0.01 mg/kg remains appropriate in conjunction with the harvest WHP of four weeks for mung beans and a harvest WHP of six weeks for other pulses.

Straw/stubble and forage

In pulse straw/stubble from Australian trials conducted at 1X the proposed GAP, residues of emamectin on a dry weight basis were <LOD (4), <LOQ, 0.0009, 0.0015 and 0.0021 mg/kg at a six week PHI. In pulse

forage, residues of emamectin on a dry weight basis were <LOD (6), 0.002 and 0.004 mg/kg at a six week PHI.

Based on the available information, the current emamectin MRL of *0.01 mg/kg established for emamectin for pulse forage and fodder remains appropriate in conjunction with a grazing WHP of six weeks.

2.5 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. Acetamiprid and emamectin have considered by the Codex. The following relevant Codex CXLs and international MRLs have been established for acetamiprid and emamectin.

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

Countries	MRL for pulses (mg/kg)	Notes
Australia (proposed)	0.1	Except field peas and lupin
Codex ⁵	-	Not established for pulses
EU ⁶	0.15	Pulses
Japan ⁷	2	Beans dried, peas, broad beans, other legume and pulses
Japan	0.3	Soya beans, dried
USA ⁸	0.03	Soya bean seed, not established on dried beans
Taiwan ⁹	1	Chickpea, cow pea, lentil, mung bean, pigeon pea
Korea ¹⁰	1	Soybean
	0.3	Mung bean

⁵ fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=246

⁶ ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.CurrentMRL&language=EN&pestResidueId=10

⁷ db.ffcr.or.jp/front/pesticide_detail?id=3100

⁸ ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl

⁹ consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&lang=1&lawid=127

¹⁰ foodsafetykorea.go.kr/residue/prd/mrls/list.do?menuKey=1&subMenuKey=161

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

Countries	MRL for pulses (mg/kg)	Notes
Australia (current)	*0.01	
Codex ¹¹	-	Not established for pulses
EU ¹²	*0.01	
Taiwan	0.02	Chickpea, soybean, lima bean

2.6 Current and proposed Australian MRLs for acetamiprid and emamectin

Table 4: Current MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
ACETAMIPRID		
MO 0105	Edible offal (mammalian)	*0.05
PE 0112	Eggs	*0.01
MM 0095	Meat [mammalian]	*0.01
ML 0106	Milks	*0.01
PO 0111	Poultry, edible offal of	*0.05
EMAMECTIN		
MO 0105	Edible offal (mammalian)	0.02
MM 0095	Meat (mammalian)[in the fat]	0.01
FM 0183	Milk fats	0.01
ML 0106	Milks	*0.001
VD 0070	Pulses	*0.01

Table 5: Current MRL Standard—Table 4

COMPOUND	FOOD	MRL (mg/kg)
ACETAMIPRID		

¹¹ fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/pesticide-detail/en/?p_id=246

¹² ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.CurrentMRL&language=EN&pestResidueId=10

COMPOUND	FOOD	MRL (mg/kg)
AB 0226	Apple pomace, dry	1
AB 0001	Citrus pulp, dry	5
AB 0226	Grape pomace, dry	2
EMAMECTIN		
	Pulse forage and fodder (fresh weight)	*0.01

Table 6: Proposed MRL Standard—Table 1

COMPOUND	FOOD	MRL (mg/kg)
ACETAMIPRID		
ADD:		
VD 0070	Pulses {except field pea (dry); lupin (dry)}	0.1

Table 7: Proposed MRL Standard—Table 4

COMPOUND	FOOD	MRL (mg/kg)
ACETAMIPRID		
ADD:		
	Pulse forage and fodder	2

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of acetamiprid 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.

Finite residues of acetamiprid are expected in pulse grain after the proposed use with the STMR of 0.01 and HR of 0.07 mg/kg. Acetamiprid MRLs have been established for some pulses at level higher than the proposed Australian MRL (0.1 mg/kg) in some overseas markets including Japan and Taiwan. Codex however has not established acetamiprid MRLs for pulse grains and therefore a potential risk to trade exists in regard to acetamiprid residues for countries which may accept Codex MRLs noting however that the STMR is at the LOQ of 0.01 mg/kg.

The risk to trade associated with emamectin residues is considered to be low as finite residues are not expected in pulse grain from the proposed use and the current MRL at *0.01 mg/kg remains appropriate.

3 CONCLUSION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Adama Australia Pty Limited for registration of Skope Insecticide, containing acetamiprid and emamectin, for use on summer and winter pulses (except field peas and lupins).

Comment is sought on the potential for Skope Insecticide to prejudice Australian trade when used on pulses according to the proposed label directions.