



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



## TRADE ADVICE NOTICE

on saflufenacil in the product Sharpen WG Herbicide

APVMA Product Number 62853

**JUNE 2016**

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), and State Departments of Primary Industry.

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 is a Trade Advice Notice.

It indicates that the 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 **Sharpen WG Herbicide** 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 **Monday 4 July 2016** 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)
- the date you made the submission.

All personal and *confidential commercial information (CCI)*<sup>1</sup> 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

PO Box 6182

Symonston ACT 2609

Phone: +61 2 6210 4701

Fax: +61 2 6210 4776

Email: [enquiries@apvma.gov.au](mailto: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: [www.apvma.gov.au](http://www.apvma.gov.au).

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<sup>1</sup> 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 BASF Australia Ltd, to vary the registration of Sharpen WG Herbicide containing 700 g/kg saflufenacil. BASF wish to add late season uses on cereals (wheat, barley and triticale), pulses (field pea, faba/broad bean, chickpea, lentil and lupin) and a new use on lucerne.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

Wheat, barley, triticale and pulses are considered to be major export commodities<sup>2</sup>, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated cereals, pulses and lucerne. Residues in these commodities resulting from the use of Sharpen WG Herbicide may have the potential to unduly prejudice trade.

### 2.2 Destination and value of exports

Total exports of barley were 6,208 kilotonnes in 2014–15, valued at \$2.14 billion. Total exports of wheat (including flour) were 16,571 kilotonnes in 2014–15, valued at \$5.55 billion (ABARES). Major export destinations are summarised below:

COMMODITY	MAJOR DESTINATIONS
Barley	China, Japan, Korea, Vietnam, Thailand, the Philippines, Taiwan, Saudi Arabia, Kuwait, United Arab Emirates
Wheat	Indonesia, Korea, China, Thailand, Malaysia, Egypt, Yemen, Iraq, New Zealand

Total exports of lupin in 2014–15 were 306 kilotonnes, valued at \$134 million. Total exports of field peas in 2014–15 were 179 kilotonnes, valued at \$91 million. Total exports of chick peas in 2014–15 were 674 kilotonnes, valued at \$414 million. Total pulse exports were 2226 kilotonnes, values at \$1.193 billion, in 2012–13 (2014–15 figures not available, ABARES).

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).

<sup>2</sup> APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B)

## 2.3 Proposed Australian use-pattern

Sharpen WG Herbicide (700 g/kg saflufenacil)

Cereal and legume/pulse crops:

CROP	TARGET	RATE	CRITICAL COMMENTS
Crop topping in Wheat, Barley and Triticale	Wild Radish ( <i>Raphanus raphanistrum</i> )—for the reduction of seed set and viability of weed seeds	34 g/ha (23.8 g ai/ha) plus 1% Hasten or high quality MSO	<p><b>ALWAYS apply SHARPEN WG with 1% v/v Hasten Spray adjuvant or high quality methylated seed oil (MSO)</b></p> <p>DO NOT apply before growth stage Z71 (BBCH71) – watery ripe where first grains have reached half their final size.</p> <p>SHARPEN WG can be applied from watery ripe stage (Z71 / BBCH 71). Applications made to an earlier growth stage may results in yield penalties.</p> <p>Application should be made as soon as the crop reaches the watery milk maturity stage to maximise reduction of weed seed set and seed viability. Weeds will be desiccated however complete control may not occur and some regrowth may occur however significant reductions in seed set will be achieved.</p> <p>Following the application of SHARPEN WG minor scarring on wheat stems and grain heads may be visible but have been shown not to cause yield or quality reductions.</p> <p>In order to guarantee good coverage it is recommended to apply SHARPEN WG at minimum 100 L/ha volume.</p> <p>SHARPEN WG may have a negative effect on triticale germination.</p> <p>DO NOT apply after BBCH 83 (early dough)</p>
Prior to harvest of Field Pea, Faba/Broad Bean, Chickpea, Lentil, Lupin	Harvest-aid to: avoid uneven maturity, improve speed of maturity, reduce broadleaf weed biomass and increase harvest efficiency	34 g/ha (23.8 g ai/ha) plus recommended label rate of glyphosate or paraquat herbicide plus 1 % Hasten or high quality MSO	<p><b>ALWAYS apply SHARPEN WG Herbicide with 1% v/v Hasten Spray adjuvant or high quality methylated seed oil (MSO).</b></p> <p>Apply at crop maturity at least 7 days before harvest as per growth stage timings described below. Earlier applications than described below may results in grain yield penalties.</p> <p>Desiccation timing:</p> <p>Faba bean: Hilum black in the pods at the top of the canopy (30–80% of pods ripe and dark)</p> <p>Field pea: 30% seed moisture or when lower 75% of pods are brown with firm seeds and leathery pods</p> <p>Chickpea: 80–85 % of pods within crop have turned yellow-brown</p>

CROP	TARGET	RATE	CRITICAL COMMENTS
			<p>Lentil: just after crop starts to yellow (or senesce)</p> <p>Narrow leaf lupin: at 80% leaf drop</p> <p>Apply SHAPREN WG to direct harvested lupin, application prior to windrowing will result in severe loss of grain yield.</p> <p>In order to guarantee good coverage it is recommended to apply SHARPEN WG at minimum 100 L/ha volume.</p> <p>SHARPEN WG may have a negative effect on lentil germination. Do not use SHARPEN WG on lentil crops for seed production.</p>

## Lucerne

CROP	TARGET	RATE	CRITICAL COMMENTS
Lucerne (Established Crops—at least 12 months old)	See Weed Table A	17–26 g/ha plus 1% Hasten or high quality MSO	<p><b>ALWAYS apply SHARPEN WG Herbicide with 1% v/v Hasten Spray adjuvant or high quality methylated seed oil (MSO)</b></p> <p>Use the lower rates on younger and smaller (up to six leaf) plants or plants growing under good conditions and the higher rates on older plants (up to 10 leaves) or plants growing under less optimum conditions. For marshmallow, Bladder ketmia use lower rates for plants up to 4 leaf and higher rates when targeting weeds up to maximum of 6 leaves. Sharpen will control subterreanean clover in lucerne.</p> <p>In order to increase spray coverage and consequently improve weed control is recommended to apply SHARPEN WG following grazing or hay cut.</p> <p>Crop damage will be visible as soon as few days following the application of SHARPEN WG. The lucerne crop fully recovers by 6 to 10 weeks after the application.</p>
	See Weed Table B	26–34 g/ha Plus 1% Hasten or high quality MSO	
	Fleabane ( <i>Conyza spp.</i> ) 1–6 leaf  Note: For suppression of fleabane in the rosette stage (6–30 leaf) before bolting use the 26–34 g rate	17–34 g/ha (up to 23.8 g ai/ha) plus 1% Hasten or high quality MSO	<p>For control of Fleabane use the lower rates for plants up to 4 leaf and the higher rates when targeting weeds up to maximum of 6 leaves. For plants greater than six leaf to bolting stage efficacy of SHARPEN WG Herbicide may be reduced and regrowth may occur.</p> <p>Fleabane can germinate in Autumn and Spring and it is important to establish size and age (check tap root as an indication) to ensure control. Fleabane that appears small may in fact be older and have</p>



CROP	TARGET	RATE	CRITICAL COMMENTS
	Prickly melon ( <i>Cucumis myriocarpus</i> ) 1–6 Leaf  Afghan melon ( <i>Citrullus lanatus</i> ) 1–6 Leaf		an established tap root and may not be completely controlled.  Note: For suppression of melon weeds over 12 leaf rosette and 4 side shoots use the 34 g rate
	For the control of broadleaf and grass weeds listed in Weed Table A as well as:  Annual ryegrass ( <i>Lolium spp.</i> ) Brome grass ( <i>Bromus spp.</i> )  Chickweed ( <i>Stellaria spp.</i> ) Silver grass ( <i>Vulpia spp.</i> )	17–26g/ha  plus  recommended label rate of paraquat herbicide plus  1% Hasten or high quality MSO	Refer to Critical Comments above and in addition:  Use of SHARPEN WG Herbicide with paraquat herbicide may increase the speed at which broadleaf and grass weeds develop visible symptoms and improve control of a range of grass and broadleaf weeds (compared to results achieved with paraquat applied alone).  Apply only as a tank mix with recommended rates of herbicide containing paraquat. Refer to the appropriate label for weed sizes and follow all label directions. Hasten at 1% v/v must be added when applying SHARPEN WG Herbicide with paraquat herbicides.

Withholding periods:

Harvest:

Wheat, barley, triticale: Not required when used as directed.

Field pea, faba bean/broad bean, chickpea, lentil, lupin: Do not harvest for seven days after application

Grazing:

Wheat, barley, triticale: Do not graze or cut for stock food for 14 days after application.

Field pea, faba bean/broad bean, chickpea, lentil, lupin: Do not graze or cut for stock food for seven days after application.

Lucerne: Do not graze or cut for stock food for four weeks 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, the export slaughter interval is observed before stock are sold or slaughtered.

#### EXPORT SLAUGHTER INTERVAL (ESI) 30 DAYS

Livestock that has grazed on or been fed treated crops should be placed on clean feed for 30 days prior to export slaughter.

This ESI requirement must be declared on any Commodity Vendor Declaration accompanying traded fodder.

## 2.4 Results from residues trials presented to the APVMA

### Cereal grains

The applicant has provided details of Australian trials involving a single application at 23.8–34 g ai/ha (1x - 1.4 xproposed) at milky dough growth stage (BBCH 73–83) to wheat (11 trials), barley (3 trials) and oats (3 trials). Saflufenacil residues<sup>3</sup> in wheat, barley and oat grain from Australian trials at 27–68 days after treatment at 23.8–34 g ai/ha applied at BBCH 73–83 were <0.010 (5), <0.0174 (2), 0.010 (2), 0.011 (2), 0.012 (2), 0.014, 0.016, 0.051 and 0.11 mg/kg. It is proposed that the current MRL of \*0.03 mg/kg for saflufenacil on GC 0080 cereal grains be increased to 0.2 mg/kg.

Processing studies have been provided for wheat and barley. Saflufenacil did not concentrate in any fractions except wheat germ (PF 0.8 and 1.4x), wheat bran (PF 1.0 and 1.4x) and barley bran (PF 1.6, 2.7, 3.1 and 3.5x).

Based on a HR of 0.11 mg/kg in cereal grains from the Australian use pattern with application at the milky dough stage, the HR-P for cereal bran is 0.385 mg/kg. An MRL of 0.5 mg/kg is proposed for saflufenacil on CM 0081 Bran, unprocessed of cereal grains.

### Pulses

Seven Australian trials on field peas (3), chickpeas (3) and faba beans (1) are supported by 10 US trials on dry beans and 9 US trials on dry peas.

Residues of saflufenacil in pulse grain from Australian and US trials (scaled for application rate) after application close to harvest were <0.010 (25 DAT), 0.016, 0.019, 0.029, <0.03 (n = 13), 0.03 (n = 2), 0.039, 0.04, 0.08, 0.086, 0.11 (n = 2) and 0.12 mg/kg.

Based on the combined Australian and scaled US data, the OECD MRL calculator recommends an MRL of 0.2 mg/kg. The STMR is 0.03 mg/kg, the HR is 0.12 mg/kg. It is proposed that the MRL of \*0.03 mg/kg for saflufenacil on VD 0070 pulses be increased to 0.2 mg/kg. This MRL is likely conservative as it is based on data after a 0 day PHI in Australian trials and 2–4 days in US trials, while the recommended harvest WHP for pulses is 7 days (insufficient grain data are available for a 7 day PHI to allow a lower pulse MRL to be established, the HR in pulse grain in 6 available trials with a 7 day PHI was 0.021 mg/kg).

### Animal feeds

#### *Cereal straw*

Saflufenacil residues in wheat, barley and oat straw at harvest from Australian trials at 27–68 days after treatment at 23.8–34 g ai/ha applied at BBCH 73–83 were 0.03, 0.037, 0.038, 0.08, 0.081, 0.11, 0.12, 0.13,

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<sup>3</sup> Residues are reported according to the Australian residue definition

0.16, 0.16, 0.19, 0.20, 0.22, 0.23, 0.26, 0.45 and 0.74 mg/kg dry weight. The OECD MRL calculator recommends an MRL of 1 mg/kg. The HR is 0.74 mg/kg, the STMR is 0.16 mg/kg.

It is proposed that the current MRLs of \*0.1 mg/kg for saflufenacil on AS 0081 straw and fodder (dry) of cereal grains and AF 0081 forage of cereal grains (green) [fresh weight] be replaced with an MRL of 1 mg/kg for forage and fodder of cereal grains.

### ***Pulse straw***

Residues in pulse straw in the Australian trials at 7 days after application at 23.8 g ai/ha were 0.27, 0.50, 0.60, 0.88, 1.02 and 1.50 mg/kg on a dry weight basis. The OECD MRL calculator recommends an MRL of 3 mg/kg, the HR is 1.50 mg/kg, the STMR is 0.74 mg/kg. It is proposed that the current MRL of \*0.1 mg/kg for saflufenacil on AL 0157 legume animal feeds [fresh weight] be increased to 2 mg/kg [dry weight].

### ***Lucerne***

In Australian trials, residues of saflufenacil in alfalfa forage at 28 days after application at 23.8 g ai/ha were <0.010 (2, fw), 0.051 and 0.60 mg/kg on a dry weight basis.

In Australian trials, residues of saflufenacil in alfalfa hay at 28 days after application at 23.8 g ai/ha were <0.010 (fw), 0.019, 0.036 and 0.58 mg/kg.

In US trials involving application at 50 g ai/ha at winter dormancy but just prior to green-up, followed by a second foliar application at 25 g ai/ha, residues in alfalfa forage at 25–28 days after the second application were <0.075 (n = 7) mg/kg fresh weight.

In US trials involving application at 50 g ai/ha at winter dormancy but just prior to green-up, followed by a second foliar application at 25 g ai/ha, residues in alfalfa hay at 25–28 days after the second application were <0.075 (n = 5) and 0.077 (n = 2) mg/kg fresh weight. The HR from the US trials on a dry weight basis is estimated as 0.09 mg/kg.

Residues of saflufenacil on alfalfa forage and fodder in conjunction with a 4 week grazing withholding period will be covered by the MRL of 3 mg/kg recommended for saflufenacil on AL 0157 legume animal feeds to cover the pulse use pattern.

### **Animal commodities**

An animal transfer study was considered for lactating cattle where the animals were dosed with saflufenacil for 29 days. The results of this study and the estimated livestock burden is considered here.

For cattle the estimated maximum livestock burden for saflufenacil is 1.50 ppm, based on a diet of 100 per cent legume animal feeds. The expected residues and established MRLs for ruminants are summarised as:

**Cattle, 500 kg bw (20 kg DM/day)**

FEEDING LEVEL (PPM)	MILK SAFLUFENACIL RESIDUE (MG/KG)	MUSCLE	LIVER	KIDNEY	FAT
5	<0.003	<0.003	16.4	0.0902	0.00933
1.5 – estimated burden	<0.003	<0.003	4.92	0.0271	0.0028
Established MRLs	*0.01 (milks)	*0.01 (meat)		*0.01 (offal)	-
Recommended MRLs	No change	No change	7		-

The only change required to the established saflufenacil animal commodity MRLs is an increase in the edible offal (mammalian) MRL from \*0.01 to 7 mg/kg.

The half-life for saflufenacil in liver is estimated to be approximately three days. It would take 27 days for the estimated HR of 4.92 mg/kg in liver to decline to the LOQ of 0.01 mg/kg. A 30 day ESI would be appropriate to ensure there are no detectable residues in offal exported to markets where appropriate MRLs have not been established.

It is noted that this ESI applies to cereal and pulse straw which may be baled and sold on after harvest. A label statement is proposed to ensure the ESI requirement is communicated to any buyer of the straw through commodity vendor declarations (see section 2.3).

## 2.5 Overseas registration and approved label instructions

The applicant has provided details of overseas labels for use patterns on similar crops in the USA.

## 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. Saflufenacil has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for saflufenacil.

Table 1: Codex and overseas MRLs for saflufenacil

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF SAFLUFENACIL (MG/KG)					
	AUSTRALIA	EU	JAPAN	CODEX	TAIWAN	USA
Residue Definition	Plants: Sum of saflufenacil and 2 metabolites  Animals: saflufenacil	Plants: Sum of saflufenacil and 2 metabolites  Animals: saflufenacil	Saflufenacil	Saflufenacil		Plants: Sum of saflufenacil and 2 metabolites  Animals: saflufenacil
Cereal grains	*0.03 (0.2 proposed)	0.03*	0.03	0.01	0.03 wheat, barley	1 barley 0.6 wheat 0.03 others
Bran, unprocessed of cereal grains	- (0.5 proposed)					1.5 barley bran
Pulses	*0.03 (0.2 proposed)	0.5 beans 0.03* lentils 0.1 Peas 0.03* lupins 0.03* others	0.3	0.3	0.3 Pea (dry) 0.03 other dry beans	0.3 pea and bean 0.1 soybean
Edible offal (mammalian)	*0.01 (7 proposed)	0.6 liver 0.3 kidney 0.3 other (Bovine + sheep)	0.8 (liver, cattle, pig and other) 0.3 (kidney, cattle, pig and other) 0.3 (offal, cattle, pig and other)	0.3	Not established	50 (liver, cattle, goat, sheep) 0.30 (meat by products, except liver, cattle, goat, sheep)

*Note: The Australian residue definition is the same as that established in the EU and USA. No MRLs for saflufenacil have been established in Korea; the applicant indicated that they are applying for import tolerances in Japan for wheat, barley and animal commodities at the same level as the US MRLs. The applicant has also stated that the 2016 JMPR will be considering new uses on cereals (desiccant uses) and animal products.*

## 2.7 Current and proposed Australian MRLs for saflufenacil

Table 2: Current MRL Standard

COMPOUND	FOOD	MRL (MG/KG)
SAFLUFENACIL		
GC 0080	Cereal grains	*0.03
MO 0105	Edible offal (Mammalian)	*0.01
PE 0112	Eggs	*0.01
VP 0060	Legume vegetables	*0.03
MM 0095	Meat (mammalian)	*0.01
ML 0106	Milks	*0.01
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat	*0.01
VD 0070	Pulses	*0.03

Table 3: Proposed MRL Standard

COMPOUND	FOOD	MRL (MG/KG)
SAFLUFENACIL		
OMIT:		
GC 0080	Cereal grains	*0.03
MO 0105	Edible offal (Mammalian)	*0.01
VD 0070	Pulses	*0.03
INSERT:		
GC 0080	Cereal grains	0.2
MO 0105	Edible offal (Mammalian)	7
VD 0070	Pulses	0.2
CM 0081	Bran, unprocessed of cereal grain	0.5

## 2.8 Potential risk to trade

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

## Cereals

Detectable residues are expected to occur in wheat, barley and triticale which are major export commodities. The proposed Australian cereal grains MRL is higher than that established by Codex. However, the median residue in the available trials matching GAP (0.011 mg/kg) is approximately at the same level as the Codex MRL (0.01 mg/kg). The proposed Australian MRL is also lower than those established in the USA for wheat and barley. Comment is sought on the risk to trade due to the proposed new use pattern on wheat, barley and triticale.

## Pulses

Detectable residues are expected to occur in pulses which are a major export commodity. However, the proposed Australian MRL for pulses is lower than that established by Codex. Comment is sought on the risk to trade due to the proposed new use pattern on pulses.

## Animal commodities

The presence of detectable residues in offal presents a risk to trade as not all markets have appropriate MRLs in place. However a 30 day export slaughter interval will ensure there are no residues of saflufenacil in animal commodities for export above a reasonable limit of quantitation of 0.01 mg/kg. The applicant has proposed to support communication of CVD requirements in stewardship materials.

## 3 CONCLUSIONS

BASF Australia Ltd have applied to vary the registration of Sharpen WG Herbicide containing saflufenacil as active constituent. BASF wish to add late season uses on cereals (wheat, barley and triticale), pulses (field pea, faba/broad bean, chickpea, lentil and lupin) and a new use on lucerne. Comment is sought on the potential for Sharpen WG Herbicide to prejudice Australian trade when used on cereals, pulses and lucerne as proposed.