



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



Trade Advice Notice

on buprofezin in the product Applaud Insecticide for use on cotton

APVMA product number 51547

May 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 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 Applaud 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 25 June 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](#).

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

1 INTRODUCTION

The APVMA has before it an application from Dow Agrosiences Australia Limited to register the use of Applaud Insecticide on cotton. The product contains 440 g/L buprofezin as its active ingredient.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Cotton seed, cotton seed oil and cotton seed meal 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 cotton. Residues in these commodities resulting from the use of Applaud Insecticide may have the potential to unduly prejudice trade.

As the mammalian and poultry dietary burdens through consumption of cotton seed, hulls or meal derived from treated cotton or through consumption of rotational crops, should be no greater than previously considered, no changes are required to the established animal commodity MRLs for buprofezin. The risk to trade in animal commodities is unchanged and does not require further consideration.

2.2 Destination and value of exports

Australian cotton seed exports for 2018–19 were 76.6 kt³. The main export markets are Japan, Korea, Saudi Arabia, Taiwan and the USA.

The cotton seed oil exports for 2018–19 were 17.4 kt.

The cotton seed meal exports for 2018–19 were 2.4 kt. The main export markets are New Zealand and the Republic of Korea.

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

³ ABARES, Agriculture commodity statistics, 2019

2.3 Proposed Australian use-pattern

Table 1: Proposed use pattern

Crop	Pest	Rate/concentration	Critical comments
Cotton	Silverleaf whitefly (<i>Bemisia tabaci</i>)	1 L/ha (= 440g a.i./ha)	Apply as part of a season long spray programme targeting pests early in the crop. The use of Applaud will conserve beneficials when used as part of an IPM system.
	Cotton mealybug (<i>Solenopsis mealybug</i>) (<i>Phenacoccus solenopsis</i>)		Spray in sufficient volume to provide adequate penetration and coverage. Thorough spray coverage is essential. Apply when pest first appears and make a second application 10–14 days later if required. Application should be aimed at the early nymph (crawlers and nymphs) stages of whiteflies and mealybugs. Conservation of beneficials is essential when controlling cotton mealybug.

Applaud Insecticide (containing 440g/L buprofezin as its only active constituent)

Withholding periods:

Harvest: Do not harvest for 14 DAYS after application.

Grazing: Do not feed cotton fodder, stubble or trash to livestock.

Trade advice information: Crops such as cotton or table grapes grown for export may require a longer interval before harvest to comply with residue standards of importing countries. Please check with your exporter before using Applaud Insecticide.

2.4 Results from residues trials presented to the APVMA

Cotton seed

In seven relevant trials conducted in Australia (n=4) or the USA (n=3), residues of buprofezin in cotton seed determined at a 14 day harvest withholding period after two applications at approximately 1x the proposed application rate were in rank order:

0.04, 0.06, 0.06, 0.11, 0.13, 0.13 and 0.13 mg/kg (STMR = 0.11 mg/kg, n = 7).

A buprofezin MRL of 0.3 mg/kg for SO 0691 Cotton seed (replacing the current Australian MRL of T1 mg/kg) is considered appropriate to cover residues in cotton seed arising from the proposed use.

A processing trial was conducted to determine the concentration of buprofezin derived residues in or on processed cotton commodities. The processing factors determined for crude and refined oils were 0.26 and

0.25x respectively. As residues in oil will be covered by the proposed cottonseed MRL at 0.3 mg/kg, an MRL for cotton seed oil is not considered necessary. The processing study also indicated that residues of buprofezin do not concentrate in cottonseed hulls or meal, so it is unnecessary to establish separate MRLs for these processed animal feed commodities.

Rotational crops

Buprofezin is currently registered for use in citrus fruit, pome fruit, grapes and protected grown tomatoes, but is not registered for use on field crops which may be commonly rotated with other crops.

The results of a confined rotational study indicates that residues of buprofezin may occur in food commodities from crops planted following a cotton crop treated with the proposed use of buprofezin. Finite residues of buprofezin were observed in radish roots and tops up to 0.05 and 0.09 mg/kg respectively following application at 1.7 kg a.i. /ha and plant back intervals of 30–119 days but were not observed in either of the other food commodities, lettuce or wheat grain. Predicted residues after seasonal application at 880g a.i./ha are 0.026 and 0.047 mg/kg for radish roots and tops.

An MRL of 0.1 mg/kg will be established for buprofezin in 'all other foods' to cover the possibility of residues in rotational crops that may be used for human consumption. As residues were not observed in grain (wheat), MRLs at the LOQ of *0.01 mg/kg will be established for cereal grains, pulses and oilseed (except cotton seed) to demonstrate that residues are not expected in these major export commodities from rotational sources.

The study also showed that residues of buprofezin may also occur in succeeding animal feed crops. For example, observed residues in wheat forage ranged up to 0.02 mg/kg fresh weight in 30 days aged soil, and in wheat straw up to 0.02 mg/kg in 119 days aged soil. Predicted residues after seasonal application at 880g a.i./ha are 0.01 mg/kg on a fresh weight basis (or 0.04 mg/kg dry weight based on 25 per cent dry matter). To cover this possibility of low finite residues that may arise in rotational crops used for animal feeds, it is recommended that a Table 4 MRL of 0.1 mg/kg be established for buprofezin in Primary feed commodities.

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. Buprofezin has been considered by Codex, however there are no cotton MRLs. The following relevant overseas MRLs have been established for buprofezin.

Table 2: Overseas MRLs

Commodity	Tolerance for residues arising from the use of buprofezin (mg/kg)				
	Australia	EU	Japan	Canada	USA
Residue definition	Buprofezin				
Cotton seed	0.3 (proposed) Current T1	*0.01	0.4	0.35 (undelinted cotton seeds)	0.35 (cotton seed subgroup 20C)
Rotational crops					
Cereals	*0.01 (proposed)	*0.01	0.5 brown rice, 2 (wheat), 6 (barley, rye, other cereal grains)	-	-
Pulses	*0.01 (proposed)	*0.01	-	-	-
Oilseeds (except cotton)	*0.01 (proposed)	*0.01	0.02 (soybean)	-	-

Note: No cottonseed MRLs are established in Korea (Rice MRL at 0.5 mg/kg) or Taiwan (Peas and beans MRL at 1.0 mg/kg, Rice MRL at 0.5 mg/kg).

2.6 Current and proposed Australian MRLs for buprofezin

Table 3: Current MRL Standard

COMPOUND	FOOD	MRL (mg/kg)
BUPROFEZIN		
SO 0691	Cotton seed	T1
OC 0691	Cotton seed oil, crude	T0.3
MO 0105	Edible offal (mammalian)	*0.05
MM 0095	Meat (mammalian) [in the fat]	*0.05
ML 0106	Milks	*0.01

Table 4: Proposed MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
BUPROFEZIN		
DELETE:		
SO 0691	Cotton seed	T1
OC 0691	Cotton seed oil, crude	T0.3
ADD:		
	All other foods	0.1
GC 0080	Cereal grains	*0.01
SO 0691	Cotton seed	0.3
SO 0088	Oilseed {except cotton seed}	*0.01
VD 0070	Pulses	*0.01

Table 5: Proposed MRL Standard—Table4

COMPOUND	FOOD	MRL (mg/kg)
BUPROFEZIN		
ADD:		
	Primary feed commodities	0.1

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of buprofezin 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 Australian MRL of 0.3 mg/kg for buprofezin in cotton seed, is higher than the MRL of *0.01 mg/kg for cotton seed established by the EU, but lower than MRLs established by the USA, Canada and Japan (0.35, 0.35 and 0.4 mg/kg respectively). It is noted that the highest observed residue in the four Australian trials carried out according to GAP, was 0.13 mg/kg. In addition, the proposed MRL change is to make the current temporary cotton seed MRL at 1 mg/kg, established to cover residues arising from a similar use pattern, lower.

Finite residues are not expected in major export commodities from the use of Applaud Insecticide on rotational crops.

The Applicant has proposed the following trade advice information to mitigate the risk to trade in exported crops:

Trade advice information: crops such as cotton or table grapes grown for export may require a longer interval before harvest to comply with residue standards of importing countries. Please check with your exporter before using Applaud Insecticide.

3 CONCLUSION

Dow Agrosiences Australia Limited have made an application to register the use of Applaud Insecticide on cotton requiring an decrease of the temporary MRL for cotton seed from T1 to 0.3 mg/kg, and the establishment of an 'all other foods' MRL to cover potential residues in rotational crops.

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