



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



## TRADE ADVICE NOTICE

on Fluensulfone in the Product Nimitz 480 EC Nematicide for use on sugarcane  
and vegetables (rotational crops)

APVMA Product Number 66678

JULY 2018

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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, Department of the Environment and Energy, 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 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 **Nimitz 480 EC Nematicide** 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 **10 August 2018** 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

**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 ADAMA Australia Pty Limited, to vary the registration of Nimitz 480 EC Nematicide, containing fluensulfone, to add uses on processing tomatoes, root vegetables and sugarcane. ADAMA also wish to change the residue definition, extend the state claims (from Queensland only to all states) and reduce plant-back intervals.

## 2 TRADE CONSIDERATIONS

### 2.1 Commodities exported

With the exception of sugar, none of the primary crops on the draft label are major export commodities. The potential trade risk for the vegetable crops that are not major export commodities will not be considered further.

Grain crops and oaten hay may be grown in rotation with some of the primary crops (such as processing tomatoes and potatoes) and 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 primary and following crops. Residues in these commodities resulting from the use of *Nimitz* may have the potential to unduly prejudice trade.

### 2.2 Destination and value of exports

#### *Sugar*

In 2016/17 Australia exported 3877 kt of raw sugar in bulk. Major export markets were the Republic of Korea, Indonesia, Japan, China, the United States, Taiwan and New Zealand. Exports of refined sugar in 2016-17 amounted to 4009 kt valued at \$2.2 billion (Australian Commodity Statistics 2017 ABARES).

#### *Rotational crops which are major export commodities*

Exports of Australian cereals, pulses, canola, and cotton, are detailed below (Agricultural Commodity Statistics 2017 ABARES).

Total exports of barley were 9537 kilotonnes in 2016/17, valued at \$2.427 billion. Total exports of wheat (including flour) were 22057 kilotonnes in 2016/17, valued at \$6.094 billion. Total exports of oats in 2016/17 were 369 kilotonnes, valued at \$126 million. Exports of sorghum in 2016/17 were 729 kilotonnes, valued at \$212 million. Maize exports in 2016/17 were 73.3 kilotonnes, valued at \$32 million.

Total oilseed exports in 2016/17 (including canola, cottonseed, linseed, peanuts, safflower, soya bean and sunflower) were 3793 kilotonnes, worth \$2.2 billion. Total vegetable oil exports (including canola, cottonseed,

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

linseed, palm, peanut, safflower, soya bean, sunflower and olive) were 196 kilotonnes, at a value of \$303 million, in 2016/17. Total oilseed meal exports in 2016/17 were 31 kilotonnes at a value of \$18 million.

Total exports of lupin in 2016/17 were 414 kilotonnes, valued at \$147 million. Total exports of field peas in 2016/17 were 225 kilotonnes, valued at \$109 million. Total exports of chick peas in 2016/17 were 1970 kilotonnes, valued at \$1.9 billion. Total pulse exports were 3698 kilotonnes, valued at \$3 billion, in 2016/17.

**Table 1: Major destinations for Australian cereal, pulse and oilseed exports**

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
Sorghum	Japan, New Zealand, Taiwan, Papua New Guinea
Cottonseed (including seed, oil, and meal)	Japan, Korea, the USA
Canola (including seed, oil and meal)	Belgium, the Netherlands, Pakistan, Japan, China

### *Hay*

Approximately 720 kilotonnes of hay is exported from Australia, to the value of ~\$230-250 million, per annum.<sup>3</sup> Approximately 85% of exports hay are oaten hay, while 10% is straw and the balance is predominantly lucerne hay and chaff. Approximately 85% of Australian export hay is destined for Japan, while the volume of hay exported to China and the UAE is increasing.

### *Animal commodities*

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>3</sup> Personal communication, AFIA, August 2010

## 2.3 Proposed Australian use-pattern

Nimitz 480 EC Nematicide (480 g/L Fluensulfone)

Table 1. Fruiting vegetables

CROP	PEST	STATE	RATE/HA	CRITICAL COMMENTS
Transplanted crops: Cucurbits Tomatoes Capsicum Chilli Eggplant Okra	Root-knot nematode ( <i>Meloidogyne spp.</i> )	All states	4 – 8 L (up to 3.84 kg ai/ha)	<p>Apply a minimum of seven (7) days before transplanting.</p> <p><b>Rate selection</b></p> <p>Use the low rate in less susceptible crops and/or under low Root-knot nematode pressure where soil counts or paddock history indicate the population density is close to the economic threshold and minor yield loss is expected.</p> <p>Use the high rate in more susceptible crops and/or under moderate to high Root-knot nematode pressure where soil counts or paddock history indicate that the population density is above the economic threshold and significant yield loss is expected.</p> <p>Apply a maximum of 8 L per hectare per year and not more than one application / crop.</p>

Table 2. Root and tuber vegetables

CROP	PEST	STATE	RATE/HA	CRITICAL COMMENTS
Carrots, Potatoes, Sweet potatoes	Root-knot nematode ( <i>Meloidogyne spp.</i> )	All states	4 – 8 L (up to 3.84 kg ai/ha)	<p>Apply a single application of NIMITZ® a minimum of seven (7) days prior to:</p> <p>Sowing carrots and potatoes; or</p> <p>Planting sweet potato vine cuttings.</p> <p><b>Rate selection</b></p> <p>Use the low rate under low Root-knot nematode pressure where soil counts or paddock history indicate the population density is close to the economic threshold and minor yield loss is expected.</p> <p>Use the high rate under moderate to high Root-knot nematode pressure where soil counts or paddock history indicate that the population density is above the economic threshold and significant yield loss is expected.</p> <p><b>Application</b></p> <p>Apply NIMITZ® as a broadcast or banded spray application and</p>

CROP	PEST	STATE	RATE/HA	CRITICAL COMMENTS
				<p>mechanically incorporate uniformly to a depth of 15-20 cm as soon as possible i.e. on the day of application.</p> <p>Refer to the band application guidelines section below for more information on calculating the rate according to the treated band width.</p> <p>Apply a maximum of 8 L per hectare per year and not more than one application / crop.</p>

Table 3. Sugarcane

CROP	PEST	STATE	RATE/HA	CRITICAL COMMENTS
Sugarcane	<p>Root-knot nematode (<i>Meloidogyne spp.</i>),</p> <p>Root lesion nematode (<i>Pratylenchus zaeae</i>)</p>	Qld, NSW, NT, WA	<p>4 L</p> <p>(1.92 kg ai/ha)</p>	<p><b>Application</b></p> <p>Apply a single application of NIMITZ® as a spray into the furrow at planting. Use a spray nozzle that will deliver a coarse spray quality in a minimum volume of 100 L/ha, in a band 30-50 cm wide over the centre of the row immediately prior to soil cover being brought in over the sett.</p> <p>Refer to the band application guidelines section below for more information on calculating the rate according to the treated band width.</p>

**Restrains:**

When applying to cucurbits, tomatoes, capsicum, chilli, eggplant, okra and sweet potatoes use only prior to planting transplanted crops and not in conjunction with direct seeded crops.

DO NOT plant any crops not specified on this label into treated land for 180 days after the last application unless otherwise stated in the rotational crop restriction table on this label.

DO NOT apply more than one application per crop, and no more than 8 L/ha per year.

DO NOT irrigate to the point of runoff within 72 hours of application.

DO NOT apply if heavy rain has been forecast within 72 hours.

DO NOT apply NIMITZ® via flood irrigation or overhead irrigation systems.

**Withholding periods:**

Harvest and Grazing: Not required when used as directed.

**Rotational crop restrictions**

Growers applying Nimitz must observe the following plant-back (recropping) intervals:

**Rotational crop restrictions after an application of Nimitz**

CROP	PLANT-BACK INTERVAL
Cover crops (green manure crops) and pastures	No restriction
Cucurbits, Tomatoes, Capsicum, Chilli, Eggplant, Okra, Carrots, Potatoes, Sugarcane, Sweet potatoes	No restriction
Other non-root/tuber vegetables	30 days
Other root and tuber vegetables	180 days
Oats and oaten hay	2 years
All other crops	180 days

**2.4 Results from residues trials presented to the APVMA***Sugar*

Residues of parent + BSA (in parent equivalents) in sugarcane billets at harvest after application at planting at the nominal rate of 1.92 kg ai/ha (1x proposed) were <0.025 mg/kg (n = 4). Residues in billets were also <0.025 mg/kg (n = 4) after application at the nominal rate of 3.84 kg ai/ha (2x proposed). An MRL of \*0.03 mg/kg is proposed for fluensulfone on GS 0659 Sugar cane.

*Rotational grain crops*

The proposed plant back interval for grain crops is 180 days. Highest residues of parent + BSA (in parent equivalents) in cereal grains after a plant back interval of 180 or more days after application at 4 kg ai/ha (approx. max. label rate) were <0.025 and 0.025 mg/kg (n=2). The sample with a finite residue contained 0.01 mg/kg BSA and <0.01 mg/kg fluensulfone.

*Rotational forage and fodder crops*

Highest residues of fluensulfone + BSA (in parent equivalents) in wheat forage from any plant back interval after application at 4 kg ai/ha (approx. max. label rate) in the field rotational crop trial were 1.3 and 2.1 mg/kg. Assuming wheat forage consists of 25% dry matter, the highest residue is 8.3 mg/kg on a dry weight basis. A Primary feed commodities [except sugar cane forage and fodder] MRL of 10 mg/kg would be required to cover use on crops that may be rotated to pasture without any plant back interval.

This MRL will also cover residues in animal feeds from grain crops following the proposed plant back interval of 180 days, or 2 years for oats and oaten hay. Based on the rotational cropping study, highest residues of BSA in wheat hay grown after a 365 day plant back interval were 0.37 mg/kg (as received), with fluensulfone <0.01 mg/kg.

### *Animal commodities*

Animal transfer studies were considered for lactating cattle where the animals were dosed with TSA and BSA (noting that residues of parent fluensulfone are not expected to occur in animal feeds as a result of the proposed uses).

Of the primary crops on the label, potential animal feeds include tomato pomace and sugar cane forage and fodder. However, the maximum livestock dietary exposure for cattle and sheep will be as a result of grazing animal feeds from grain crops or pasture grown in rotation with the primary crop as 100% of the diet. The highest residue in animal feeds from the field crop rotation trial was 8 mg/kg (dry wt.) (fluensulfone + BSA in fluensulfone equivalents) or 5 mg/kg (dry wt.) as BSA.

### *Cattle*

FEEDING LEVEL (PPM (BSA))	MILK BSA RESIDUE (MG/KG)	MUSCLE	LIVER	KIDNEY	FAT
5.25	<0.003	<0.003	<0.003	<0.003	<0.003
Established MRLs	*0.03 (milks)	*0.03 (meat)	*0.03 (offal)		-
Recommended MRLs	*0.01	*0.01	*0.01		-

Based on the feeding study, residues of BSA are not expected to occur in mammalian animal commodities as a result of the proposed uses. The fluensulfone mammalian commodity MRLs will be amended to \*0.01 mg/kg respectively to reflect the recommended change to the residue definition for animal commodities which will just be fluensulfone.

## 2.5 Overseas registration and approved label instructions

The applicant indicated that fluensulfone products are registered for use on various vegetable crops (cucurbits, fruiting vegetables, leafy vegetables, some berry crops, brassica vegetables, various root and tuber crops), sugar cane, coffee, black pepper and soybean in the USA, Canada, Japan, Korea, Taiwan, Israel, Mexico, Dominican Republic, Panama, Chile, Honduras, South Africa and Brazil.

## 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. Fluensulfone has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established in major export commodities for fluensulfone.

Table 2: International MRLs for fluensulfone in major export commodities

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLUENSULFONE (MG/KG)				
	AUSTRALIA	EU	JAPAN	CODEX	USA
Residue Definition	For plant commodities for compliance with MRLs: Fluensulfone + BSA expressed as fluensulfone.  For animal commodities: Fluensulfone	-	BSA	For plant commodities for compliance with MRLs: Fluensulfone + BSA expressed as fluensulfone.  For animal commodities: Fluensulfone	For compliance: BSA
All other foods	1	-	-	-	-
Cereals	0.05 (PROPOSED)	-	-	-	0.06 (Barley, oat and wheat grain)
Oilseeds	0.05 (PROPOSED)	-	-	-	-
Pulses	0.05 (PROPOSED)	-	-	-	-
Sugar cane	*0.03	-	-	-	0.04 (molasses 0.2)
Edible offal (Mammalian)	*0.01 (PROPOSED)	-	-	*0.01	-
Meat [mammalian]	*0.01 (PROPOSED)	-	-	*0.01 (fat)	-
Milks	*0.01 (PROPOSED)	-	-	*0.01	-

The applicant indicated that they are in the process of applying for import tolerances in the EU. The proposed residue definition is Fluensulfone + BSA in fluensulfone equivalents.

## 2.7 Current and proposed Australian MRLs for fluensulfone

Table 3: Current MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
FLUENSULFONE		
	All other foods	1
MO 0105	Edible offal (Mammalian)	*0.03
PE 0112	Eggs	*0.03
VC 0045	Fruiting vegetables, Cucurbits	2
VO 0050	Fruiting vegetables, other than Cucurbits	1
MM 0095	Meat [mammalian]	*0.03
ML 0106	Milks	*0.03
PO 0111	Poultry, Edible offal of	*0.03
PM 0110	Poultry meat	*0.03
VR 0508	Sweet potato	T1

Table 4: Proposed MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
FLUENSULFONE		
DELETE:		
MO 0105	Edible offal (Mammalian)	*0.03
PE 0112	Eggs	*0.03
VC 0045	Fruiting vegetables, Cucurbits	2
MM 0095	Meat [mammalian]	*0.03
ML 0106	Milks	*0.03
PO 0111	Poultry, Edible offal of	*0.03
PM 0110	Poultry meat	*0.03
VR 0508	Sweet potato	T1
ADD:		
GC 0080	Cereal grains	0.05
MO 0105	Edible offal (Mammalian)	*0.01
PE 0112	Eggs	*0.01

COMPOUND	FOOD	MRL (mg/kg)
VC 0045	Fruiting vegetables, Cucurbits	0.5
MM 0095	Meat [mammalian]	*0.01
ML 0106	Milks	*0.01
SO 0088	Oilseeds	0.05
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat	*0.01
VD 0070	Pulses	0.05
VR 0075	Root and tuber vegetables	2
GS 0659	Sugar cane	*0.03

**Table 3**

COMPOUND	RESIDUE
DELETE:	
<b>Fluensulfone</b>	Sum of fluensulfone, 3,4,4-trifluorobut-3-ene-1-sulfonic acid (M-3627) and 5-chloro-thiazole-2-sulfonic acid (M-3625)
ADD:	
<b>Fluensulfone</b>	Commodities of plant origin for enforcement: Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (M-3627), expressed as fluensulfone Commodities of plant origin for dietary exposure assessment: Fluensulfone Commodities of animal origin: Fluensulfone

**Table 4**

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
FLUENSULFONE		
ADD:		
	Primary feed commodities [except Sugar cane forage and fodder]	10
	Sugar cane forage and fodder	*0.03
	Tomato pomace, dry	2

## 2.8 Potential risk to trade

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

### *Residue definitions*

It is proposed to change the Australian residue definition for fluensulfone to align with that established by Codex (i.e. for plant commodities for enforcement = parent + BSA (M3627) in parent equivalents, for animal commodities = parent). Other definitions have been established overseas for fluensulfone in the USA and Japan (BSA only) and in Canada (parent + BSA expressed as parent equivalent).

### *Sugar*

Quantifiable residues of parent and BSA are not expected to occur in sugarcane billets as a result of the proposed use. The risk to trade in Australian sugar is low, based on currently established residue definitions for fluensulfone.

### *Rotational grain crops*

Low levels of BSA at the LOQ (0.01 mg/kg) may be expected in rotational grain crops (including cereals, pulses and oilseeds) as a result of the proposed uses. However, of the primary crops, it is considered likely that only processing tomatoes and potatoes may be grown in rotation with grain crops and therefore the proportion of grain crops that may be exposed to fluensulfone via rotational sources is expected to be limited. Given also grain is bulked and blended prior to export, the risk to trade in rotational grain crops is considered to be low based on currently established international residue definitions for fluensulfone.

### *Animal commodities*

Quantifiable residues of fluensulfone or its metabolites are not expected to occur in animal commodities as a result of the proposed uses. The risk to Australia's export trade in animal commodities is low.

### *Oaten Hay*

The highest residue of BSA in wheat hay grown after a 365 day plant back interval was 0.37 mg/kg (as received), with fluensulfone <0.01 mg/kg. While the rotational crop studies did not address a plant back interval later than 365 days, a 2 year plant back interval has been proposed for oats and oaten hay as a risk mitigation measure. For oaten hay, Japanese standards for fluensulfone are not currently established in 'The Ordinance on the Specifications and Standards of Feeds and Feed Additives' (to March 2015<sup>4</sup>) and the trade risk for oaten hay grown in rotation with treated crops is currently considered to be low. It is noted that the USA have established an MRL of 8 mg/kg for fluensulfone (based on BSA only) on oat hay as an indirect or inadvertent residue.

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<sup>4</sup> [http://www.famic.go.jp/ffis/feed/obj/shore\\_eng.pdf](http://www.famic.go.jp/ffis/feed/obj/shore_eng.pdf)

### 3 CONCLUSIONS

ADAMA Australia Pty Limited have made an application to vary the registration of Nimitz 480 EC Nematicide containing fluensulfone. ADAMA propose to add uses on processing tomatoes, root vegetables and sugarcane. ADAMA also wish to change the residue definition, extend the state claims and reduce plant-back intervals.

Comment is sought on the potential for Nimitz 480 EC Nematicide to prejudice Australian trade when used on sugarcane and vegetables that may be rotated with grains crops.