



## Trade Advice Notice

Australian Pesticides & Veterinary Medicines  
Authority

### Caprimec broad spectrum oral antiparasitic solution for goats

APVMA Product Number 60420

**June 2007**

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This Trade Advice Notice for Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats (APVMA Product Number 60420) is published by the Australian Pesticides & Veterinary Medicines Authority.

The APVMA invites comments on this Trade Advice Notice until 6 July 2007.  
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## 1. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Virbac (Australia) Pty Limited for the registration of a new product, *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats*, which contains 0.8 mg/mL of abamectin. The product is an oral drench that is to be used for the treatment and control of abamectin-sensitive strains of internal parasites of goats (including benzimidazole-, levamisole- and morantel-resistant strains).

The application involves consideration of the proposal to extend the use of abamectin to a new food-producing animal species (goats), along with the establishment of Australian Maximum Residue Limits (MRLs) for abamectin in goat commodities (meat, offal and milk). Additionally, the application requires the setting of meat and milk withholding periods (WHPs), establishment of an export slaughter interval (ESI), and approval of the proposed product label.

## 2. RESIDUES IN LIVESTOCK

In support of the application, Virbac (Australia) Pty Limited provided details of one (1) residues trial conducted in meat goats, and one (1) residues trial conducted in lactating dairy goats.

### 2.1. Tissue residues trial

In an Australian residues trial, meat goats (n=15) were orally dosed with 0.2 mg abamectin/kg bw (equivalent to 0.69× the maximum proposed label rate). Groups of goats (n=5) were sacrificed at 14, 28 and 42 days after treatment, and samples of liver, kidney, muscle, peri-renal fat and subcutaneous fat were collected and stored frozen until analysed for their residues concentrations. The results from the residues trial were corrected to reflect the maximum 1× label dose rate.

Fat was identified as the ‘critical tissue’ for abamectin residues in treated goats, and it is the decline of abamectin residues in this tissue that determines the duration of the slaughter WHP (and ESI) that applies to use of the new product.

Analysis of the residues data for abamectin subcutaneous and peri-renal fat from treated goats, and application of a correction factor of 1.45 to address the maximum 1× dose rate, shows that a period of 14 days is required for residues to decline to below the proposed abamectin MRL of 0.1 mg/kg for goat fat.

#### 2.1.1. Meat WHP

Thus, a 14 day meat WHP is recommended for the use of *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats* in goats.

#### 2.1.2. MRLs for goat tissues

The following abamectin MRLs are recommended to cover the occurrence of abamectin residues in edible goat tissues after the 14 day WHP has been observed:

goat fat:	0.1 mg/kg;
goat muscle:	0.01 mg/kg;
goat liver:	0.05 mg/kg;
goat kidney:	0.01 mg/kg.

## 2.2. Milk residues trial

In an Australian residues trial, lactating goats (n=20; Anglo Nubian and British Alpine breeds) were administered a single oral dose of 0.22 mg abamectin/kg bw (equivalent to 0.85× the maximum proposed label rate) using the product intended for registration. Milk samples were collected twice daily (at approximately 12 hourly intervals) for the first 5 days after treatment, and on the morning of Day 7. Samples were stored frozen until analysed for their content of abamectin (avermectin B<sub>1a</sub>) residues. The results from the residues trial were corrected to reflect the maximum 1× label dose rate.

### 2.2.1. Milk WHP

The applicant has proposed that a milk WHP of 4 days (8 milkings) be assigned to the new product. The highest abamectin residue in milk (0.034 mg/kg) occurred at the 2<sup>nd</sup> milking after treatment. At the 8<sup>th</sup> milking post-treatment, milk residues ranged from non-detectable (<0.01 µg/kg) to 4.4 µg/kg. At the 9<sup>th</sup> milking (ie the proposed earliest time where milk would enter the human food chain), residues ranged from <0.01 to 3.1 µg/kg.

### 2.2.2. MRL for goat milk

These data support the assignment of a milk WHP of 4 days (8 milkings) to the product, and the establishment of an abamectin MRL of 0.005 mg/kg for goat milk.

## 2.3. Re-treatment interval

The results from the milk and tissue residues trials demonstrate that abamectin residues in all edible commodities have declined to levels below the method LOQ at 28 days after treatment. Thus, repeat treatment of goats at 28 day intervals is not expected to result in accumulation of abamectin residues in edible goat tissues.

The proposal that a minimum re-treatment interval of 28 days be assigned to *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats* is supported.

### 3. RESIDUES-RELATED ASPECTS OF TRADE

#### 3.1. Commodities exported

Australian exports of goat meat and offal and live goats could be affected by the use of *Capripec Broad Spectrum Oral Antiparasitic Solution for Goats*.

#### 3.2. Destination and value of exports

##### 3.2.1. Goat meat exports

Australia exported ~17.9 ktonne of goat meat during 2005-06, which was valued at \$AUS 82.2 million. Details of the top export markets for Australian goat meat are provided below.

##### Goat meat exports in 2005-06 (Source: MLA)

Rank (by \$ value)	Importing country	Quantity (tonne)	Value (\$A m)
1	United States	9847.2	45.05
2	Taiwan	5442.8	20.47
3	Caribbean	1271.2	6.49
4	Canada	823.6	3.86
5	Japan	179.0	0.82
6	Korea	125.3	0.66
7	Other	214.8	4.77
<b>Total</b>		<b>17,904</b>	<b>82.2</b>

### 3.2.2. Live goat exports

Australia exported approximately 43,770 head of live goats during 2005-06, which were valued at \$AUS 5.5 million. Details of the top export markets for Australian live goats are provided below.

#### Live goat exports in 2005-06 (Source: MLA)

Rank (by \$ value)	Importing country	Quantity (no. of animals)	Value (\$A m)
1	Malaysia	30,112	3.78
2	Singapore	9,235	1.16
3	Brunei	1,970	0.25
4	Indonesia	569	0.07
5	Other	1,882	0.24
<b>Total</b>		<b>43,768</b>	<b>5.5</b>

### 3.3. Proposed Australian use pattern

#### Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats (0.8 mg abamectin/mL)

Host	Pest/Disease	Rate	Critical Comments
Goats (meat and dairy)	For the treatment and control of abamectin-sensitive strains of adult and immature gastrointestinal worms, and lungworms.	<p><b>Nominal</b> 0.2 mg abamectin/kg bw</p> <p><b>Maximum (meat)</b> 0.29 mg abamectin/kg bw (when 7.5 mL product is administered to a 21 kg goat)</p> <p><b>Maximum (milk)</b> 0.26 mg abamectin/kg bw (when 10 mL product is administered to a 31 kg doe).</p>	Minimum re-treatment interval is 28 days.

#### 3.3.1. Re-treatment interval

DO NOT re-treat goats for 28 days after last treatment.

#### 3.3.2. Withholding periods

MEAT DO NOT USE less than 14 days before slaughter for human consumption.

MILK collected from does within 4 days (8 milkings) following treatment MUST NOT BE USED for human consumption or processing, or fed to bobby kids.

#### 3.3.3. Trade advice

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT slaughter for export for 28 days after last treatment.

### 3.4. Overseas registrations

Virbac (Australia) Pty Limited has not provided details of the overseas registration status of abamectin-based products and their use in goats.

### 3.5. Comparison of the (proposed) Australian MRLs with Codex 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. Abamectin has been considered by Codex. Additionally, abamectin MRLs/tolerances have been established by a number of overseas countries, and these are tabulated below along with the proposed Australian MRLs.

#### Comparison of proposed Australian, and overseas abamectin MRLs/tolerances

Commodity	Overseas MRLs/tolerances (mg/kg)					Proposed Australian MRLs (mg/kg)
	‡ Codex	‡ Europe	† Japan	‡ USA	Taiwan	
Goat meat	*0.01	*0.01	--	0.02	--	0.01
Goat, edible offal of	0.1	*0.01	--	--	--	--
Goat meat by-products	--	--	--	0.02	--	--
Goat muscle	--	--	0.01	--	--	--
Goat fat	--	--	0.04	--	--	0.1
Goat liver	--	--	0.1	--	--	0.05
Goat kidney	--	--	0.1	--	--	0.01
Goat milk	0.005	--	--	--	--	0.005
Milk	--	0.005	0.005	0.005	--	--

‡ MRLs based on transfer of residues from contaminated feeds (rather than direct veterinary application)

† Provisional Japanese MRLs

\* MRL set at or about the limit of quantification for the analytical method

### 3.6. Potential Risk to Trade

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

#### 3.6.1. Goat meat exports

Australia's main export markets for goat meat are the USA and Taiwan. Taiwan is identified as the most sensitive export market, as there are no known Taiwanese MRLs for abamectin residues in edible goat tissues. It is concluded that the appropriate "endpoints" for the ESI determinations for *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats* are the limits of quantification (LOQs) of the analytical method ie 0.001 mg/kg for all goat tissues.

The results from the tissue residues trial demonstrate that abamectin residues in all edible commodities have declined to levels below the method LOQ at 28 days after treatment. Thus, an export slaughter interval (ESI) of 28 days is recommended for *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats*.

#### 3.6.2. Trade advice statements

The following trade advice statement is to be included on the product label:

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT slaughter for export for 28 days after last treatment.

## 4. CONCLUSIONS

The risk to Australia's export trade in goat commodities, arising from the use of *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats* is considered to be low when an ESI of 28 days is observed, because abamectin residues in edible tissues from treated goats are expected to be below the limit of quantification.

However, the APVMA seeks comment from relevant industry groups and stakeholders in relation to whether the proposed use of abamectin in the product *Caprimec Broad Spectrum Oral Antiparasitic Solution for Goats* poses an undue prejudice to Australia's export trade in goat meat.

The APVMA also welcomes comment on any residues aspects of trade.

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