Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on monepantel in the product Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Cattle

APVMA Product Number 82001

DECEMBER 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, 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 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 Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Cattle 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 6 January 2017 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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)*[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
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4701
Email: enquiries@apvma.gov.au

Further information

Further information on public release summaries can be found on the APVMA website at www.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 Elanco Animal Health Pty Ltd, to register ZOLVIX Monepantel Broad Spectrum Oral Anthelmintic for Cattle for use in beef cattle and non-lactating dairy cattle.

2 RESIDUES IN LIVESTOCK

2.1 Proposed Australian use pattern

Table 1: Proposed use pattern

<table>
<tr><th>TARGET SPECIES</th><th>PURPOSE</th><th>DOSE RATE</th></tr>
<tr><td>Beef and non-lactating dairy cattle</td><td>For the control of gastro-intestinal nematode infections in beef cattle and non-lactating dairy cattle</td><td>Zolvix is a ready-to-use oral drench solution. The dose for cattle is 5 mL/50 kg (1 mL/10 kg) (equivalent to 2.5 mg monepantel/kg liveweight).
<table>
<tr><th rowspan="2">Body Weight (kg)</th><th rowspan="2">Dose (mL)</th><th colspan="6">Number of animals treated per:</th></tr>
<tr><th>0.25 L</th><th>0.5 L</th><th>1 L</th><th>2.5 L</th><th>5 L</th><th>10 L</th></tr>
<tr><td>70–100</td><td>10</td><td>25</td><td>50</td><td>100</td><td>250</td><td>500</td><td>1000</td></tr>
<tr><td>101–150</td><td>15</td><td>16</td><td>33</td><td>66</td><td>166</td><td>332</td><td>664</td></tr>
<tr><td>201–250</td><td>25</td><td>10</td><td>20</td><td>40</td><td>100</td><td>200</td><td>400</td></tr>
<tr><td>251–300</td><td>30</td><td>8</td><td>16</td><td>33</td><td>83</td><td>166</td><td>332</td></tr>
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<tr><td>401–450</td><td>45</td><td>5</td><td>11</td><td>22</td><td>55</td><td>110</td><td>220</td></tr>
<tr><td>451–500</td><td>50</td><td>5</td><td>10</td><td>20</td><td>50</td><td>100</td><td>200</td></tr>
<tr><td>501–550</td><td>55</td><td>4</td><td>9</td><td>18</td><td>45</td><td>90</td><td>180</td></tr>
<tr><td>551–600</td><td>60</td><td>4</td><td>8</td><td>16</td><td>41</td><td>82</td><td>164</td></tr>
<tr><td>601–650</td><td>65</td><td>3</td><td>7</td><td>15</td><td>38</td><td>76</td><td>152</td></tr>
</table>
Cattle in excess of 650 kg body weight should be dosed at 5 mL/50 kg.</td></tr>
</table>

Re-treatment interval

Do not re-treat less than 21 days after the last treatment. After three consecutive treatments, 10 weeks must elapse before treating again with ZOLVIX.

Withholding periods

Meat: do not use less than 7 days before slaughter for human consumption.

Milk: do not use in lactating cows or within 49 days of calving where milk may be used or processed for human consumption.

Trade advice

Export slaughter interval (ESI): do not use less than 10 weeks before slaughter for export.

3 RESIDUES-RELATED ASPECTS OF TRADE

3.1 Commodities exported

Cattle meat, milk, and offal are considered to be major export commodities[2]. Monepantel residues in cattle commodities resulting from the use of Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Cattle may have the potential to unduly prejudice trade.

3.2 Destination and value of exports

Cattle exports

Meat and offal

In 2014–15, Australia exported 1,349 kt of beef and veal (worth $B 8.86)[3]. The significant export markets for Australian beef meat and offals are listed in the APVMA regulatory guidelines—data guidelines: veterinary—overseas trade (Part 5B).

[2] APVMA regulatory guidelines—data guidelines: veterinary—overseas trade (Part 5B)

[3] ABARES (2015), agricultural commodity statistics 2015.

Dairy

The value of Australian dairy exports in 2014–15 was $2.9 billion[4]. Asia (excluding South East Asia, $1214 million, 42%), South East Asia ($1022 million, 35%) and the Middle East ($303 million, 11%) are the significant regions for Australian dairy exports.

The major export markets for Australian dairy products including butter and butterfat, cheese, milk, milk powder and other dairy products in 2014–2015 are presented in the following table:

COUNTRY	GREATER CHINA*	JAPAN	SINGAPORE	INDONESIA	MALAYSIA	PHILIPPINES	THAILAND	NEW ZEALAND
Volume (tonnes)	136,400 (18%)	103,900 (14%)	86,600 (11%)	59,400 (8%)	51,100 (7%)	40,900 (5%)	31,000 (4%)	28,470 (4%)
Value (A$ million)	424 (15%)	483 (17%)	243 (8%)	256 (9%)	201 (7%)	124 (4%)	127 (4%)	129 (4%)

*Includes China, Hong Kong, and Macau

3.3 Overseas registrations

The applicant has indicated that Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Cattle is undergoing registration in the European Union, with relevant cattle MRLs recently being established.

[4] Dairy Australia and ABS (2015), Australian Dairy Industry in Focus 2015, www.dairyaustralia.com.au/Industry-information/About-Dairy-Australia/~/media/Documents/Stats%20and%20markets/Australian%20Dairy%20Industry%20In%20Focus/Australian%20Dairy%20Industry%20In%20Focus%202015.pdf

3.4 Comparison of the (proposed) Australian MRLs with Codex and overseas MRLs

Table 2: Comparison of Australian and Overseas MRLs

COMPOUND	OVERSEAS MRL/TOLERANCE (mg/kg)	PROPOSED AUSTRALIAN MRLS (mg/kg)
	EU	
Monepantel		
Cattle, muscle	0.3	0.3
Cattle, fat	7	7
Cattle, liver	2	2
Cattle, kidney	1	1
Cattle, edible offal	-	-
Milks	-	*0.05

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

It should be noted that relevant monepantel MRLs have not been set by: China, Japan, Taiwan, Russia, the United States, Singapore, and Codex.

3.5 Potential risk to trade

Cattle exports

As major export markets have not established monepantel MRLs for cattle commodities, residues of monepantel must be below the limit of quantification (LOQ) to prevent an undue risk to international trade. Previously, 0.01 mg/kg (10 µg/kg) has been considered an appropriate endpoint for determining ESIs for monepantel.

Meat and offal

A residue depletion study investigated the decline in monepantel residues in edible tissues from cattle to below the LOQ, following application of monepantel at the maximum proposed rate of 3 doses at 3.71 mg monepantel/kg body weight, administered 21 days apart. The data demonstrated that monepantel residues in edible tissues declined to below 0.005 mg/kg at 85 days after last application (based on sampling at 21, 42, 56, and 85 days post treatment).

A statistical analysis was performed to determine the likelihood of residues in all edible tissues declining to the ESI endpoint of 0.01 mg/kg. This analysis indicates that residues above 0.01 mg/kg should not occur in the muscle, fat, liver, or kidney of cattle treated with monepantel according to the proposed use after 10 weeks.

Dairy

A residue depletion study investigated the decline in monepantel residues in colostrum and milk from dairy cattle. Pregnant heifers were treated orally with 2.9 mg monepantel/kg BW, an estimated 49 days prior to presumed calving. Following calving, animals were milked twice daily for 8 days (16 milkings) and colostrum and milk samples were analysed for monepantel residues. No residues above the LOQ of 0.05 mg/kg were detected in any colostrum or milk samples from any cattle. The data support the proposed 49 day pre-calving treatment interval.

3.6 Trade advice statements

A 10 week Export Slaughter Interval (ESI), is to be associated with the proposed use of Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Cattle.

4 CONCLUSIONS

Key export markets of Australian beef, and dairy products have not established monepantel MRLs for cattle commodities. However, the risk to Australia's export trade is considered to be low and acceptable, as residues above 0.01 mg/kg are not expected in edible cattle tissues when the proposed ESI of 10 weeks is observed for Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Cattle.

Additionally, the risk to Australia's export trade in cattle dairy products is considered to be low and acceptable, as residues above the LOQ of 0.05 mg/kg are not expected in milk when the proposed pre-calving treatment interval of 49 days is observed for Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Cattle.

Comment is sought on the proposed risk to trade in beef and dairy products from the proposed use.