



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



TRADE ADVICE NOTICE

on thiaclopid in the Product Piranha® Dip for Sheep

APVMA Product Number 63766

FEBRUARY 2013

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ISSN: 2200-3894 (electronic)

ISBN: 978-1-922188-20-5 (electronic)

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator 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, the Office of Chemical Safety (OCS) within the Department of Health and Ageing, Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), and relevant state and territory departments.

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 proposed extensions of use for existing chemicals where there may be trade implications, as defined in *Vet MORAG: Manual of Requirements and Guidelines* Part 5B.

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 register the new product, Piranha® Dip for Sheep, 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 matters relate to the **trade implications** of the use of the product. Comments received outside these matters cannot be considered by the APVMA. Submissions should state the grounds on which they are based.

Submissions must be received by the APVMA by close of business on **22 March 2013** 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)**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:

Contact Officer, Veterinary Medicines
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Australian Pesticides and Veterinary Medicines Authority
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Further information

Further information on trade advice notices can be found on the APVMA website:
www.apvma.gov.au/registration/assessment/trade.

For additional information please refer to the contact details provided above.

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 Bayer Australia Limited (Animal Health), for the registration of a new product, Piranha® Dip for Sheep, which contains the approved active constituent thiacloprid (480 g/L). The new product is a plunge dip that is intended for the control of the sheep body louse (*Bovicola ovis*) on short wool sheep.

To date, there are no products containing thiacloprid that are registered for use on food-producing animal species. However, there are two thiacloprid-based products registered for agricultural uses in Australia.

The existing Australian maximum residue limits (MRLs) for thiacloprid in animal commodities were established to cover the occurrence of residues as a result of animals consuming feedstuffs containing thiacloprid residues. Therefore, the current application does not involve the establishment of Australian MRLs for thiacloprid in edible sheep tissues.

However, the application does require 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

2.1 Proposed Australian use pattern

The use-pattern for thiacloprid on sheep is tabulated below.

Table 1: Proposed use pattern for thiacloprid on sheep

HOST	PURPOSE	DOSE RATE	CRITICAL COMMENTS
For use on short wool sheep (10 days to 6 weeks after shearing)	For the control of the sheep body louse (<i>Bovicola ovis</i>) on short wool sheep.	<p>Nominal</p> <p><u>Plunge dip:</u> Initial charge – dilute at a rate of 10 mL product in 100 L of water (equivalent to 48 mg thiacloprid/L water).</p> <p>Topping up – dilute at a rate of 10 mL product in 100 L of fresh water and top up when dip level falls by approximately 25 %.</p>	<p>Plunge dips should be at least 9 m in length to ensure adequate contact time between sheep and dip solution. Sheep should be pushed under twice and heads dunked to improve the opportunity for thorough fleece wetting. Do not allow dip volume to drop below a suitable working volume which allows the sheep to be completely dunked. For effective control of lice, thorough wetting to skin level is essential.</p> <p>Allow shearing cuts to heal before dipping.</p> <p>Dipping sheep heavily infested with grass seed is not recommended.</p> <p>This is a non-stripping dip. Reinforcement with undiluted concentrate is not required when topping up. When dipping out (ie the level of dip wash falls by more than 25 %) add 10 mL of Piranha Dip for Sheep in 100L of water each time the level of dip wash falls by 500 L.</p> <p>Dip should be discarded if it becomes excessively fouled, and at the end of each day's dipping.</p> <p>Do not use this product for hand jetting, in jetting races or in shower dips.</p>

Restraints

DO NOT dip sheep less than 10 days after shearing.

DO NOT dip sheep more than 6 weeks after shearing.

DO NOT USE on ewes which are producing or may in the future produce milk that may be used or processed for human consumption.

Repeat Treatment

DO NOT APPLY more than once each year.

Withholding periods

MEAT: DO NOT USE less than 42 days before slaughter for human consumption.

MILK: DO NOT USE on ewes which are producing or may in the future produce milk that may be used or processed for human consumption.

WOOL: DO NOT USE less than 3 months before shearing or fibre collection.

Trade advice

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT slaughter for export less than 60 days (2 months) after treatment. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current

ESI from the Bayer Website www.farmadvisor.com.au or via the APVMA website at www.apvma.gov.au/residues/ or by calling Bayer Australia Ltd on 1800 678 368.

2.2 Current Australian MRLs and residues definition

The current relevant entries for thiacloprid in the *MRL Standard* are listed below.

Table 1

COMPOUND	FOOD	MRL (mg/kg)
Thiacloprid		
MO 0105	Edible offal (mammalian)	*0.02
MM 0095	Meat (mammalian)	*0.02
ML 0106	Milks	*0.01

* denotes that the MRL was set at or about the limit of quantification (LOQ) of the analytical method used to generate the residue data

The existing thiacloprid MRLs for meat (mammalian) of *0.02 mg/kg and edible offal (mammalian) of *0.02 mg/kg are based on a maximum anticipated exposure of ~8.4 mg thiacloprid/animal/day, as a result of lactating cows consuming pome fruit pomace (20 % of the diet) containing 3 ppm thiacloprid residues.

Table 3

COMPOUND	RESIDUE
Thiacloprid	Thiacloprid

Metabolism and pharmacokinetic data: It was concluded that the metabolic pathways for thiacloprid in rats (laboratory species used to set the health standards) are comparatively similar to those found in livestock species (goats and chickens). Based on scientific argument, it was also concluded that the metabolism of thiacloprid in sheep is unlikely to differ significantly from that observed in other mammalian species.

Residue definition /marker residue: It was concluded that the current residues definition / marker residue of parent thiacloprid remains appropriate, and is consistent with the use of the JECFA-approach to assessing residues of veterinary drugs.

Ratios of marker residues to total residues in sheep tissues: The data provided were not sufficient to enable estimates of the ratios of marker residues (MR) to total residues (TR) in edible sheep tissues to be made. However, considering the fact that:

- the current application does not require any changes to the existing Australian thiacloprid MRLs;
- monitoring and surveillance testing for thiacloprid residues in sheep tissues cannot differentiate the source of the residues ie via direct treatment or indirect exposure to contaminated feed; and
- the APVMA has previously determined that consumption of thiacloprid residues at the existing MRL is unlikely to constitute an undue risk to human health,

it was concluded that Bayer does not need to submit further metabolism data for thiacloprid in sheep. However, should any (future) application to register a direct veterinary use-pattern involve an increase in the existing animal commodity MRLs for thiacloprid, then the additional sheep metabolism/pharmacokinetic studies will be required.

2.3 Residues in livestock

Bayer submitted details of five (5) tissue residues trials conducted in Australia. The first was a pilot trial; the second and third trials nominally addressed the APVMA's requirements for "winter" and "summer" trials to address the effects of climate on residues resulting from the use of ectoparasiticides. The fourth trial was largely designed to address issues relating to identifying the "worst case" residues scenario. The fifth and final trial was the "critical" residues trial, incorporating the components of the "worst case" residues scenario.

Trial location, timing and temperature: Qualitative examination of the residues data provided for Piranha® Dip for Sheep suggested that higher (and more persistent) thiacloprid residues were associated with treatment and housing of sheep at warmer temperatures.

Animals: Residues trials were conducted using a combination of adult Merino sheep, and tropically adapted first cross (Coolalee x Merino) lambs, which had growth characteristics and body compositions similar to those of second cross lambs.

Timing of treatment (wool length): The proposed use-pattern for Piranha® Dip for Sheep involves plunge dipping short-wool sheep between 10 days to 6 weeks after shearing. The effect of fleece length on tissue thiacloprid concentrations was examined by plunge dipping sheep with either 10 days or 6 weeks of wool growth. Statistical analyses of the data showed that there were no significant differences in the concentrations of thiacloprid residues in edible tissues from sheep with different fleece lengths.

Application rate (dip strength) and dipping process: The proposed use-pattern for Piranha® Dip for Sheep involves plunge dipping short-wool sheep in a solution containing 48 mg thiacloprid/L. The generally accepted "Good Practice" to plunge dipping is for animals to swim a length of nine (9) metres or more, with a minimum 20 second swim and two head dunks in addition to the initial splash entry.

Most of the residues trials were conducted at elevated rates (1.5 to 2 x the label rate), and different dipping processes were used in each trial. The variability of the dipping processes seen in the residues trials is likely to reflect the variability of on-farm practices. Further, there is a broad range of factors that impact on the residues profiles of treated sheep. Therefore, in this instance, it was not considered appropriate to correct the residues data for dip strength (to the 1x rate). Analysis of the residues data, without correction for dose rate, reflects the "worst case" residues scenario.

Identification of "target tissues": Review of the residues results revealed that liver and kidney are the target tissues for thiacloprid residues in treated sheep.

Domestic WHP "endpoint": The existing Australian MRLs for thiacloprid residues in animal tissues (meat and offal) are *0.02 mg/kg. Therefore, the "endpoint" for the determination of the domestic WHP is 0.02 mg/kg.

Export Slaughter Interval (ESI) "endpoint": In the absence of MRLs for thiacloprid residues in sheep tissues in China, CIS and Saudi Arabia (see Section 3.4 of this trade advice notice), the ESI needs to be long enough for thiacloprid residues in all edible sheep tissues to decline to concentrations below an appropriate method LOQ. Therefore, the selected ESI "endpoint" for thiacloprid is 5.0 µg/kg (0.005 mg/kg).

2.4 Withholding periods (WHPs)

Meat

The residues decline data for thiacloprid in liver and kidney (target tissues) from treated sheep were statistically analysed using the EMA's 'Meat' program (which determines the upper 95 % confidence limit of the 95th percentile). The results of the analyses revealed that periods up to 39 days were required for thiacloprid residues in liver to decline to below the MRL of *0.02 mg/kg in each of the residues trials. Similarly, periods up to 30 days were required for thiacloprid residues in kidney to decline to below 0.02 mg/kg in each of the residues trials.

On the basis of these results, a meat WHP of 42 days is recommended for Piranha® Dip for Sheep.

Milk

In the absence of any milk residues data for treated sheep, the following milk WHP is recommended for Piranha® Dip for Sheep:

MILK: DO NOT USE on ewes which are producing or may in the future produce milk that may be used or processed for human consumption.

2.5 Export slaughter interval (ESI)

The residues decline data for thiacloprid in liver and kidney (target tissues) from treated sheep were statistically analysed using the EMA's 'Meat' program (which determines the upper 95 % confidence limit of the 95th percentile). The results of the analyses revealed that periods up to 57 days were required for thiacloprid residues in liver to decline to below the LOQ of 0.005 mg/kg in each of the residues trials. Similarly, periods up to 45 days were required for thiacloprid residues in kidney to decline to below 0.005 mg/kg in each of the residues trials.

On the basis of these results, an ESI of 60 days is recommended for Piranha® Dip for Sheep.

3 RESIDUES-RELATED ASPECTS OF TRADE

3.1 Commodities exported

Australian exports of lamb/mutton and live sheep could be affected by the use of Piranha® Dip for Sheep

3.2 Destination and value of exports

Consultation within Commonwealth and State Government agencies and with Sheepmeat Council of Australia has determined that the APVMA will consider the standards of China, Commonwealth of Independent States (CIS), European Union (regarded as 27 countries as of January 2007), Japan, Saudi Arabia, United Arab Emirates (UAE) and USA, along with the Maximum Residue Limit Standard of the Codex Alimentarius Commission, when determining Export Slaughter Intervals for sheep [see http://www.apvma.gov.au/registration/morag/notices/docs/op_notice_markets_consideration_esi.pdf].

3.3 Overseas registrations

Piranha® Dip for Sheep is not currently registered for use in any overseas countries.

3.4 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. Some countries may accept Codex CXLs when importing foods. Thiacloprid has been considered by Codex (JMPPR), and CXLs have been established for animal commodities (mammalian meat and offal) on the basis of animal transfer data. Further, thiacloprid MRLs/tolerances have been established by a number of overseas countries, and these are tabulated below along with the existing Australian MRLs.

Table 2: Comparison of Australian and Overseas Thiacloprid MRLs

	OVERSEAS MRL/TOLERANCE (mg/kg)					AUSTRALIAN MRL(mg/kg)
	CODEX	EU	USA	JAPAN	UAE	
Residue definition	(b)	(b)	(a)	Unknown	(b)	(b)
Sheep muscle	0.1	0.05	0.03	0.03	0.1	0.02
Sheep fat	--	0.05	0.02	0.02	--	0.02
Sheep liver	0.5	0.3	0.15	0.09	0.5	0.02
Sheep kidney	0.5	0.3	0.05	0.04	0.5	0.02
Sheep, edible offal	--	*0.01	0.05	0.04	0.5	0.02

(a) Combined residues of the insecticide thiacloprid ([3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene] cyanamide) and metabolites retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se*.

(b) Thiacloprid (parent) only.

* MRL set at or about the LOQ of the analytical method used to generate the residue data.

No MRLs/tolerances have been established by China, the Russian Federation (CIS), or Saudi Arabia for thiacloprid in sheep meat and offal.

3.5 Potential risk to trade

Export of treated produce containing finite (measurable) residues of thiacloprid 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 establishment of an ESI aids in managing the potential risks to trade arising from the use of Piranha® Dip for Sheep.

3.6 Determination of the ESI end point

In the absence of MRLs for thiacloprid residues in sheep tissues in China, CIS and Saudi Arabia, the ESI needs to be long enough for thiacloprid residues in all edible sheep tissues to decline to concentrations below the appropriate method LOQ. A method LOQ of 0.005 mg/kg is considered appropriate, and it is this LOQ (0.005 mg/kg) that has been used for the ESI determination for thiacloprid.

Review of the results of statistical analyses using the EMA's "Meat" program (see Section 2.5 of this notice) shows that a period of 60 days is required for thiacloprid residues in in edible sheep tissues to decline to below the method LOQ of 0.005 mg/kg. Therefore, an ESI of 60 days is recommended for Piranha® Dip for Sheep.

3.7 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 less than 60 days (2 months) after treatment. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI from the Bayer Website www.farmadvisor.com.au or via the APVMA website at www.apvma.gov.au/residues or by calling Bayer Australia Ltd on 1800 678 368.

4 CONCLUSIONS

The APVMA has considered whether the use of Piranha® Dip for Sheep in accordance with the label instructions could potentially unduly prejudice trade and commerce between Australia and places outside Australia, as per Section 14(3)(e)(iv) of the Agvet Code.

The risk to Australia's export trade in sheep meat and live sheep is considered to be low when the recommended ESI of 60 days (2 months) is observed for Piranha® Dip for Sheep, as residues in all tissues are expected to be below the method LOQ (<0.005 mg/kg).

The APVMA is seeking comment from relevant industry groups and stakeholders in relation to the perceived level of risk to Australia's export trade in sheep meat and live sheep.

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