





APPENDIX 2

TEMPLATE FOR RELEVANT LABEL PARTICULARS (RLPs) (Veterinary Products)

Select appropriate:

- New Product (include all applicable RLPs) OR
 Variation (highlight instructions that are being varied). Approval no. of label being varied:...
 68946/59451

Signal heading:	CAUTION KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS FOR ANIMAL TREATMENT ONLY	
Product name:	BAYCOX[®] COCCIDIOCIDE for piglets and cattle	
Active constituent/s:	50 g/L TOLTRAZURIL	
Statement of claims:	<p>For the control of coccidiosis in neonatal piglets caused by <i>Isospora suis</i>, and in cattle up to 9 months of age caused by <i>Eimeria bovis</i> or <i>Eimeria zuernii</i>.</p> <p>BAYCOX[®] is effective in one dose because it attacks all stages of the parasite in the animal.</p> <p>Piglets: BAYCOX[®] controls coccidiosis caused by <i>Isospora suis</i> infection of young piglets. <i>Isospora suis</i> infection is a major cause of diarrhoea, dehydration, loss of appetite, poor growth, and occasional mortality in piglets between birth and 3-4 weeks of age.</p> <p>Cattle: BAYCOX[®] is for the treatment of clinical coccidiosis, and as an aid in the prevention of coccidiosis in cattle up to 9 months of age. BAYCOX[®] controls coccidiosis caused by <i>Eimeria bovis</i> or <i>Eimeria zuernii</i> in young cattle. Coccidiosis typically occurs in cattle less than a year old causing diarrhoea which is often blood stained. Recently weaned calves are susceptible to outbreaks of clinical disease.</p>	
Net contents:	250mL, 1L, [1L backpack]	
Directions for Use		

Heading:	READ THE ATTACHED LEAFLET BEFORE USING THIS PRODUCT DIRECTIONS FOR USE														
Restrains:	DO NOT RE-TREAT calves for 75 days after the last treatment. DO NOT TREAT piglets later than 8 days of age.														
Contraindications:															
Precautions:															
Side effects:															
Dosage & administration:	<p>SHAKE THE CONTAINER BEFORE USE Give by mouth. Ensure the applicator is delivering a full dose before starting treatment. The applicator should be set to deliver a full dose per stroke.</p> <table border="1"> <thead> <tr> <th></th> <th>Dose</th> <th>Prevention</th> <th>Treatment</th> </tr> </thead> <tbody> <tr> <td>Piglets</td> <td>1 mL</td> <td>Treat at 3-6 days old</td> <td>Treat at onset of coccidial diarrhoea. Treat all piglets in infected litters and all infected and 'at risk' litters in the farrowing house.</td> </tr> <tr> <td>Cattle</td> <td>3mL per 10kg bodyweight</td> <td>In the case of history of coccidiosis on farm, treat 1 week before expected onset of clinical signs. For prevention of coccidiosis in recently weaned calves, treat at weaning time when milk feeding ceases.</td> <td>Treat at onset of diagnosed clinical signs.</td> </tr> </tbody> </table>				Dose	Prevention	Treatment	Piglets	1 mL	Treat at 3-6 days old	Treat at onset of coccidial diarrhoea. Treat all piglets in infected litters and all infected and 'at risk' litters in the farrowing house.	Cattle	3mL per 10kg bodyweight	In the case of history of coccidiosis on farm, treat 1 week before expected onset of clinical signs. For prevention of coccidiosis in recently weaned calves, treat at weaning time when milk feeding ceases.	Treat at onset of diagnosed clinical signs.
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General directions:	<p>Piglets: In the case of diarrhoea in neonatal piglets, obtain a veterinary diagnosis of coccidiosis before using this product. Clinical coccidiosis of piglets appears in piglets from 5 to 30 days of age. Control of the disease is most effective when BAYCOX[®] is given as a preventive before intestinal damage occurs and diarrhoea begins.</p> <p>Cattle: In the case of diarrhoea in calves, obtain a veterinary diagnosis of coccidiosis before using this product. Early treatment of calves as soon as the diagnosis is obtained will prevent further intestinal damage in affected animals and prevent infection of the herd. To obtain maximum benefit on farms with a</p>														

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	history of coccidiosis, BAYCOX [®] should be given approximately 1 week before expected onset of clinical signs. Treatment of newly weaned calves at the time of milk withdrawal will control coccidiosis associated with weaning
Withholding Period/s:	MEAT (PIGS): DO NOT USE less than 70 days before slaughter for human consumption. MEAT (CATTLE): DO NOT USE less than 56 days before slaughter for human consumption. MILK (CATTLE): DO NOT USE in lactating or pregnant cows where milk may be used or processed for human consumption.
Trade Advice:	EXPORT SLAUGHTER INTERVAL (ESI) PIGS: An ESI has not been established for this product for pigs. Note – observing the meat withholding period may not be sufficient to mitigate potential risks to export trade. Trade advice should be sought from Bayer Animal Health on 1800 678 368 before using this product. EXPORT SLAUGHTER INTERVAL (ESI) CATTLE: DO NOT slaughter cattle for export for 75 days after last treatment. The ESI for cattle on this label was correct at the time of label approval. Before using this product, confirm the current ESI from the manufacturer on 1800 678 368 or the APVMA website: www.apvma.gov.au/residues
Safety Directions:	When using the product wear rubber gloves. After each day's use wash gloves.
First Aid:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
Additional user safety:	
Environmental statements:	Do not contaminate ponds, waterways or drains with this product or used container.
Disposal:	[250mL] Dispose of empty container by wrapping with paper and placing in the garbage. [1L, 1L backpack] This container can be recycled if it is clean, dry, free of visible residues and

	has the drumMUSTER logo visible. Triple or pressure rinse container for disposal. Dispose of rinsate or any undiluted chemical according to State legislative requirements. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management program site. The cap should not be replaced but may be taken separately.
Storage:	Store below 30°C (room temperature)
Name & address:	<p>Bayer Bayer Australia Ltd 875 Pacific Highway PYMBLE NSW 2073 ACN 000 138 714</p> <p>CUSTOMER INFORMATION LINE Australia 1800 678 368 TOLL FREE 9.00 am to 4.00 pm (Eastern Time) Monday to Friday www.farmadvisor.com.au</p> <p>MANUFACTURED IN GERMANY BAYCOX® is a registered trademark for Bayer AG, Leverkusen, Germany</p>

The following is for APVMA use only:

APVMA approval no.	APVMA No: 68946/62604
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