



**PERMIT TO ALLOW MINOR USE AND SUPPLY
OF AN AGVET CHEMICAL PRODUCT**

PERMIT NUMBER -PER8660

This permit is issued to the Permit Holder in response to an application granted by the APVMA under section 112 of the Agvet Codes of the jurisdictions set out below. This permit allows a Supplier (as indicated) to possess the product for the purposes of supply and to supply the product to a person who can use the product under permit. This permit also allows a person, as stipulated below, to use the product in the manner specified in this permit in the designated jurisdictions. This permit also allows the Permit Holder, the Supplier (if not one and the same) and any person stipulated below to claim that the product can be used in the manner specified in this permit.

THIS PERMIT IS IN FORCE FROM 15 December 2009 to 31 December 2012

Permit Holder:

BAYER AUSTRALIA LTD
875 Pacific Highway
Pymble NSW 2073

Supplier:

The above PERMIT HOLDER and veterinary wholesalers approved by, and acting on behalf of, Bayer Australia Ltd.

Persons who can use the product under this permit:

This product is to be used by or under the direction of a registered veterinary surgeon by sheep producers and Mulesing contractors.

CONDITIONS OF USE

Product to be used:

**TRI-SOLFEN TOPICAL ANAESTHETIC & ANTISEPTIC SOLUTION FOR PAIN RELIEF
IN SHEEP**

Containing: 40.6g/L Lignocaine (as hydrochloride); 4.2g/L Bupivacaine (as hydrochloride);
24.8 mg/L Adrenaline (as tartrate) and 5.0 g/L Cetrimide as its only active
constituents.

Directions for Use:

FOR USE ONLY as a one off treatment of lambs that are to be kept as wool-producing sheep, for the relief of pain associated with surgical mulesing as directed on the label at Attachment A.

Critical Use Comments:

Approved as a topical gel spray applied using a pour-on applicator for a single application to wounds following mulesing of lambs.

Withholding Period:

This product is only approved for use as a one off treatment of lambs that are to be kept for their wool production.

MEAT: Treated sheep must not be supplied or sold for slaughter for human consumption for at least 90 days following treatment with this product.

MILK: This product must not be used in sheep where milk or milk products may be used for human consumption.

Jurisdiction:

ALL States

Additional Conditions:

1. This product can only be supplied to a registered veterinary surgeon upon presentation of a written request using the request form at Attachment B.
2. Bayer Australia Ltd must maintain a record of all veterinary surgeons supplied with this product. At the conclusion of this Permit, a copy of this record will be submitted to the APVMA before this Permit is renewed or extended.
3. Registered Veterinary Surgeons who supply this product must maintain a record of all clients supplied with the product.
4. Bayer Australia Ltd must report any adverse experiences to the APVMA.
5. People who wish to prepare for use and/or use the product for the purposes specified in this permit must read this permit or have it read to them. Registered Veterinary Surgeons who supply this product must provide appropriate instructions to animal owners and/or their authorized contractors or employees covering the proper use of the product.
6. The supplier must supply the product in a container that complies with the requirements of section 18(1) of the Agricultural and Veterinary Chemicals Code Regulations. Attached to the container must be a label which is identical in content and format to the label in Attachment A. The product label must show an expiry date which is not to exceed 15 months from the date of manufacture.

Issued by

Allen Bryce
Delegate

**PRESCRIPTION ANIMAL REMEDY
READ SAFETY DIRECTIONS BEFORE USING
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY**

TRI-SOLFEN

**Topical Anaesthetic & Antiseptic Solution
for Pain Relief in Sheep**

ACTIVE CONSTITUENTS: 40.6 g/L Lignocaine (as hydrochloride), 4.2 g/L Bupivacaine (as hydrochloride), 24.8 mg/L Adrenaline (as tartrate), 5.0 g/L Cetrimide

This product is NOT REGISTERED and is only available under APVMA Permit from a registered veterinary surgeon. Read the Permit before using.

1L [2.5L, 5L, 10L, 15L, 20L, 22L]

TRI-SOLFEN is a local anaesthetic and antiseptic gel spray for use on lambs to provide pain relief following Mulesing.

DIRECTIONS FOR USE:

FOR TOPICAL USE ONLY

Apply TRI-SOLFEN spray to wound immediately after Mulesing. Ensure that entire wound area is evenly covered with spray, particularly wound edges.

Application Rate:	Lambs (5-10 kg)	6 mL
	Lambs (11-15 kg)	8 mL
	Lambs (16-20 kg)	10 mL
	Lambs (over 20kg)	12 mL

The special TRI-SOLFEN applicator applies 2mL per application. Insecticidal preparations can be applied to the wound after application of TRI-SOLFEN to prevent fly strike.

WITHHOLDING PERIODS:

This product is only approved for use as a one off treatment of lambs that are to be kept for their wool production.

MEAT: Treated sheep must not be supplied or sold for slaughter for human consumption for at least 90 days following treatment with this product.

MILK: This product must not be used in sheep where milk or milk products may be used for human consumption.

SAFETY DIRECTIONS:

May irritate the eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. If product on skin immediately wash area with soap and water. When opening the container and using the product wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length PVC gloves. Wash hands after use. After each day's use, wash gloves and contaminated clothing.

Do not rehandle sheep until after the product has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length PVC gloves.

FIRST AID:

If poisoning occurs, contact a doctor or Poisons Information Centre. *Phone Australia 131126.*

Bayer Australia Ltd
875 Pacific Highway
Pymble NSW 2073
Phone: 1800 678 368

DISPOSAL:

Do not dispose of undiluted chemicals on-site. Puncture or shred and bury empty containers in a local authority landfill. If no landfill is available, bury containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Empty containers and product should not be burnt.

Store below 30°C (Room Temperature). Do not store at a low temperature. Protect from light.

[B]

Expiry:

PER8660 ATTACHMENT B

APVMA REQUEST FORM FOR THE SUPPLY OF UNREGISTERED PRODUCT TO REGISTERED VETERINARIANS.
 (This form to be retained by the permit holder)

COMPANY AND PRODUCT DETAILS	
Permit Holder	Bayer Australia Ltd
Manufacturer APVMA GMP Licence number	Vetlab Pty Ltd 39 Harris Street, t Marys, NSW 2760 Licence No 2206
Product name	Tri-Solfen
APVMA Permit No	PER8660
Proposed use	Topical anaesthetic & antiseptic for pain relief

TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN			
Clinic Name			
Name of prescribing Veterinarian			
Street address			
Postal address			
Date of request			
Quantity required	5L <input type="checkbox"/>	10L <input type="checkbox"/>	20L <input type="checkbox"/>
Name of producer(s) to be supplied	1) 2) 3)		
Signature of prescribing Veterinarian			

TO BE COMPLETED BY THE VETERINARY WHOLESALER	
Wholesaler branch	
Date of supply	
Quantity supplied	
Batch No.	
Name of person supplying the product	
Signature of person supplying the product	

This form must be faxed to your veterinary wholesaler to allow supply