



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

**PERMIT TO ALLOW THE OFF LABEL USE OF AN REGISTERED VETERINARY
CHEMICAL PRODUCT**

PERMIT NUMBER – PER12555

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 persons, as stipulated below, to use the product in the manner specified in this permit in the designated jurisdictions. This permit also allows any person to claim that the product can be used in the manner specified in this permit.

THIS PERMIT IS IN FORCE FROM 23 DECEMBER 2010 TO 31 DECEMBER 2014

Permit Holder:

Mr Greg Richards
Manager,
TIME ANIMAL HEALTH PTY LTD
707 McCutcheon's Rd
CAVENDISH VIC 3314

Persons who can use the product under this permit:

Persons authorised and trained by Mr Greg Richards in the use of the Richards Submersible Cage Dipping System (also known as the Dipping Dynamics Constant Replenishment System).

CONDITIONS OF USE

Product to be used:

COOPERS Diazinon Sheep Blowfly Dressing and Cattle, Goat and Pig Spray
(APVMA Product Number 62353).

Containing: 200.00 g/L DIAZINON as the only active constituent.

DIRECTIONS FOR USE:

Restraints:

- DO NOT dip in wet or very hot weather
- DO NOT dip sheep with untreated shearing cuts or other wounds
- DO NOT dip hot and thirsty sheep
- DO NOT dip ewes heavy in lamb
- DO NOT dip sheep more than six weeks after shearing
- DO NOT use on ewes, which are producing or may in future produce milk or milk products for human consumption

Animal	Pest	Method	Initial Charge in Sump	Constant Replenishment Tank
Sheep	Sheep Body Louse (<i>Bovicola ovis</i>)	Richards Submersible Cage Dipping System.	100mL/100L water	100mL/100L water Maintain maximum sump levels.
		Also known as Dipping Dynamics Constant Replenishment System	Comments: Do not allow dip to become excessively dirty in order to safeguard against wool staining and possible infection.	

General Instructions:

Thoroughly clean the dip, sump and spray lines before charging the dip.
 The product does not contain a bacteriostat. Post dipping lameness is best controlled by dip hygiene and draining the sump each night.

Critical Use Comments:

For use on sheep with more than 2 weeks and not more than 6 weeks wool growth (short wool), as per the cancelled label instructions for constant replenishment dipping (refer Attachment 1).
 Do not dip hot or thirsty sheep. Wherever possible sheep should be mustered into the yards the evening before to allow them to cool down and empty out before dipping.
 Dip after shearing cuts have healed. Prevent fresh injuries from biting dogs, etc. before dipping. Dipping sheep heavily infested with grass seeds is not recommended.
 For effective control of lice, thorough wetting to skin level is essential.

All relevant label instructions pertaining to the use of products containing diazinon for constant replenishment dipping of sheep are to be followed, including personal protective equipment, first aid and safety instructions, precautions, meat/milk withholding periods, trade warnings and storage and disposal. Additional record keeping, management and waste management requirements apply and are specified in this permit.

Withholding Period:

SHEEP:

- MEAT: DO NOT USE less than 14 days before slaughter for human consumption
- MILK : DO NOT USE on lactating or pregnant ewes where milk or milk products may be used for human consumption.
- WOOL: DO NOT USE less than two months before shearing or fibre collection

Export Slaughter Interval (ESI):

DO NOT USE less than 21 days before slaughter for export.

Jurisdiction:

ALL States

Additional Conditions:

- 1) Time Animal Health may use the product shown in this permit (above) containing diazinon and which is registered for use on sheep. This product may be used 'off-label' for the cage dipping of sheep, up to a maximum of 1,000,000 sheep per annum.
- 2) Time Animal Health must follow all relevant label instructions for the dipping of sheep. Refer to attached copy of Cooper's DI-JET labels (now cancelled) at Attachment 1, revised First Aid and Safety Directions and Rehandling and Warnings (refer Attachments 2 and 3 respectively). In addition the waste dip solution must be de-activated with a suitable bio-remediation enzyme (Landgard) prior to disposal.
- 3) The product must be supplied in a container that complies with the requirements of Section 18 (1) (a-e) of the Agricultural and Veterinary Chemical Code Regulations. Attached to this container must be a label, which is identical to the APVMA approved labels for the product, as per Attachment 1 of this permit, or an amended label that has been approved by the APVMA.
- 4) Persons who wish to prepare for use and/or use the products for the purposes specified in this permit must read, or have read to them, the permit particularly the information included in DETAILS OF PERMIT and CONDITIONS OF PERMIT.
- 5) It is the permit holder's responsibility to ensure that the owner/manager of treated sheep is aware that there is a 6 week sheep rehandling interval during in which personal protective equipment (as outlined below) must be worn if treated animals are to be handled. Sheep must not be shorn during the sheep rehandling interval.
- 6) It is the permit holder's responsibility to advise the owner/manager of treated sheep that wool from treated sheep may contain chemical residues of diazinon that may be a risk to the environment, particularly in the first 4 months after treatment, and that wool from treated sheep may contain chemical residues that may pose a risk to trade if the harvested wool is exported for processing overseas. Treated wool should be identified at point of sale as wool that may contain residues of diazinon.
- 7) The permit holder must maintain a register of all product usage, including a cumulative record of the number of animals treated. The number of sheep treated must not exceed the limit of 1 million animals per annum without the prior approval of the APVMA.
- 8) The permit holder must report to the APVMA on an annual basis the numbers of sheep treated and their locations at the end of each calendar/financial year.
- 9) The permit holder must alert the APVMA within at least 6 months of any expected unavailability of the bio-remediation enzyme (Landgard) and propose an alternative method of deactivation.
- 10) The permit holder must ensure that all operators that are licensed to use the Richards Cage Dipping System have been appropriately trained and that they fully understand their obligations that apply to them under this permit.

11) The issuing of this permit is subject to the outcomes of the APVMA Diazinon Review

Protection of wildlife, Fish, Crustacea and the Environment

DO NOT discharge waste liquid into drains, waterways or streams.

Refer to Condition 2 above.

First Aid and Safety Instructions:

Refer to Attachment 2

Rehandling and Additional Warning Statements:

Do not re-handle sheep until 6 weeks after treatment, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing).

Refer to Condition 6 above and Attachment 3.

Issued by

Dr Karina Tyson
Delegated Officer

ATTACHMENTS

Attachment 1 (3 pages)

COOPERS DI-JET SHEEP DIP/JETTING FLUID, CATTLE AND PIG SPRAY (CANCELLED LABEL)

Attachment 2 (1 pages)

REVISED FIRST AID AND SAFETY DIRECTIONS

Attachment 3 (1 pages)

REHANDLING, STORAGE AND ADDITIONAL WARNING STATEMENTS

ATTACHMENT 1 (page 1 of 3 pages)

COOPERS DI-JET SHEEP DIP/JETTING FLUID, CATTLE AND PIG SPRAY

NOTE: THIS IS LABEL HAS BEEN CANCELLED


POISON

KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING
FOR ANIMAL TREATMENT ONLY

COOPERS®

Di-Jet®


Sheep Dip/Jetting Fluid, Cattle and Pig Spray



ACTIVE CONSTITUENT: 200 g/L DIAZINON
(an anticholinesterase compound)
Solvent: 548 g/L LIQUID HYDROCARBONS

For the control of lice, ked and blowfly on sheep, lice and buffalo fly on cattle, lice on goats, lice and mange on pigs.

20 Litres



COOPERS

ATTACHMENT 1 (page 2 of 3 pages)

COOPERS DI-JET SHEEP DIP/JETTING FLUID, CATTLE AND PIG SPRAY

NOTE: THIS IS LABEL HAS BEEN CANCELLED

COOPERS®
Di-Jet® Sheep Dip/Jetting Fluid, Cattle and Pig Spray

GENERAL INSTRUCTIONS
Dipping Procedure
1. Dip all sheep on the property at the same time after a clean muster.
2. It is important that sheep remain in the bath or shower long enough to ensure thorough wetting to the skin.
3. Always aim to keep the dipping fluid as fresh as possible to prevent bacterial build-up and hence possible infection from the dip. At the completion of a day's dipping, add the required amount of concentrate needed for reinforcing and topping up. On the following day the requisite amount of water is added before dipping commences again. Should the dip not be in use each day, particularly in warm weather, add 200mL of "Hibitane" Disinfectant to 100 litres of dip wash the evening before dipping commences again. Clean out and recharge the dip when necessary.

Jetting for Blowfly Control
Body Strike
Jet along the backline from poll to rump with a strip 18-20 cm wide, taking care to wet the wool to the skin. Pay particular attention to the area around the withers and down over the shoulder.

Poll Strike
Thoroughly saturate the wool on the poll and around the horns.

Breech Strike
Jet thoroughly the entire breech area including butt of tail and thighs down to the hocks. The development of blowflies in many areas tolerant to blowfly jetting fluids makes it imperative to jet efficiently and thoroughly to obtain good control of these parasites. Thorough saturation of the wool to the skin is essential. This can only be achieved by correct jetting technique combined with the application of adequate jetting fluid — 1-2 litres along the backline and the same quantity around the breech will be needed. Jetting pressures required will vary from 500 to 800 kPa depending upon the length and density of the wool. Use needle type jetting wands which should be combed through the wool taking care that the jets of fluid are directed at a right angle to the skin to obtain better penetration of the fleece. Do not use extra wetting agents. There is ample in the product to wet wool and the use of additional wetters could result in the scouring of the wool wax that assists in holding the diazinon to the wool fibre.

For further information contact Coopers Customer Service on 1 800 226 511.

PROTECTION OF WILDLIFE, FISH, CRUSTACEA AND ENVIRONMENT
Do not discharge waste liquid into drains, dams, waterways or streams.

SAFETY DIRECTIONS
Product is poisonous if swallowed. Will irritate the eyes and skin. Repeated minor exposure may have a cumulative poisoning effect. Obtain an emergency supply of Atropine Tablets 0.6mg. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing the spray or dip and using the prepared spray or dip, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat and elbow-length PVC gloves and water resistant footwear. If clothing becomes contaminated with product, remove clothing immediately. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and contaminated clothing.

FIRST AID
If poisoning occurs, contact a doctor or Poisons Information Centre (Phone 131126). If swallowed, give one atropine tablet every 5 minutes until dryness of the mouth occurs – if poisoned by skin absorption or through lungs, remove any contaminated clothing, wash skin thoroughly and give atropine tablets as above. Get to a doctor or hospital quickly. Additional information is listed in the Material Safety Data Sheet.

Warranty
Schering-Plough Pty Ltd (SPPL) warrants that this product is of merchantable quality and fit for its intended purpose. SPPL's liability for any loss, including consequential losses or injury caused by any act or omission, including negligent acts or omissions, by SPPL or its agent, is limited to replacing or repairing the product at the option of SPPL. If possible, a sample of any product causing concern should be retained or delivered to SPPL within 30 days for a scientific examination.


DISPOSAL
Triple or (preferably) pressure rinse containers into medicated dip. Do not dispose of undiluted chemicals on site. Break, crush, or puncture and bury empty containers in a local authority landfill. If no landfill is available bury the containers below 500mm 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) in the closed original container, in a well ventilated area, as cool as possible. Do not store for prolonged periods in direct sunlight.

BATCH
EXPIRY

COOPERS ANIMAL HEALTH
A division of Schering-Plough Pty Ltd
11 Gibbon Road, Baulkham Hills NSW 2153

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ATTACHMENT 1 (page 3 of 3 pages)
COOPERS DI-JET SHEEP DIP/JETTING FLUID, CATTLE AND PIG SPRAY

NOTE: THIS IS LABEL HAS BEEN CANCELLED

Di-Jet[®]

Sheep Dip/Jetting Fluid, Cattle and Pig Spray

CLAIMS
 For the control of Lice (*Bovicola ovis*), Ked (*Melophagus ovinus*) and Blowfly (*Lucilia cuprina*) on sheep, Lice (*Bovicola bovis*, *Linognathus vituli*, *Haematopinus eurysternus*) and Buffalo Fly (*Haematobia irritans exigua*) on cattle, Lice (*Bovicola caprae*) on goats, Lice (*Haematopinus auis*) and Mange (*Sarcoptes spp.*) on pigs.

DIRECTIONS FOR USE:
RESTRAINTS:


- Do not dip sheep more than 6 weeks after shearing.
- Dipping within 2 weeks of shearing is not recommended.
- Do not dip hot or thirsty sheep. Sheep should be mustered into the yards the evening before to allow them to cool down and empty out before dipping.
- Dip after shearing cuts have healed. Prevent fresh injuries from biting dogs etc. before dipping.
- Dipping sheep heavily infested with grass seed is not recommended.
- For effective control of lice, thorough wetting to skin level is essential.
- Do not allow water to enter the container during use or storage.
- Do not rinse lid with water.

ANIMAL	PEST	METHOD	INITIAL CHARGE	REINFORCEMENT (always reinforce before topping up)	TOPPING UP (when dip/ump falls by approximately 25%)	
SHEEP	Lice (<i>Bovicola ovis</i>)	Plunge and shower dip	50mL/100L water	DO NOT ADD WATER 150mL/100L drop in level of dip wash	REINFORCE FIRST 50mL/100L water added	
	Ked (<i>Melophagus ovinus</i>)	Constant Replenishment Shower Dip	50mL/100L water	Maintain maximum sump level	50mL/100L water	
	<i>Critical Comments:</i> Do not allow the dip level to fall by more than one quarter of its capacity or 1000L before topping up or reinforcement. Dip 10-14 days off shears when shearing cuts have healed. Do not allow dip to become excessively dirty in order to safeguard against wool staining and possible infection.					
	Blowfly (<i>Lucilia cuprina</i>)	Plunge and Shower Dip	100mL/100L water	DO NOT ADD WATER 250mL/100L drop in level of dip wash	REINFORCE FIRST 100mL/100L water	
	Ked (<i>Melophagus ovinus</i>)	Constant Replenishment Shower Dip	100mL/100L water	Maintain maximum sump level	100mL/100L water added	
GOATS	Lice (<i>Bovicola caprae</i>)	Hand Spray	50mL/20L water	-	-	
	<i>Critical Comments:</i> Thoroughly wet goats with spray. A second spraying may be necessary 16-17 days later.					
CATTLE	Lice (<i>Bovicola bovis</i> , <i>Linognathus vituli</i> , <i>Haematopinus eurysternus</i>)	Hand Spray	250mL/100L water	-	-	
	<i>Critical Comments:</i> Spray thoroughly using 5-10L per head. A second spraying 16-17 days later is necessary to break the life cycle of the lice.					
PIGS	Lice (<i>Haematopinus auis</i>) and Mange (<i>Sarcoptes spp.</i>)	Hand Spray	50mL/20L water	-	-	
	<i>Critical Comments:</i> Thoroughly wet pigs with spray. Use three applications at 10 day intervals.					
CATTLE (WA, QLD, NSW ONLY)	Buffalo Fly (<i>Haematobia irritans exigua</i>)	Backrubber	500mL/10L of oil	-	-	
<i>Critical Comments:</i> Soak backrubber thoroughly. Re-treat as necessary.						

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

WITHHOLDING PERIODS

CATTLE: MEAT:	DO NOT USE LESS THAN 3 DAYS BEFORE SLAUGHTER FOR HUMAN CONSUMPTION.
MILK:	NIL.
SHEEP, PIGS & GOATS: MEAT:	DO NOT USE LESS THAN 14 DAYS BEFORE SLAUGHTER FOR HUMAN CONSUMPTION.
GOATS: MILK:	MILK TAKEN FROM GOATS WITHIN 48 HOURS FOLLOWING TREATMENT MUST NOT BE USED FOR HUMAN CONSUMPTION OR PROCESSING.



UN No. 3018
 ORGANOPHOSPHORUS,
 PESTICIDES, LIQUID, TOXIC, N.O.S.
 (20% DIAZINON, 55% LIQUID
 HYDROCARBONS)
 Hazchem Code: 3WE
 Packaging Group: III

In a transport emergency Dial 000 Police or Fire Brigade	SPECIALIST ADVICE IN EMERGENCY ONLY Schering-Plough Pty Ltd 1 800 226 511 ALL HOURS – AUSTRALIA WIDE
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Attachment 2 (1 page)
REVISED FIRST AID AND SAFETY DIRECTIONS

First Aid Instructions:

If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone e.g. Australia 131 126; New Zealand 0800 764 766) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

Safety Directions:

Amended Entry		<i>Statement Codes</i>
Diazinon	EC 215 g/L or less in liquid hydrocarbons other than xylene 650 g/L or less, with surfactants	120 130 133 161 162 164 190 210 211 220 222 279 280 281 282 by cage dipping 290 292a 294c 298b 330 332 340 342 350 360 361 366

The statement codes above translate into the following safety directions:

HAZARDS	
Product is poisonous if swallowed	120 130 133
Will irritate the eyes and skin	161 162 164
Repeated minor exposure may have a cumulative poisoning effect	190
PRECAUTIONS	
Avoid contact with eyes and skin	210 211
Do not inhale vapour	220 222
MIXING OR USING	
When opening the container and preparing dip, and using the prepared dip by cage dipping wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, and elbow-length chemical resistant gloves and water resistant footwear.	279 280 281 282 by cage dipping 290 292a 294c 298b
If clothing becomes contaminated with product, remove clothing immediately	330 332
If product on skin, immediately wash area with soap and water	340 342
AFTER USE	
After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water	350
After each day's use wash gloves and contaminated clothing	360 361 366

REHANDLING, STORAGE AND ADDITIONAL WARNING STATEMENTS

Rehandling Statement

No re-handling directions have been set for these products. A proposed 'sheep rehandling interval' of six weeks was established in the sheep ectoparasiticide preliminary review findings (PRF) published in April 2006 (APVMA 2006b). This has not yet been translated to labels as the review has yet to be finalised. However, for the purpose of this application the following re-handling statement is considered appropriate:

Do not re-handle sheep until 6 weeks after treatment, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing).

The permit holder should provide this advice in writing to the wool producer prior to treatment.

Warning Statements and General Safety Precautions

The following precautions were proposed as a result of the APVMA Diazinon Review and should be followed (in addition to other precautions on labels) until the regulatory outcome for diazinon veterinary products has been finalised.

- DO NOT apply this product to sheep by hand spray or pressure sprayer as these methods of application may result in exposure to a level of diazinon that is harmful to health.
- DO NOT use this product if it is out of date as the toxicity of this product may increase markedly over time.
- DO NOT allow water to enter this container.
- DO NOT rinse the lid with water.
- DO NOT use oil or kerosene to dilute this product. Dilute this product in water only.

Storage

Store in tightly closed original containers under cool, dry, dark conditions.

Protection of wildlife, Fish, Crustacea and the Environment

DO NOT discharge waste liquid into drains, waterways or streams.