

Company Name: ELANCO ANIMAL HEALTH A DIV OF ELI LILLY AUST PTY LTD
Product Name: ELANCO AH0493 EXTINOSAD POUR-ON FOR SHEEP
APVMA Approval No: 60117/105241



Label Name:	ELANCO AH0493 EXTINOSAD POUR-ON FOR SHEEP
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Signal Headings:	KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS BEFORE OPENING OR USING
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Constituent Statements:	20 g/L SPINOSAD
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Claims:	For the control of spinosad-susceptible lice (<i>Bovicola ovis</i>), including strains resistant to Synthetic Pyrethroids (SPs), in sheep up to 7 days off-shears and sheep with long wool.
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Net Contents:	5L 20L 25L
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Directions for Use:	This section contains file attachment. File Name: ExPO 7 d off-shears label Dec15 V4 as submitted.pdf File Size: 38640 bytes
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Restrains:	DO NOT USE on ewes that are producing or may in the future produce milk that may be used or processed for human consumption.
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Contraindications:	
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Precautions:	
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Side Effects:	
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<p>Dosage and Administration:</p>	<p>SHAKE CONTAINER GENTLY SEVERAL TIMES BEFORE USE</p> <p>Apply EXTINOSAD POUR-ON evenly along the backline from the poll to the base of the tail using a manual or powered applicator with an EXTINOSAD POUR-ON 4-hole t-bar nozzle. Halve the dose volume and apply in 2 bands, approximately 5cm from the mid-point of the backline on each side. Applying the product to the flanks will improve the spread of EXTINOSAD POUR-ON.</p> <p>Dosage and Administration [Dose table in attached document]</p> <p>Critical use comments: Off-shears: Dose rates are to be based on the heaviest sheep in each group (ewes, rams, lambs). Sheep in each group should be weighed. Drafting into two or more lines may be appropriate, to avoid excessive overdosing. Do not underdose; check the accuracy of equipment before and during treatment. Use only on sheep that have been cleanly shorn. This product has not been tested on sheep shorn using “cover-combs”. Long wool: Sheep treated with long wool should be re-treated after shearing. Reduced effectiveness is likely if used on sheep with lumpy wool. For ewes with suckling lambs, treat lambs at the appropriate rate, see table.</p> <p>DO NOT mix treated sheep with untreated sheep.</p> <p>This section contains file attachment. File Name: ExPO 7 d off-shears label Dec15 V4 as submitted.pdf File Size: 38640 bytes</p>
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<p>General Directions:</p>	<p>General Directions: EXTINOSAD POUR-ON is a short-acting, non-residual product. Maximum lice kill at treatment and strict quarantine conditions for treated sheep are necessary for effective lice control.</p> <p>It is recommended that a thorough muster be conducted so that no untreated sheep remain. Boundary fences should be checked to ensure animals are contained and stray sheep are excluded. Treated sheep must be kept separate from lice infested sheep or sheep of unknown lice status. For effective lice control, every sheep on the property should be treated at the same time.</p> <p>Efficacy and safety studies using EXTINOSAD POUR-ON involved treatment of ewes, rams, wethers and lambs. Lice efficacy was not specifically evaluated in lambs less than 6 months of age, however, lice control was achieved in ewes with lambs at foot when both were treated at the recommended rate. It is good agricultural practice not to treat ewes within 6 weeks of the commencement of lambing.</p> <p>EXTINOSAD POUR-ON is spread over the body by passive diffusion and physical contact (e.g. rubbing with other sheep). Studies have shown that penning sheep closely in the yards immediately after application facilitates product movement.</p> <p>It is good agricultural practice not to treat animals when they are wet or if rain is likely. However, moderate rainfall (20mm in 20 minutes) following treatment does not adversely affect the effectiveness of the product.</p> <p>EXTINOSAD POUR-ON contains a blue dye to identify treated sheep. Traces of blue dye may still be visible at shearing, but the dye is scourable from the wool. Do not leave container, hose or applicator in the sun for long periods of time. At the end of use, clean out the applicator, nozzle and hose by pumping through with clean water.</p>
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NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER THE APPROPRIATE LEGISLATION.

Withholding Periods:

MEAT:
Off Shears: DO NOT USE less than 14 days before slaughter for human consumption
Suckling lambs: DO NOT USE less than 14 days before slaughter for human consumption
Long wool: Zero (0) days

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: Zero (0) days

Trade Advice:

Export Slaughter Interval (ESI): DO NOT USE less than 21 days (off shears and suckling lambs), or 0 days (long wool) before slaughter for export. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI from Elanco Animal Health (1800 226 324) or the APVMA website <http://www.apvma.gov.au/residues>. Use of this product may result in wool residues that may not comply with European Union environmental quality standards. Wool treated with this product may contain detectable residues; adequate treatment records should be kept and made available, if requested by wool buyers.

Safety Directions:

May irritate the skin. Will damage eyes. Avoid contact with eyes and skin. If product in eyes, wash it out immediately with water. Wash hands after use. When using the product wear elbow-length PVC gloves and goggles. After each day's use wash gloves.

First Aid Instructions:

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

First Aid Warnings:

Additional User Safety:

Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling. Additional information is listed in the Material Safety Data Sheet.

Environmental Statements:

Disposal:

Triple-rinse container and dispose of rinsate in compliance with relevant local, state or territory government regulations.
Do not dispose of undiluted chemicals on-site. If recycling, replace cap and return clean container to recycler or designated collection point. If not recycling, break, crush, or puncture container and deliver to an approved waste management facility. If an approved waste management facility is not available, bury the broken, crushed or punctured containers 500 mm below the surface in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

Storage:

Store below 30oC (Room Temperature) in a dry place in tightly closed original container. Do not freeze. Do not store in direct sunlight.

Company Confidential Information
Relevant Label Particulars
ELANCO AH0493 EXTINOSAD POUR-ON FOR SHEEP

**READ SAFETY DIRECTIONS BEFORE OPENING OR USING
FOR ANIMAL TREATMENT ONLY**

ELANCO AH0493 Extinosad[®] Pour-On for Sheep

ACTIVE CONSTITUENT: 20g/L spinosad

For the control of spinosad-susceptible lice (*Bovicola ovis*), including strains resistant to Synthetic Pyrethroids (SPs), in sheep up to 7 days off-shears, unshorn lambs and sheep with long wool.

5 [20/25] LITRES

READ DIRECTIONS FOR USE BEFORE OPENING OR USING THIS PRODUCT

Spinosad, the active ingredient in EXTINOSAD POUR-ON, is the first member of the spinosyn class of insecticides and has a unique action on the insect nervous system.

DIRECTIONS FOR USE:

Restraints:

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

DO NOT mix treated sheep with untreated sheep.

SHAKE CONTAINER GENTLY SEVERAL TIMES BEFORE USE

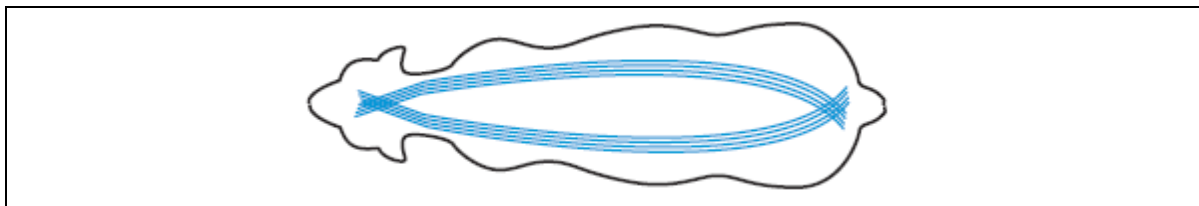
Apply EXTINOSAD POUR-ON evenly along the backline from the poll to the base of the tail using a manual or powered applicator with an EXTINOSAD POUR-ON 4-hole t-bar nozzle. Halve the dose volume and apply in 2 bands, approximately 5cm from the mid-point of the backline on each side. Applying the product to the flanks will improve the spread of EXTINOSAD POUR-ON.

Dosage and Administration

Sheep Category	Bodyweight (kg)	Dose (mL)	No. of sheep treated / pack
<i>Off-shears</i> (Within 7 days after shearing)	20-30	15	333 [1333, 1666]
	31-40	20	250 [1000, 1250]
	41-50	25	200 [800, 1000]
	51-60	30	166 [666, 833]
	61-70	35	142 [571, 714]
	Add 2 mL for each 5 kg above 75 kg		
<i>Suckling lambs</i> (Unshorn)	Up to 9	5	1000 [4000, 5000]
	10-19	7.5	666 [2666, 3333]
	20-29	15	333 [1333, 1666]
	Add 3.5 mL for each 5 kg above 29 kg		
<i>Long wool</i> (6 – 12 months after shearing)	Adult (>6 months old)	50	100 [400, 500]

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Critical use comments:

Off-shears: Dose rates are to be based on the heaviest sheep in each group (ewes, rams, lambs). Sheep in each group should be weighed.

Drafting into two or more lines may be appropriate, to avoid excessive overdosing.

Do not underdose; check the accuracy of equipment before and during treatment.

Use only on sheep that have been cleanly shorn.

This product has not been tested on sheep shorn using “cover-combs”.

Long wool: Sheep treated with long wool should be re-treated after shearing.

Reduced effectiveness is likely if used on sheep with lumpy wool.

For ewes with suckling lambs, treat lambs at the appropriate rate, see table.

General Directions: EXTINOSAD POUR-ON is a short-acting, non-residual product. Maximum lice kill at treatment and strict quarantine conditions for treated sheep are necessary for effective lice control.

It is recommended that a thorough muster be conducted so that no untreated sheep remain. Boundary fences should be checked to ensure animals are contained and stray sheep are excluded. Treated sheep must be kept separate from lice infested sheep or sheep of unknown lice status. For effective lice control, every sheep on the property should be treated at the same time.

Efficacy and safety studies using EXTINOSAD POUR-ON involved treatment of ewes, rams, wethers and lambs. Lice efficacy was not specifically evaluated in lambs less than 6 months of age, however, lice control was achieved in ewes with lambs at foot when both were treated at the recommended rate. It is good agricultural practice not to treat ewes within 6 weeks of the commencement of lambing.

EXTINOSAD POUR-ON is spread over the body by passive diffusion and physical contact (e.g. rubbing with other sheep). Studies have shown that penning sheep closely in the yards immediately after application facilitates product movement.

It is good agricultural practice not to treat animals when they are wet or if rain is likely. However, moderate rainfall (20mm in 20 minutes) following treatment does not adversely affect the effectiveness of the product.

EXTINOSAD POUR-ON contains a blue dye to identify treated sheep. Traces of blue dye may still be visible at shearing, but the dye is scourable from the wool. Do not leave container, hose or applicator in the sun for long periods of time. At the end of use, clean out the applicator, nozzle and hose by pumping through with clean water.

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

WITHHOLDING PERIODS:

MEAT: Off-Shears: DO NOT slaughter for human consumption for 14 days after treatment.

Unshorn lambs: DO NOT slaughter for human consumption for 14 days after

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Company Confidential Information
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treatment.

Long wool: Zero (0) days

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

WOOL: Zero (0) days

TRADE ADVICE:

Export Slaughter Interval (ESI): DO NOT USE less than 21 days (off shears and unshorn lambs), or 0 days (long wool) before slaughter for export. The ESI on this label was correct at the time of label approval. Before using this product, confirm the current ESI from Elanco Animal Health (1800 226 324) or the APVMA website <http://www.apvma.gov.au/residues>.

Use of this product may result in wool residues that may not comply with European Union environmental quality standards. Wool treated with this product may contain detectable residues; adequate treatment records should be kept and made available, if requested by wool buyers.

SAFETY DIRECTIONS: May irritate the skin. Will damage eyes. Avoid contact with eyes and skin. If product in eyes, wash it out immediately with water. Wash hands after use. When using the product wear elbow-length PVC gloves and goggles. After each day's use wash gloves.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

ADDITIONAL USER SAFETY INFORMATION

Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling. Additional information is listed in the Material Safety Data Sheet.

DISPOSAL: Triple or (preferably) pressure rinse container with water and dispose of rinsate in a disposal pit set up for this purpose clear of waterways, vegetation and roots. Do not dispose of undiluted chemicals on site. Break, crush or puncture and bury empty containers in a local authority landfill. If not available, bury the containers below 500mm in a disposal pit. Empty containers and product should not be burnt.

STORAGE: Store below 30°C (Room Temperature) in a dry place in tightly closed original container. Do not freeze. Do not store in direct sunlight.

KEEP OUT OF REACH OF CHILDREN.

APVMA Approval No.: 60117/XXXXX

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112 WHARF ROAD WEST RYDE, N.S.W. 2114
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BATCH NUMBER:

EXPIRY DATE:

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