UNITED STATES	OI Reg	ONMENTAL PROTECTION AGENCY ffice of Pesticide Programs pistration Division (H7505C)	EPA Reg. Number: 72642-1	Date of Issuance: SEP 2 7 2002
A LOCAL DE LA		00 Pennsylvania Ave., N.W. Washington, D.C. 20460	Term of Issuance:	[]
MAL PROTECT				U nconditional
		gistration registration	Name of Pesticide Pr	roduct:
(under FIFRA, as amended)			Extinosad	
Name and Address of Reg	gistrant (include ZIP C	Code):		
Elanco Animal He	ealth			
PO Box 708 2001 W. Main Str	reet			
Greenfield, IN 46				
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		rom that accepted in connection with this reg immerce. In any correspondence on this pro		
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Please submit two (2) copies of your final printed label for before your release the product for shipment. Please refer to the A-79 enclosure for a further description of final printed labeling. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. If you have any questions regarding this action, please contact Dr. William Sproat of my team at (703) 308-8587.

Sincerely,

George T. LaRocca Product Manager 13 Insecticide Branch Registration Division (7505C)

Enclosure

Front Panel

ACCEPTED with COMMENTS in EPA Letter Dated

X SEP 2 7 2002

Under the Federal Insecticide, Fungicide, and Redenticide Act as amended, for the posticide registered under EPA Reg. No. 72642-1

Topical Insect Control Agent

ELANCO* AH 0492

Extinosad®

- Pour-on or dilutable spray for control of horn flies and lice on lactating and non-lactating dairy and beef cattle.
- Dilutable spray for control of stable and house flies on agricultural animal premises.

ACTIVE INGREDIENT

Spinosad (A mixture of spinosyn A and spinosyn D) OTHER INGREDIENTS 97.54% TOTAL 100.00% 2.46%

Keep Out of Reach-of Children

CAUTION

Elanco Animal Health, A Division of Eli Lilly and Company Indianapolis, IN 46285 www.elanco.com Questions or comments call 1-800-428-4441

Net Contents: _____ Liter(s)

(Label Booklet Cover-Back Panel)

ELANCO* AH 0492

Extinosad®

Topical Insect Control Agent

- Pour-on or dilutable spray for control of horn flies and lice on lactating and non-lactating dairy and beef cattle.
- Dilutable spray for control of stable and house flies on agricultural animal premises.

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Environmental Hazards

This product is highly toxic to molluscs. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning or disposing of equipment washwaters. Apply this product only as specified on this label.

Notice: Shake Well Before Use—Avoid Freezing. Read the entire label before using. Use only according to label directions. See Directions for Use including storage and disposal inside label booklet.

EPA Reg. No: 72642-1 EPA Est. No.: 37429-GA-02

Peel Back Logo

(Label Booklet: Page 1 through end)

ELANCO* AH 0492

Extinosad®

Topical Insect Control Agent

- Pour-on or dilutable spray for control of horn flies and lice on lactating and non-lactating dairy and beef cattle.
- Dilutable spray for control of stable and house flies on agricultural animal premises.

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ENVIRONMENTAL HAZARDS

This product is highly toxic to molluscs. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning or disposing of equipment washwaters. Apply this product only as specified on this label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all Directions for Use carefully before applying.

- Pour-on or dilutable spray for control of horn flies and lice on lactating and non-lactating dairy and beef cattle.
- Dilutable spray for control of stable and house flies on agricultural animal premises.

Notice: Shake well before use: Avoid freezing.

MIXING FOR APPLICATIONS THAT REQUIRE DILUTION

Fill the tank of the sprayer with water to about ½ of the total spray volume required. Start agitation and add the required amount of EXTINOSAD. Continue mixing and agitation while filling the spray tank to the required spray volume. Maintain sufficient agitation during the application to ensure uniformity of the spray. Prepare spray fresh for each use.

APPLICATIONS

Use according to the tables below.

AS A POUR-ON:

Apply To:	To Control:	Dilution	Application Rate
Apply To: Lactating and non-lactating dairy and beef cattle	To Control: Horn flies Lice (chewing and sucking)	Dilution No dilution required	Application Rate 16 mL per 440 lbs. body weight. Applied undiluted as a pour-on. Pour along the back and down the face. For horn fly control, repeat applications as needed, but not more often than every fourteen (14) days. Do not make more than 5 consecutive treatments of this product. For optimal lice control, an initial application followed by a second treatment 45 to 60 days
			later is recommended. Do not apply this product within 2 days
		,	of slaughter. THERE IS NO WITHHOLDING PERIOD FOR MILK.

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AS AN ON-ANIMAL SPRAY:

Notice: Spray lactating dairy animals only after milking is complete.

Apply To:	To Control:	Dilution	Application Rate
Apply To: Lactating and non-lactating dairy and beef cattle	To Control: Horn flies Lice (chewing and sucking)	Dilution Dilute 10 ounces (Approx. 300 mL) to 5 gallons water to give 0.04% spinosad	Application Rate 1-2 qt. of coarse spray per animal or until runoff over whole body surface. For horn fly control, repeat applications as needed, but not more often than every seven (7) days. Do not make more than 5 consecutive treatments of this
			consecutive treatments of this product. For optimal lice control, an initial application followed by a second treatment 45 to 60 days later is recommended. Do not apply this product within 2 days of slaughter. THERE IS NO WITHHOLDING PERIOD FOR MILK.

Notice: Lactating dairy and beef cattle and horses not intended for human consumption may be present at the time of premise treatment. Do not use in milking rooms. When used in poultry and swine houses or sheep premises, do not apply where animals are present and allow treated surfaces to dry completely before restocking or reintroducing livestock or poultry. Do not apply dilutions for premise treatment directly onto poultry or livestock other than cattle according to the directions above. Feeders, waterers and feedcarts should be covered before application to prevent contamination. Do not contaminate

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Apply To:	To Control:	Dilution	Application Rate
Premises, in and	House flies	Dilute 20 ounces	Spray fly-inhabiting surfaces in
around poultry, beef,	Stable flies	(approx. 600 mL) to 5	animal premises to the point of
dairy, horse, swine,		gallons water to give	runoff. Use approximately 1 gal.
and sheep premises		0.08% spinosad	of diluted spray per 500-1000
			sq. ft. (20 ounces of Extinosad
			will treat approximately 2,500 to
			5,000 sq. ft) Timing and
			frequency of application should
			be based upon flies reaching
			nuisance levels but not more
}			often than once a week. Apply
		~	to vertical and overhead
1			surfaces where flies may
			congregate. Pay attention to
	,		animal areas including fence
			railings, alleyways, stanchions,
			pipes, windows and doors, side
)			walls, the ends of buildings,
[upper sides of posts, and crossbeams and other areas
			where flies congregate. Spray in early morning when flies are
			resting.
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feedstuffs or water with premise treatment.

INTEGRATED PEST AND RESISTANCE MANAGEMENT

Extinosad is a member of a new unique class of insect control agents (Naturalyte[™]) with no pre-existing levels of resistance to any other insect control agents and can be rotated with all other classes, such as pyrethroids and organophosphates. Horn flies and other insects have demonstrated the ability to develop resistance to insect control products. Continual exposure of horn flies and other insects to a single class of insecticide may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies and other insects developing resistance to Extinosad and other classes of insecticides, it is important to rotate, on a seasonal basis, the class of insecticide used and/or the method of horn fly control. The following IRM strategy will help ensure the prolonged usefulness of Extinosad and other conventional insecticides.

- Do not use less than the labeled rate of any insect control product
- Apply Extinosad and other insect control agents when target pest populations have reached the economic threshold
- Include multiple tactics (cultural or biologic controls) within an Integrated Pest Management Program

For advice concerning current control practices with relation to specific local conditions, consult resources in resistance management programs, your Cooperative Agricultural Extension Service, or your Elanco Animal Health representative (800-428-4441).

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal

Storage: Store in original container only. In case of leak or spill, remove with absorbent materials and dispose of as waste.

Disposal: Wastes resulting from the use of this product may be disposed of on site according to label use directions or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerator, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with the use of this product. Lack of performance or other unintended consequences may result because of such factors as use of the product contrary to label instructions, abnormal conditions, presence of other materials, the manner of application, or other factors which are beyond the control of Elanco Animal Health or the seller. All such risks are assumed by the buyer.

LIMITATIONS OF REMEDIES

The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Elanco Animal Health's election, one of the following:

(1) Refund of purchase price paid by buyer or user for product bought, or

(2) Replacement of amount of product used

Elanco Animal Health shall not be liable for losses or damages resulting from the handling or use of this product unless Elanco Animal Health is promptly notified of such loss or damage in writing. In no case shall Elanco Animal Health be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Elanco Animal Health or the seller is authorized to vary or exceed the terms of Warranty Disclaimer of this Limitation of Remedies in any manner

Elanco Animal Health, A Division of Eli Lilly and Company Indianapolis, IN 46285 www.elanco.com Questions or comments call 1-800-428-4441

EPA Reg. No: 72642-1 EPA Est. No.: 37429-GA-02

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*Elanco®, Extinosad®, and the diagonal color bar are trademarks of Eli Lilly and Company