

72642-1

07-01-2003

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JUL 1 2003

Ms. Katherine M. Ehrenfried
Regulatory Manager
ELANCO ANIMAL HEALTH A Division of Eli Lilly and Company
2001 W. Main Street
Greenfield, IN 46140

Dear Ms. Ehrenfried:

This is in response to your request dated May 30, 2003 to change the primary brand name for EPA Registration 72642-1 from Extinosad® Topical Insect Control Agent to:

ELECTOR™ INSECT CONTROL AGENT

Your request for the name change is **accepted** and the change will be made to the Agency's records. All future correspondence on this product should reference the new name.

Sincerely yours,



Sherada D. Hobgood
Notifications Review Coordinator
Registration Division (7505C)

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United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-1	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Extinosad	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly and Co. 2001 W. Main Street Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. NOTIFICATION Product Name JUL - 1 2003	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 See attached cover letter.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1L, 5L		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Katherine M. Ehrenfried	Title Regulatory Manager	Telephone No: (Include Area Code) (317)277-3362
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Katherine M. Ehrenfried</i>	3. Title Regulatory Manager	
4. Typed Name Katherine M. Ehrenfried	5. Date <i>30 May 2003</i>	

Summary of Changes

Action	Date Submitted	Date Received from EPA
EPA Approval (Stamped Label)		September 27, 2002
<p>Notification</p> <ol style="list-style-type: none"> 1. Change in the primary brand name from Extinosad to Elector. 2. The text in each of the fourth columns contained in the tables in the Application section under the uses, "AS A POUR-ON", "AS AN ON-ANIMAL SPRAY" and "AS A PREMISE SPRAY," was removed from the table (shown as text with strikethrough) and added (as it previously appeared in the table) as text (highlighted in gray) underneath each of the tables with the heading "Application Rate" because the configuration and size of the bottle were not wide enough to allow for legible tables with four columns. 3. Text was added to the Application Rate section for the pour-on use (the added text is highlighted in gray) to make it easier for the user of the product to calculate and understand the amount of product to apply to the animal. The previous wording (16 mL per 440 lbs of body weight) could cause confusion and result in the usage of a rate that is higher than the approved use rate, which is 4 mL per 110 lbs of body weight (2 mg/kg). The added text represents the same use directions already approved by the EPA. 4. The text in the "Notice" found in the application table for the premise spray use (the added text is highlighted in gray) was revised to provide greater clarity to the end user so that the product can be used safely and in accordance with the label. The revised text represents the same use directions already approved by the EPA. 5. The word "Topical" was removed (shown as text with a strikethrough) from the phrase "Topical Insect Control Agent" that appeared on the front label panel, the back label panel, and the back inside label booklet because of its redundancy. 6. Four pictures have been added to the front label panel and are pictures of cattle that are in accordance and representative of the approved label claims. 	May 30, 2003	N/A

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Front Panel

ELANCO* AH 0492

NOTIFICATION

JUL - 1 2003

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.

ACTIVE INGREDIENT

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

Notice: Shake Well Before Use—Avoid Freezing. Read the entire label before using. Use only according to label directions. See Directions for Use on the inside label booklet on the back of this bottle.

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

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

Net Contents: _____ Liter(s)

Front Panel Pictures



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(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.**

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.

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.

Peel Back Logo

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(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.

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.

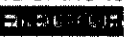
DIRECTIONS FOR USE

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 1/2 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
Lactating and non-lactating dairy and beef cattle	Horn flies Lice (chewing and sucking)	No dilution required	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.

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.**

AS AN ON-ANIMAL SPRAY:

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

Apply To:	To Control:	Dilution	Application Rate
Lactating and non-lactating dairy and beef cattle	Horn flies Lice (chewing and sucking)	Dilute 10 ounces (Approx. 300 mL) to 5 gallons water to give 0.04% spinosad	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 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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[REDACTED]

INTEGRATED PEST AND RESISTANCE MANAGEMENT

EXTINOSAD [REDACTED] 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 [REDACTED] 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 IPM strategy will help ensure the prolonged usefulness of EXTINOSAD [REDACTED] and other conventional insecticides.

- Do not use less than the labeled rate of any insect control product
- Apply EXTINOSAD [REDACTED] 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).

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

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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

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