

72642-7

8/28/2008

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

72642-7

Date of Issuance:

08/28/08

Term of Issuance:

Conditional

Name of Pesticide Product:

Spinosad Ear Tag

NOTICE OF PESTICIDE:

Registration

Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (Include ZIP Code):

Elanco Animal Health
2001 W. Main St.
Greenfield, IN 46140

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, subject to the following listed comments and/or terms:

1. Make the following labeling changes before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No. 72642-7"

Signature of Approving Official:

George LaRocca
Product Manager (RM 13)
Insecticide Branch
Registration Division (MC 7505P)

Date:

August 28, 2008

- b. Revise the statements under Environmental Hazards on the "Label Booklet: Page 1 through end" page to be consistent with those on the "Label Booklet Cover-Back Panel" page. You may also revise the statement "This product is highly toxic to mollusks" to read "***This product is toxic to aquatic invertebrates***".
 - c. Revise the sentence under Disposal to read "Tags ***and other wastes resulting from . . . disposal facility***" (i.e., add "Tags and other" to the beginning of the sentence). You may also delete the statement "***Avoid freezing***" under Storage – stated under DFU, thus, redundant
 - d. Under "Limitation of Remedies", add "***To the extent consistent with applicable laws***" to the beginning of the following paragraphs: "The exclusive remedy for losses or damages . . . etc." and "Elanco Animal Health shall not be liable for losses . . . etc"; and revise the sentence "In no case shall . . . damages or losses" to read "***To the extent consistent with applicable laws, Elanco Animal Health shall not be liable . . . damages or losses***".
2. Submit a revised data matrix citing appropriate data for the acute dermal toxicity and dermal sensitization requirements (See enclosed Agency's product toxicity review dated June 9, 2008).
 3. Submit to the Agency, data on one year storage stability testing (830.6317), conducted concurrently with the corrosion characteristics study (830-6320) at 0, 3, 6, 9 and 12 months of warehouse storage.

If you fail to satisfy any of the conditions imposed on this registration, the Agency may issue notice to cancel this product. You must also submit the final printed label bearing the above stated revisions prior to releasing this product for sale. See enclosed copy of the stamped label for your records. If you have any questions concerning this action, please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Enclosure

**ACCEPTED
with COMMENTS
In EPA Letter Dated:
AUG 28 2008**

[Front panel]
Elanco* Animal Health AHXXXX

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
72642-7**

SPINOSAD EAR TAG

FOR CONTROL OF HORN FLY (*Haematobia irritans*), FACE FLY AND LICE ON BEEF
CATTLE AND LACTATING DAIRY CATTLE

ACTIVE INGREDIENT

<i>Spinosad</i> [A mixture of spinosyn A and spinosyn D].....	15.0%
INERT INGREDIENTS	<u>85.0%</u>
TOTAL	100.0%

NOVEL DELIVERY OF SPINOSAD INSECTICIDE

EFFECTIVE AGAINST FACE FLIES AND PYRETHROID RESISTANT HORN FLIES
FOR UP TO 5 MONTHS

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENT

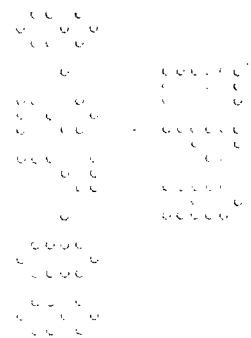
Each ear device weighs 33 g (17g formulation, 16g plastic components)
Contents: 40 devices and attachment buttons

Elanco Animal Health
A Division of Eli Lilly & Company
2001 West Main Street
Greenfield, IN 46140
www.elanco.com

Questions or comments call: 1-800-428-4441

*Elanco®, SPINOSAD EAR INSECTICIDE DELIVERY SYSTEM™, and the diagonal color bar are trademarks of Eli Lilly and Company.

EPA Reg. No. 72642-X
EPA Est. No. 81564-IN-01



(Label Booklet Cover-Back Panel)
ELANCO* AHXXXX

SPINOSAD EAR INSECTICIDE DELIVERY SYSTEM

FOR CONTROL OF HORN FLY (*Haematobia irritans*), FACE FLY AND LICE ON BEEF CATTLE AND LACTATING DAIRY CATTLE.

Environmental Hazards

This product is highly toxic to molluscs. Do not apply to any body of water. Do not contaminate water by disposal of used tags. Apply this product only as specified on this label.

Notice: 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.

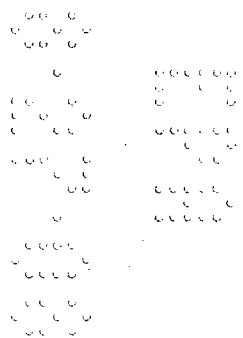
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Each ear device weighs 33 g (17g formulation, 16g plastic components)
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Peel Back Logo



(Label Booklet: Page 1 through end)

SPINOSAD EAR INSECTICIDE DELIVERY SYSTEM

FOR CONTROL OF HORN FLY (*Haematobia irritans*), FACE FLY AND LICE ON BEEF CATTLE AND LACTATING DAIRY CATTLE.

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.

Notice: Avoid freezing.

1. Remove protective cap to expose device tip.
2. Apply device to the inner, flat surface near the center of the ear using the buttons provided.
3. Do not allow male stud to penetrate cartilage ribs or blood vessels, as ear damage could occur.
4. Do not apply to calves < 6 months of age, as ear damage may result.

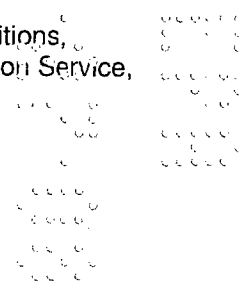
For optimum fly control, all animals greater than 6 months of age should be treated. Use one ear device per animal. Apply when flies first appear. Ear devices remain effective for up to 5 months. Remove ear devices when flies are no longer being controlled.

INTEGRATED PEST AND RESISTANCE MANAGEMENT

This product is a member of a unique class of insect control agents (spinosyns) with no pre-existing levels of resistance to any other insect control agents and can be rotated with all other classes, such as synthetic pyrethroids and organophosphates. Horn flies and other insects have demonstrated the ability to develop resistance to insect control products. Continual exposure of flies and other insects to a single class of insecticide may lead to the development of resistance to that class of insecticide. The following resistance management strategy will help ensure the prolonged usefulness of this product, as well as other conventional insecticides:

- Apply this product and other insect control agents only according to label directions
- Do not use less than the labeled rate of any insect control product
- Include multiple control tactics (cultural and/or biological controls) within an Integrated Pest Management Program
- Rotate this product with other classes of insecticides (synthetic pyrethroid, organophosphate) during a fly season

For advice concerning integrated pest management practices in relation to specific local conditions, consult resources in resistance management programs, your Cooperative Agricultural Extension Service,



or your Elanco Animal Health representative (1-800-428-4441).

STORAGE AND DISPOSAL

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

Storage: Store in original container only. Store in a cool place away from direct sunlight. Avoid freezing.

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.

Ear Delivery System Disposal: Remove ear devices before slaughter. Dispose of devices in a sanitary landfill or by incineration, 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.

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