



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:

72642-8

Date of Issuance:

DEC 22 2008

Term of Issuance:

Conditional

Name of Pesticide Product:

Gammacyhalothrin Ear Tag

NOTICE OF PESTICIDE:

- ☒ Registration
☐ Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Elanco Animal Health
2001 West Main Street
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 product is **conditionally** registered in accordance with FIFRA sec. 3(c)(7)(A) subject to the following provisions:

1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. You will make the following label changes before you release the product for shipment:
 - a) Revise the EPA Registration Number to read "EPA Reg. No. 72642-8."
 - b) On page 2, add the heading *Precautionary Statements* above the Signal word Caution. Revise the sentence "*Data indicate this product to be a contact allergenic*" to read "*Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.*"
 - c) The acute toxicity profile of this product is as follows:

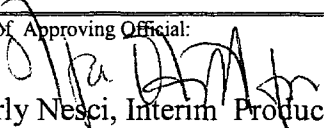
| | |
|-------------------------|-----------------------------------|
| Acute Oral ----- III | Primary Eye Irritation ----- IV |
| Acute Dermal --- IV | Primary Dermal Irritation --- IV |
| Acute Inhalation --- IV | Skin Sensitization ----- Negative |

Since the product is in Toxicity Category IV for all but the oral route of exposure, only the "*If swallowed*" statements are required under First Aid. You may retain the other first aid statements, but the "*If swallowed*" statements must be listed first.

- d) Add "*and other aquatic organisms*" to the first sentence under Environmental Hazards. Revise the remaining sentences as follows: "*Do not contaminate water by disposal of used tags. Apply this product only as specified on this label.*"
- e) Add "*To the extent consistent with applicable law*" in front of:
- o "*Elanco Animal Health makes no other express warranty...*"
 - o "*The exclusive remedy for losses or damages...*"
 - o "*Elanco Animal Health should not be liable...*"
 - o "*In no case shall Elanco Animal Health be liable...*"
3. You have indicated that the Company has data on file to support the efficacy claims for this product.
4. The product chemistry data submitted to support registration of this formulation have been reviewed and found acceptable to fulfill the data requirements of 830 Series subgroup A and Subgroup B with the exception of storage stability (830.6317) and corrosion characteristics data (830.6320). **One year storage stability and corrosion characteristics data must be submitted to the Agency.** Refer to the enclosed Product chemistry review memo for details concerning the requested data.
5. The Confidential Statement of Formula (CSF) dated 23-Nov-2007 is acceptable. A copy of the CSF has been placed in the file for the subject product.
6. Please submit two (2) copies of your final printed labeling before releasing the product for shipment. 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 revised labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have questions regarding this action, please contact Olga Odiott at (703) 308-9369.

Signature of Approving Official:


Kimberly Nesci, Interim Product Manager (13)
Insecticide Branch/Registration Division (7505P)

Date:

DEC 22 2008

Enclosure

GAMMACYHALOTHRIN EAR TAG

- FOR CONTROL OF HORN FLIES (*Haematobia irritans*) AND FACE FLIES (*Musca autumnalis*) ON BEEF CATTLE AND NON-LACTATING DAIRY CATTLE

CAUTION

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Remove contaminated clothing and wash before re-use. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear rubber or non-permeable gloves when applying this product. Data indicate this product to be a contact allergenic.

FIRST AID

If on the skin or clothing:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rise slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything to an unconscious person.

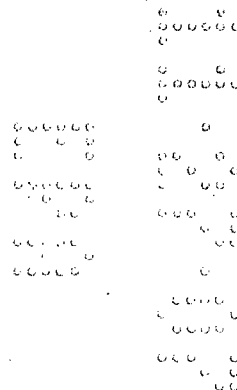
Have product container label, container, or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-428-4441 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. 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 wash waters. Apply this product only as specified on this label.

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



PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or an open flame.

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.

1. Remove tag from tray.
2. Apply tag to the front, flat surface near the center of the ear using the buttons provided. Alternatively, the tag may be applied to the back side of the ear.
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.

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

INTEGRATED PEST AND RESISTANCE MANAGEMENT

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 as frequently as possible

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. In case of leak or spill, remove with absorbent materials and dispose of as waste. Store in a cool place away from direct sunlight. Do not store near food or feed. 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 Tag Disposal: Remove ear tags 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.

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WARRANTY DISCLAIMER

INHERENT RISKS OF USE

LIMITATIONS OF REMEDIES

[illegible]