



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 19, 2023

J. Todd Frank
Senior Regulatory Affairs Consultant
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

Subject: Registration Review Label Mitigation for Permethrin
Product Name: Ear Force Tags
EPA Registration Number: 11556-169
Application Date: 3/24/2021
Decision Number: 572576

Dear J. Todd Frank:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin Interim Decision and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

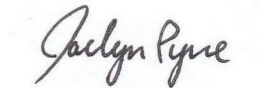
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently

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approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Carolyn Smith by phone at (202) 566-2273, or via email at smith.carolyn@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Jaclyn Pyne". The signature is written in a cursive style with a light blue circular stamp behind it.

Jaclyn Pyne
Team Leader
Risk Management & Implementation Branch III
Pesticide Re-evaluation Division
Office of Pesticide Programs

Enclosure

Reason to Issue: EPA updates.

Date: 03/24/2021

Supersedes: 02/09/2010

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EAR FORCE TAGS

FOR USE ON DRY OR LACTATING DAIRY AND BEEF CATTLE AND CALVES TO CONTROL HORN FLIES, FACE FLIES, GULF COAST TICKS, SPINOSE EAR TICKS, AND AS AN AID TO CONTROL LICE, STABLE FLIES AND HOUSEFLIES.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side and end panels for additional directions for use.

ACTIVE INGREDIENT:

Permethrin (CAS # 52645-53-1)..... 10.0%

OTHER INGREDIENTS..... 90.0%

Total 100.0%

PERMETHRIN	GROUP	3A	INSECTICIDE
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[Note to reviewer: box will be in the upper right corner of front panel.]

EPA Reg. No. 11556-169

EPA Est. No.

FIRST AID

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 by poison control center or doctor.
- Do not give anything by mouth to an unconscious person

IF IN EYES:

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

IF ON SKIN OR CLOTHING

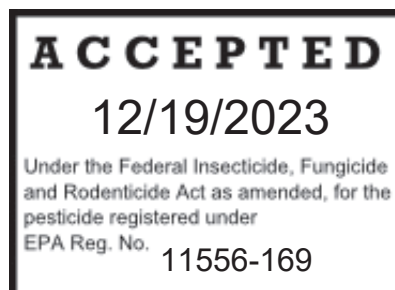
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes
- Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center, or doctor, or going for treatment. You may also contact 1-800-322-8177 for emergency medical treatment information.

Net Weight: 10 Grams Per Tag
Contents: 24 Tags

Manufactured By: Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes and socks, and
- Chemical-resistant gloves made of any waterproof material.

User Safety Requirements

- Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.
- Discard clothing and other absorbent materials that have been heavily contaminated with this product. Do not reuse them.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if-pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENT AL HAZARDS: This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water by disposal of used tags.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, Permethrin II contains a Group 3A insecticide. Any insect population may contain individuals naturally resistant to Permethrin II. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same sites. Appropriate resistance-management strategies should be followed.

Contact your local extension specialist advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific pest problems in your area.

For adequate control of horn flies, attach one tag per animal. For optimum control of flies, Gulf Coast ticks, spinose ear ticks, and as an aid in the control of lice, stable flies and houseflies, attach one tag to each ear (two per animal) for each season (up to 5 months). Replace as necessary. Apply as indicated (Figures 1-5). Calves less than 3 months of age should not be tagged as ear damage may result. **Remove tag prior to slaughter.**

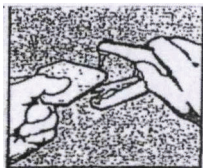


Figure 1. Place female tag under clip by depressing lever. Collar on tag must be pointing down.

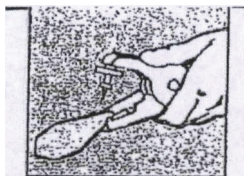


Figure 2. Slide rivet on pin. Align tip of rivet with female portion of tag. Tag and rivet are now ready for application.

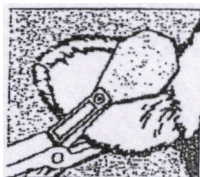
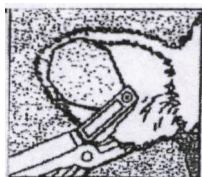


Figure 3 and Figure 4. Position tag on the inner flat surface in center of ear. Do not allow the shaft of the male rivet to penetrate any cartilage rib or blood vessel or ear damage may result. We recommend that tag be rotated at a 90° angle (Fig. 3) for ease of application. Tag may also be extended outward from the pliers in a straight manner (Fig. 4)

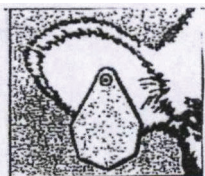


Figure 5. When properly positioned, the tag should hang as shown.

DIRECTIONS FOR USE (For Duflex Tagging System)

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

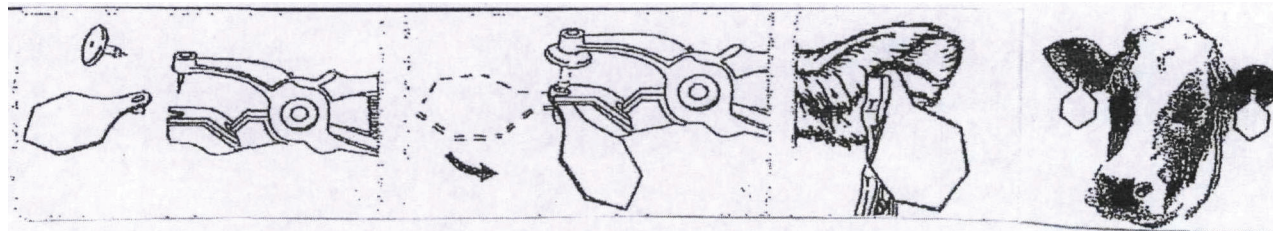


FIG. 1

FIG. 2

FIG. 3

FIG. 4

Figure 1: Place female tag under clip by depressing lever. Collar on tag must be pointing down.

Figure 2: Slide male stud on pin until it is firmly seated. Tag and stud are ready for application. Disinfect pliers and tags prior to application.

Figure 3: Position tag on the flat surface in center of ear. Do not allow shaft of the male stud to penetrate any cartilage rib or blood vessel. Ear damage may result. When properly positioned, the tag should hang down as shown in Figure 4.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Dispose of empty pouch in a landfill or by incineration. Do not burn unless allowed by state and local ordinances.

CONDITIONS OF SALE:

The directions on this label were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions both indoors and outdoors similar to those that are ordinary and customary where the product is to be used. Insufficient control of pests or plant injury may result from the occurrence of extraordinary or unusual conditions, or from failure to follow label directions. In addition, failure to follow label directions may cause injury to animals, man, and damage to the environment. To the extent permitted by applicable law, Elanco offers, and the buyer accepts and uses, this product subject to the conditions that extraordinary or unusual environmental conditions, or failure to follow label directions are beyond the control of Elanco and are, therefore, the responsibility of the buyer.

WARRANTY AND LIMITATION OF DAMAGES:

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.