



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

November 14, 2023

Todd Frank
Senior Regulatory Affairs Consultant, Pesticides and General Product Support, R&D
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

Subject: Label Amendment – Label changes based on the 2022 National Marine Fisheries Service Biological Opinion on Diazinon and Voluntary Request for Label Changes
Product Name: Patriot Cattle Ear Tag
EPA Registration Number: 11556-176
Application Date: October 24, 2022
Decision Numbers: 594589, 587499

Dear Todd Frank:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Diazinon 2022 Biological Opinion and voluntary request for label changes including addition of pictograms and text revisions. The Agency has concluded that your submission is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved by the Agency. 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 approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to the company’s website on your label, please be aware that the website becomes labeling under FIFRA 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) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced

Page 2 of 2
EPA Reg. No. 11556-176
Decision Nos. 594589, 587499

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Alex McKee at 202-566-1939 or at mckee.alex@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Dana L. Friedman". The signature is written in a cursive style with a large initial "D".

Dana L. Friedman, Chief
Risk Management and Implementation Branch 1
Pesticide Re-Evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

Enclosure

CC: Tamica Cain, Registration Division, PM10

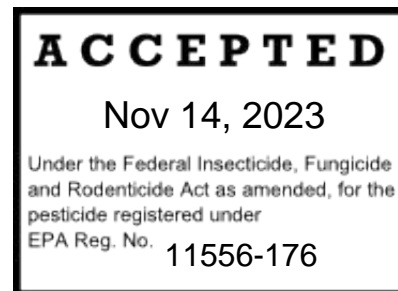
Reason To Issue: Add ESA statement and resistance management information.

Date: 10/19/2022
Supersedes: 12/08/2011

NOTE TO REVIEWER: Braces “{ }” indicate notes to reviewer. Brackets “[]” indicate optional language.

**PATRIOT
DEFENSE SYSTEM
INSECTICIDE CATTLE EAR TAG**

**Contains Closed Tip Rivets.
Apply with Allflex™ Blunt Pin.**



[Large, visual image of a cow [with ear tags]]

For use on Beef and Non-lactating Dairy Cattle to control Horn Flies (including pyrethroid resistant populations), Gulf Coast Ticks, Spinose Ear Ticks*, and as an aid to control Face Flies, Lice*, Stable Flies* and House Flies*.

*Not for use on this pest in California

**KEEP OUT OF REACH OF CHILDREN
WARNING**

See Side Panels for Precautionary Statements [and] [First Aid]

DIAZINON	GROUP	1B	INSECTICIDE
-----------------	--------------	-----------	--------------------

{Note to reviewer: box will be in the upper right corner of front panel.}

ACTIVE INGREDIENT:	% by Weight
Diazinon (CAS #333-41-5).....	40.0%
OTHER INGREDIENTS:	60.0%
Total:.....	100.0%

FIRST AID	
Contains an organophosphate that inhibits cholinesterase.	
If on Skin or Clothing:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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 Swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow.

- | | |
|--|---|
| | <ul style="list-style-type: none">• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious or convulsing person. |
|--|---|

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. [For emergency medical treatment, call 1-800-428-4441. For customer service or to obtain product information, including SDS, call 1-800-428-4441.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.] or CHEMTREC at 1-800-424-9300, 24 hours per day, 7 days per week.

NOTE TO PHYSICIAN

This product is a cholinesterase inhibitor. If symptoms of cholinesterase inhibition are present, atropine sulfate by injection is antidotal. 2-PAM is also antidotal and may be administered, but only in conjunction with atropine.

Net Weight: 15 Grams Per Tag (0.53 oz. per tag)

Contents: [2] [12] Pouches of 10 Tags Each

[[2] [12] bags of 10 rivets]

EPA Est. No. TBD

EPA Reg No. 11556-176

PRECAUTIONARY STATEMENT

HAZARDS TO HUMANS

WARNING: May be fatal if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear chemical-resistant gloves made of rubber or any waterproof material (thickness equal to or greater than 14 mils) when applying tags.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes and socks
- Chemical resistant gloves made of rubber or any waterproof material (thickness equal to or greater than 14 mils).

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.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- 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.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds, fish and other wildlife. Do not apply directly to water. Do not contaminate water by disposal of used tags.

DIRECTIONS FOR USE

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

Endangered Species Protection Requirements:

It is a Federal offense to use any pesticide in a manner that results in an unauthorized "take" (e.g., kill or otherwise harm) of an endangered species and certain threatened species under the Endangered Species Act section 9. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. You must obtain a Bulletin no earlier than six months before using this product. To obtain Bulletins, consult <http://www.epa.gov/espp/>, call 1-844-447-3813, or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product.

Reporting Ecological Incidents: To report ecological incidents, including mortality, injury, or harm to plants and animals, call 1-800-428-4441.

INTEGRATED PEST AND RESISTANCE MANAGEMENT

For resistance management, Patriot contains a Group 1B insecticide. Any insect population may contain individuals naturally resistant to Patriot and other Group 1B insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay insecticide resistance, take the following steps:

- Rotate the use of Patriot or other Group 1B insecticides, with different groups that control the same pests.
- Adopt an integrated pest management program for insecticide/acaricides use that includes scouting, uses historical information related to pesticide use, crop rotation, record keeping, and which considers cultural, biological and other chemical control practices.
- Monitor after application for unexpected target pest survival. If the level of survival suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.
- [For further information or to report suspected resistance contact Elanco US Inc at 1-800-428-4441.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.]

Reformulation or repackaging of this product is prohibited.

For adequate control of horn flies, attach one tag per animal. For optimum control of horn flies, control of ear ticks, and as an aid in the control of face flies, lice, stable flies, and house flies, attach one tag to each ear (two per animal). Replace as necessary. PATRIOT tags have been proven to be effective against pyrethroid resistant horn flies for up to five months. Apply as indicated (Figures 1-5). Calves less than 3 month of age should not be tagged as ear damage may result. **Remove tag prior to slaughter.**



Figure 1. Disinfect pliers prior to use. Place female tag under clip by depressing lever. Collar on tag must be pointing down.

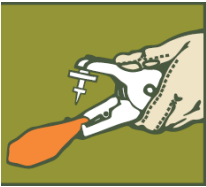


Figure 2. Slide male button on pin. Align tip of male button with female portion of tag. Tag and button are now ready for application.



Figure 3 [and] **Figure 4**

Position tag on the inner flat surface in center of ear. Do not allow 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 plier in a straight manner (Fig. 4).



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

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. If burned, stay out of smoke.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Elanco US Inc 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. ELANCO MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Elanco is authorized to do so except in writing and with a specific reference to this warranty. In no event shall Elanco's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140 USA

EPA Est. No. TBD
EPA Reg No. 11556-176