



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

November 7, 2025

Elizabeth Kile Vehring
Director, US Regulatory Affairs, R&D
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

Subject: Label Amendment - Registration Review Mitigation for Cyfluthrin
Product Name: Cylence Ultra Insecticide Cattle Ear Tag
EPA Registration Number: 11556-131
Application Date: February 20, 2021
Case Number: 478236

Dear Elizabeth Kile Vehring:

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 Cyfluthrin 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 and must be used at your next label printing. 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 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 Lauren Weissenborn via email at weissenborn.lauren@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cathryn Britton". The signature is fluid and cursive, with the first name "Cathryn" and last name "Britton" clearly distinguishable.

Cathryn Britton
Chief, Risk Management and Implementation
Branch V
Pesticide Re-evaluation Division (7508M)
Office of Pesticide Programs

ENCLOSURE: Stamped label

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

Beta-CYFLUTHRIN	GROUP	3A	INSECTICIDE
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Note to reviewer: box will be in the upper right corner of front panel.

**CYLENCE ULTRA™
INSECTICIDE CATTLE EAR TAG**

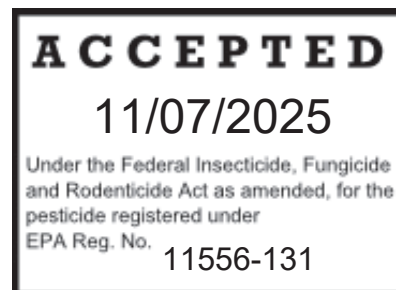
For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

ACTIVE INGREDIENTS:	% by Weight
Beta-cyfluthrin	8%
Piperonyl butoxide	20%
OTHER INGREDIENTS:	<u>72%</u>
TOTAL	100%

EPA Est. No. TBD
EPA Reg. No. 11556-131

For outdoor use only.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**



See [label location] for [Directions for use], [First Aid], [Precautionary Statements], and [Storage and Disposal.]

Net Contents: [XX Pouches of] XX Tags [each] - 0.5 oz per tag

Manufactured For:
Elanco US Inc
450 Elanco Circle
Indianapolis, IN 46221

[Product of India]

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

[Selected optional marketing claims bulleted here from page 4]
[Selected optional pictograms and image of tag from page 4]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes or on clothing. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves made of any waterproof material.

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

User 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. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID

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 a 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.
If Inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing call 911 or an ambulance then give artificial respiration, preferable mouth-to-mouth if possible.

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.]

ENVIRONMENTAL HAZARDS: This product is toxic to aquatic organisms, including fish and aquatic invertebrates. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, CYLENCE ULTRA INSECTICIDE CATTLE EAR TAG contains a Group 3A insecticide. Any insect population may contain individuals naturally resistant to CYLENCE ULTRA INSECTICIDE CATTLE EAR TAG and other Group 3A insecticides. 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 the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Use the Allflex Universal Total Tagger with the red pin and black clip to apply tags to cattle.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

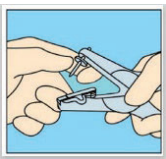


Figure 1

Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.



Figure 2

Slide tag under the clip of the pliers by depressing the lever.

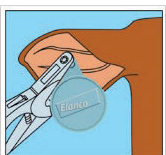


Figure 3
Position tag in center portion of the front side of the ear.

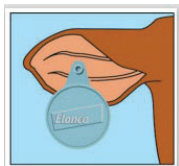


Figure 4
Apply the tag between the second and third rib cartilage.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in 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: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

[EPA Est. No. TBD]

[EPA Reg. No. 11556-131]

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Elanco US Inc warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, 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 with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

{{Optional marketing claims appearing on any location:}}

1. Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
2. Kills and Repels Face Flies - mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle.
3. Synergized for extra performance.

{{Optional marketing pictograms and pictures appearing on any location:}}

