

11556-131

8.22.2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 22, 2011

Douglas A. Spilker, Ph. D.  
Bayer Health Care LLC  
Animal Health  
P.O Box 390  
Shawnee Mission, KS 66201-0390

**Subject: Amended Reregistration Label**  
**Product Name: Cylence Ultra Insecticide Cattle Ear Tag**  
**EPA Registration No. 11556-131**  
**EPA Decision Number: 450422**

Dear Dr. Spilker:

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 reregistration of the referenced product in connection with the **Piperonyl Butoxide RED**, and has concluded that your submission is acceptable.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated March 8, 2002

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

**PLEASE NOTE:** This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

A copy of your label stamped "Accepted" is enclosed. If you have any questions about this letter, please contact Driss Benmhend at (703) 308-9525 or via e-mail at Benmhend.driss@epa.gov

Sincerely Yours,

Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

Enclosures: Label stamped "Accepted with Comments"  
000121-00034 D400841

Reason to Issue: Label Modifications according to PBO  
RED

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Pouch

**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.

|                    |                              | Percent By<br>Weight |
|--------------------|------------------------------|----------------------|
| Active Ingredients | Beta-cyfluthrin. ....        | 8%                   |
|                    | Piperonyl butoxide . . . . . | 20%                  |
| Other Ingredients  | .....                        | 72%                  |
| Total              | .....                        | 100%                 |

**Keep Out of Reach of Children**

**CAUTION**

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag

Manufactured for  
Bayer HealthCare, Animal Health Division  
P.O. Box 390  
Shawnee Mission, KS 66201 U.S.A.

**ACCEPTED**  
**AUG 22 2011**  
Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for the  
pesticide registered under:

EPA Est. No. XXX-XX-X  
EPA Reg. No. 11556-131

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Box (Front)

**CYLENCE® ULTRA**

**INSECTICIDE CATTLE EAR TAG**

For Use with Allflex Universal Total Tagger with red pin and black clip.

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

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

|                    |  | Percent By<br>Weight |
|--------------------|--|----------------------|
| Active Ingredients | Beta-cyfluthrin. . . . .               | 8%                   |
|                    | Piperonyl Butoxide Technical . . . . . | 20%                  |
| Other Ingredients  | . . . . .                              | 72%                  |
| Total              | . . . . .                              | 100%                 |

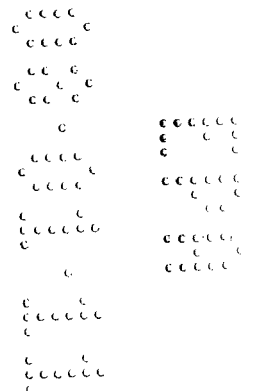
**Keep Out of Reach of Children**

**CAUTION**

See Side Panel for Additional Precautionary Statements

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Bayer HealthCare, Animal Health Division  
P.O. Box 390  
Shawnee Mission, KS 66201 U.S.A.



Box (Side Panel)

**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"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>   |
| If in Eyes:             | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>  |
| If Swallowed:           | <ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> </ul> |

Reason to Issue: Label Modifications according to PBO  
RED

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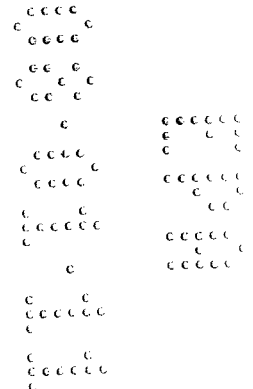
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- If Inhaled:
- Move person to fresh air.
  - If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

**HOTLINE 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 1-800-422-9874. For customer service or to obtain product information, including MSDS, call 1-800-633-3796.

**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.



Box (Back)

**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.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

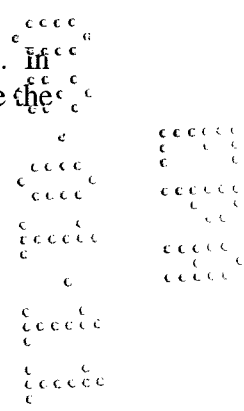
All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags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

| (Illustration)   | (Illustration)  | (Illustration)   | (Illustration)  |
|--|---|--|---|
| <b>Figure 1</b>  | <b>Figure 2</b>   | <b>Figure 3</b>  | <b>Figure 4</b>   |
| Disinfect pliers prior to use. Place male button onto pin until it projects through the tip. | Slide tag under the clip of the pliers by depressing the lever. | Position tag in the center portion of the front side of the ear. | Apply the tag between the second and third rib cartilage. |

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta-cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.



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**Storage and Disposal:**

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

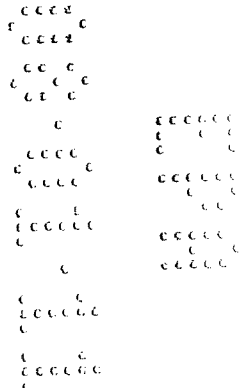
Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

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. XXX-XX-X

EPA Reg. No. 11556-131



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Box (Side Panel)

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### LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer 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.

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