



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 4, 2015

Dr. Douglas A. Spilker
Manager – EPA Regulatory Affairs
Bayer HealthCare, LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: PRIA Label Amendment – Addition of Control Claims for Gulf Coast Tick
Product Name: M937 Cattle Ear Tag Insecticide
EPA Registration Number: 11556-185
Application Date: May 14, 2015
Decision Number: 505067

Dear Dr. Spilker:

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable under FIFRA sec 3 (c)(5). You must submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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 18 months from the date of this letter. After 18 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, 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.

SEE NEXT PAGE

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 Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at Rodia.Carmen@epa.gov.

Sincerely,



Michael Walsh
Product Manager 11
Invertebrate & Vertebrate Branch 2
Registration Division
Office of Pesticide Programs

*Enclosures: Stamped Accepted Label, dated 11/4/2015
Efficacy Review #1, dated 09/24/2015
Efficacy Review #2, dated 10/28/2015*

Note to Reviewer: Brackets [] and parentheses () denote optional language

M937 Cattle Ear Tag Insecticide

ABN: Tolfenpro Insecticide Ear Tag

Cattle Ear Tag for use on Beef and Dairy Cattle (including lactating) to Control Horn Flies (including pyrethroid- and organophosphate-resistant horn flies) and Face Flies for up to 5 Months, and Gulf Coast ticks for up to 3 Months.

For Use with Allflex® Universal Total Tagger with red pin and black clip.
With FyberTek™

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-
- [Selected optional label claims bulleted here from page 7.]
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ACTIVE INGREDIENT:

Tolfenpyrad; 1 H-Pyrazole-5-carboxamide, 4-chloro-3-ethyl-1-methyl-N-[[4-(4-methylphenoxy)phenyl]methyl]-	15%
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OTHER INGREDIENTS	85%
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Total:	100%
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Net Contents: XX tags – XX oz (XX grams) per tag	
EPA Reg. No. 11556-185	EPA Est. No. TBD

STOP - Read the label before use.

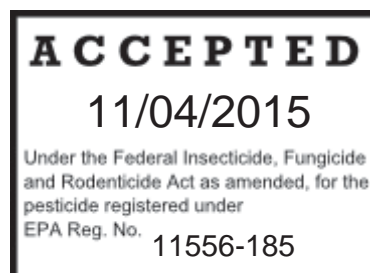
Keep out of reach of children.

CAUTION

See [location on package] for Precautionary Statements

PRECAUCION AL USUARIO: Si usted no puede leer o entender inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read or understand English, do not use this product until the label has been fully explained to you.)



Reason to Issue: To add control of Gulf Coast ticks.

Date: 11/04/2015

Supersedes: 02/24/2015

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FIRST AID	
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. For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), you may call 1-800-422-9874, twenty-four (24) hours per day, seven (7) days per week.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking chewing gum, using tobacco, or using the toilet. Wear long-sleeved shirt and long pants, shoes and socks, and chemical-resistant gloves when applying the ear tags. Remove and wash contaminated clothing before reuse.

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PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves

USER SAFETY REQUIREMENTS

Follow the 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. 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.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of used tags.


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[M937 Cattle Ear Tag Insecticide] <i>QuickFacts</i>	
	<ul style="list-style-type: none">•• [Selected optional label claims bulleted here from page 7.]•
WHERE TO APPLY	<ul style="list-style-type: none">• Beef and Dairy Cattle (including lactating)
HOW TO APPLY	<ul style="list-style-type: none">• Use Allflex Universal Total Tagger with red pin and black clip to apply tags to cattle.
COVERAGE	<ul style="list-style-type: none">• [All mature animals in the herd should be tagged.]• [For optimum control of horn flies and face flies, attach two tags per mature animal (one tag per ear).]• [Use one ear tag per calf] [for face fly control.]• [For adequate control of horn flies and face flies attach one tag per mature animal.]
RE-APPLY	<ul style="list-style-type: none">• [M937 Insecticide Cattle Ear Tag is effective against horn flies and face flies for up to five (5) months, and Gulf Coast ticks for up to three (3) months.]• [Replace as necessary.]• [Remove tags at the end of fly season or prior to slaughter (, whichever comes first).]
QUESTIONS? 	<ul style="list-style-type: none">• For questions or comments, call toll-free 1-800-633-3796.

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 possession of the user at the time of pesticide application.

IMPORTANT: Read the entire Directions for Use, Conditions of Sale and Disclaimer of Limited Warranty and Limitations of Damages before using this product.

Reformulation or repackaging of this product is prohibited.

Use for the control of horn flies (including pyrethroid-, and organophosphate-resistant horn flies) and face flies on beef and dairy cattle (including lactating).

For adequate control of horn flies and face flies, attach one tag per mature animal. For optimum control of horn flies and face flies attach two tags per mature animal (one per ear). For calves apply one tag per animal [for face fly control]. Replace as necessary. M937 Cattle Ear Tag Insecticide is effective against horn flies and face flies for up to five (5) months, and Gulf Coast ticks for up to three (3) months.

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

Apply as indicated (Figures 1-4). Remove tags at end of fly season or prior to slaughter (,whichever comes first).

(illustration)	(illustration)	(illustration)	(illustration)
Figure 1	Figure 2	Figure 3	Figure 4
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.

RESISTANCE MANAGEMENT

M937 Cattle Ear Tag Insecticide contains the active ingredient tolfenpyrad, which is classified by IRAC in Group 21A - mitochondrial electron transport inhibitors (METI). Continual exposure of horn flies to a single class of insecticide (e.g., pyrethroid, organophosphate or avermectin) may lead to the development of resistance to that insecticide class. In order to reduce the possibility of horn flies developing resistance, it is important to rotate the insecticide class used and/or the method of horn fly control on a seasonal or annual basis. Also, for more information about Insect Resistant Management (IRM), visit the Insecticide Resistance Action Committee (IRAC) on the web at www.irc-online.org.

Storage and Disposal

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

Pesticide Storage: Keep this product in its tightly closed original container. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals. 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: Non-refillable container. Do not reuse or refill this container. Dispose of empty pouch (tray) in a sanitary landfill or by other procedures approved by State and Local authorities.

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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, Bayer 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 Bayer and are, therefore, the responsibility of the buyer.

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 WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, and no agent of Bayer is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use of handling of this product.

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

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Optional/Alternative Marketing Claims

- [(Effective against) (Controls)] horn flies (including pyrethroid- and organophosphate-resistant horn flies) [for up to 5 months].
- [(Effective against) (Controls)] face flies – mechanical vector of *Moraxella bovis* bacteria causing “pink eye” of cattle [for up to 5 months].
- [(Effective against) (Controls)] horn flies and face flies [for up to 5 months].
- Use in rotation with [Bayer’s] [CyLence Ultra® Insecticide Cattle Ear Tag] [pyrethroid insecticide cattle ear tag(s)]
- Use in rotation with [Bayer’s] [(Corathon®) and (Patriot™ Insecticide Cattle Ear Tag)] [organophosphate] [insecticide cattle ear tag(s)]
- Use in rotation with pyrethroid, organophosphate, or avermectin cattle ear tags
- Can be used with other insecticide pour-ons, sprays, dusts and oral larvicides
- Can be used with other classes of [(chemicals)(insecticides)]
- [(Gray)(smoky)(charcoal) (color) ear tag
- [Cellulose] fiber [matrix] for [(dependable) (effective)] (fly) [control]
- Maximum insecticide [holding] capacity [(tag) (technology) (matrix)]
- Contains insecticide holding [cellulose] fibers
- [(FiberTech) (FiberCell)(FyberTek™)] matrix: [(effective) (dependable) (long lasting)] (fly) control [for up to 5 months]
- Fiber [(tag) (matrix)] [FyberTek™] provides even dispersion of insecticide
- [(Controls) (prevents)] horn fly and face fly feeding and irritation
- Reduces horn fly blood-feeding (on cattle)
- Reduces blood loss (in cattle) (due to horn fly feeding)
- Controls [(Gulf Coast)(ear ticks)(*Amblyomma maculatum*)] [for up to 3 months]
- Prevents attachment of [(Gulf Coast)(ear ticks)(*Amblyomma maculatum*)] [for up to 3 months]