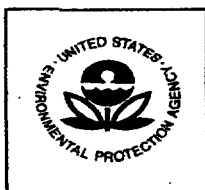


11556-148

3/3/2009

10910



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

11556-148

Date of Issuance:

MAR - 3 2009

NOTICE OF PESTICIDE:

- x Registration
Reregistration
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

M904 Insecticide Cattle Ear Tag

Name and Address of Registrant (include ZIP Code):

Bayer HealthCare, LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Submit the results of a one-year Storage Stability study, Guideline 63-17 (830.6317), and Corrosion Characteristics study, Guideline 63-20 (830.6320). It is required that the storage stability and corrosion characteristics observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in the electronic format and as well as a hard copy.
3. Make the labeling changes listed below before you release the product for shipment:
a. Add the phrase "EPA Registration No. 11556-148".

Signature of Approving Official:

Kimberly Nesci
Product Manager 11
Insecticide Branch
Registration Division (7505P)

Dana R. Palitt
for Kimberly Nesci

Date:

MAR - 3 2009

- b. In the Note to Physician, revise the end of the third sentence to read "...administered, but only in conjunction with atropine".
- c. Delete the small User Safety Recommendations (without the outline box) appearing under the Hazards to Humans text. The correct User Safety Recommendations in the required outline box appears on the next page of your label.
- d. Under the heading Directions For Use, there is a sentence referring the user to "Disclaimer of Warranties and Limitations of liability", but there is no such section on this label. The Agency reserves the right to review the wording of such a section before it is added to the label. If it is not your intention to add such a section, then delete reference to it from the "Important" sentence. If you intend to add such text, then immediately forward your proposed text for Agency review prior to preparing actual finished labeling. If, instead, you intend to add a Limited Warranty and Limitations of Damages section as found on your other recent ear tag label, then be sure to add "To the extent consistent with applicable law," before "Any damages arising..." when preparing that text for Agency review. Also, the referral sentence would require a change to reflect the change in the section heading.
- e. In the ninth marketing claim, the term "New" may appear on the label for a period of 6 months after product introduction.
- f. In the tenth marketing claim, delete the word "Advanced".
- g. Delete the thirteenth marketing claim, the fiber does not kill the pests.
- h. Delete the sixteenth marketing claim, "Kills [cattle] disease carrying ticks".
- i. Delete the seventeenth marketing claim, "Kills flies and ticks that may [(transmit) (carry) (vector) [cattle] disease".
- j. In the nineteenth marketing claim, delete "Advanced".
- k. Delete the twentieth marketing claim "[New](cellulose)(fiber) technology holds 25% more (organophosphate) insecticide".
- l. In the twenty-first marketing claim, delete "Advanced".
- m. In the twenty-second marketing claim, the term "New" may appear on the label for a period of 6 months after product introduction.

- n. Delete the twenty-third marketing claim, "Contains 25% more [(organophosphate insecticide)(active ingredient) than leading (organophosphate) ear tags".

Submit three copies of the revised final printed label for the record. Note the submission requirement in item "d" above prior to preparing the final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

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

M904 Insecticide Cattle Ear Tag

For use on Beef and Non-Lactating Dairy Cattle to Control Horn Flies (including pyrethroid-, chlorinated hydrocarbon- and avermectin-resistant horn flies), Face Flies, Gulf Coast Ticks, and Spinose Ear Ticks for up to 5 Months.

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

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

ACTIVE INGREDIENT:

Coumaphos	15%
Diazinon	35%
OTHER INGREDIENTS	50%
Total:	100%

Net Contents: XX tags – 0.5 oz (14 grams) per tag	
EPA Reg. No. 11556-xxx	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.)

**ACCEPTED
with COMMENTS
EPA Letter Dated:
MAR - 3 2009**

*Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
11556-148*

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

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.
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 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 do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person 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 1-800-422-9874. For customer service or to obtain product information, including the MSDS, call 1-800-633-3796.	
Note to Physician: This product contains cholinesterase inhibitors. If symptoms of cholinesterase inhibition are present, atropine sulfate, by injection, is antidotal. 2-PAM is also antidotal and may be administered in conjunction with atropine.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

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

User Safety Recommendations: Wash hands with soap and water after use and before eating, drinking, chewing gum, using tobacco or using the toilet.

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

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 washable 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 highly toxic to birds, fish, and wildlife. Do not apply directly to water. Do not contaminate water when disposing of used tags.

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

M904 Insecticide Cattle Ear Tags <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 Non-Lactating Dairy Cattle
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, face flies, Gulf Coast ticks, and spinose ear ticks, attach one tag to each ear (two tags per animal) per mature animal].] • [Use one ear tag per calf] [for face fly control.] • [For adequate control of horn flies, face flies, Gulf Coast ticks, and spinose ear ticks, attach one tag per mature animal.]
RE-APPLY	<ul style="list-style-type: none"> • [M904 Insecticide Cattle Ear Tags have been proven to be effective against horn flies and face flies for up to five months.] • [Replace as necessary.] • [Remove tags at end of fly season or prior to slaughter.]
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 Warranties and Limitations of liability before using this product.

Conditions of Sale: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer HealthCare LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

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

Reformulation or repackaging of this product is prohibited.

For the control of horn flies (including pyrethroid-, chlorinated hydrocarbon-, and avermectin-resistant horn flies), face flies, Gulf Coast ticks, and spinose ear ticks on beef and non-lactating dairy cattle

For adequate control of horn flies, face flies, Gulf Coast ticks, and spinose ear ticks attach one tag per mature animal. For optimum control of horn flies, face flies, Gulf Coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal) per mature animal. For calves apply one tag per animal. Replace as necessary. M904 Insecticide Ear Tags have been proven to be effective against horn flies and face 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). Remove tags at end of fly season or prior to slaughter.

(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.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids, organophosphates, chlorinated hydrocarbons or avermectin) 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. M904 Insecticide Cattle Ear Tag contains the organophosphate insecticides coumaphos and diazinon.

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: Non-refillable container. Do not reuse or refill this container. 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.

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

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.

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

Optional/Alternative Marketing Claims

- [(Effective against) (Controls)] horn flies (including pyrethroid-, chlorinated hydrocarbon- and avermectin-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
- [(Effective against) (Controls)] Gulf Coast ticks and spinose ear ticks
- Contains two [organophosphate] insecticides [Coumaphos and Diazinon]
- Contains 50% [(active ingredient) (organophosphate insecticides)]
- Use in rotation with [Bayer’s] M910 Insecticide Cattle Ear Tags
- Use in rotation with pyrethroid, chlorinated hydrocarbon or avermectin cattle ear tags
- [New] [(green) (grey) (brown)] color [ear tag]
- [Advanced] [cellulose] fiber [technology] [for [(dependable) (effective)] (fly and tick) control]
- Maximum insecticide [holding] capacity [(tag) (technology) (matrix)]
- Contains insecticide holding [cellulose] fibers
- Fiber [(technology) (tag) (matrix)] effectively kills flies and ticks
- [(FiberTech) (FiberCell)] matrix: [(effective) (dependable) (long lasting)] (fly and tick) control [for up to 5 months]
- Fiber [(technology) (tag) (matrix)] provides even dispersion of insecticide
- Kills [cattle] disease carrying ticks
- Kills flies and ticks that may [(transmit) (carry) (vector)] [cattle] disease.
- [(Controls) (prevents)] horn fly and face fly feeding and irritation
- Advanced [(cellulose) (fiber)] technology holds 25% more insecticide than [Bayer’s] Co-Ral Plus Insecticide Cattle Ear Tags
- [New] [(cellulose) (fiber)] technology holds 25% more (organophosphate) insecticide
- [Advanced] [fiber] technology [(holds) (contains)] [25%] more [(organophosphate insecticide) (active ingredient)] than [Bayer’s] Co-Ral Plus Insecticide Cattle Ear Tag
- [New] fiber [(technology) (tag) (matrix)] holds more insecticide
- Contains 25% more [(organophosphate insecticide)(active ingredient)] than leading (organophosphate) ear tags