



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

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

JUL 16 2008


RE: Notification for Label Revisions  
EPA Reg. No.: 11556-123  
Date of Submission: June 02, 2008

Dear Dr. Spilker:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated June 2, 2008, for the product Co-Ral Plus Insecticide Cattle Ear Tag. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

  
Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form

 United States <b>Environmental Protection Agency</b> Washington, DC 20480	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 11556-123	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Plus Insecticide Cattle Ear Tag	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Healthcare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: <b>NOTIFICATION</b> EPA Reg. No. _____ Product Name _____ JUL 16 2008	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

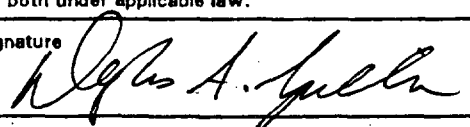
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Enclosed with this Application for Pesticide Notification is a draft label for Co-Ral Plus Insecticide Cattle Ear Tag, dated May 28, 2008, which has been modified only to change those items that fall under the scope of Pesticide Registration Notice (PRN) 98-10, PRN 97-5 or may be accomplished as Non-notifications. See attachment for further detail.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Douglas A. Spilker, Ph.D	Title Manager, EPA Reg Affairs	Telephone No. (Include Area Code) (913) 268-2751
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, EPA Regulatory Affairs	
4. Typed Name Douglas A. Spilker, Ph. D.	5. Date 02 June 2008	

ATTACHMENT FOR  
APPLICATION FOR PESTICIDE REGISTRATION  
June 2, 2008

Co-Ral<sup>®</sup> Plus Insecticide Cattle Ear Tag (EPA Reg. No. 11556-123)

Enclosed with this Application for Pesticide Notification is a draft label for Co-Ral Plus Insecticide Cattle Ear Tag, dated May 28, 2008, which has been modified only to change those items (see highlighted copy) that fall under the scope of Pesticide Registration Notice (PRN) 98-10, PRN 97-5 or may be accomplished as Non-notifications, and include:

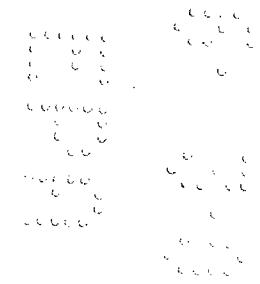
- 1. Due to a change in the manufacturer's tradename of the applicator device for the ear tag, the applicator name for the ear tags has been changed in two places (pages 1 and 4) on the draft label -

from: "For use with Allflex<sup>®</sup> Global Applicator with red pin and white clip"  
to: "For use with Allflex<sup>®</sup> Universal Total Tagger with red pin and black clip."

- 2. Delete the long chemical names in the ingredient statement to only list common chemical names (coumaphos and diazinon). This is allowed pursuant to PRN 97-5.
- 3. Change of address to add more specific address (add P.O. Box number) in two places on the draft label (pages 1 and 5).
- 4. Change emergency telephone numbers; we are transitioning to another medical service, but the previous telephone numbers will remain in effect for some time.
- 5. Change the Warranty Statement as directed by the Agency to include the phrase "To the extent consistent with applicable law....."
- 6. Change establishment number (to another approved site) in two places on the draft label (pages 5 and 6).

**Please note that we have opted not to change the storage and disposal statements at this time (pursuant to PR Notice 2007-4), awaiting further clarification from the Agency on these obviously non-refillable ear tag products.**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been proposed for the labeling or the confidential statement of formula for this product. Bayer understands that it is a violation of 18 U.S. C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



Reason to Issue: Minor label modifications  
[Notification]

Date: 05/28/2008  
Supersedes: 08/07/2007  
Page 1 of 6

Bag (Front)

**CO-RAL® PLUS**  
**INSECTICIDE CATTLE EAR TAG**

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

For use on Beef and Non-Lactating Dairy Cattle to control Horn Flies (including pyrethroid-resistant horn flies), Gulf Coast Ticks, Spinose Ear Ticks, And As An Aid To Control Face Flies.

	<u>Percent By Weight</u>
Active Ingredients:	
Coumaphos . . . . .	20%
Diazinon . . . . .	20%
Other Ingredients . . . . .	<u>60%</u>
Total . . . . .	100%

**Keep Out of Reach of Children**

**CAUTION**

See Back of Bag For Additional Precautionary Statements and Full Labeling

Net Contents: 20 Tags - 0.5 oz per tag

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

**NOTIFICATION**

**JUL 16 2008**

Reason to Issue: Minor label modifications  
[Notification]

4/11  
Date: 05/28/2008  
Supersedes: 08/07/2007  
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Bag (Rear)

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## 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 Recommendation:** Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

#### FIRST AID

Contains organophosphates that inhibits cholinesterase.

- If on skin or clothing:**
- Take off contaminated clothing.
  - Rinse skin immediately with plenty of water for 15 – 20 minutes.
  - Call 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 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 instructed to do so by the poison control center or doctor.
  - Do not give anything by mouth to an unconscious or convulsing person.

Reason to Issue: Minor label modifications  
[Notification]

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Bag (Rear)

**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.

**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.

**PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Applicators and other handles 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.

Reason to Issue: Minor label modifications  
[Notification]

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Bag (Rear)

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**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.

Reformulation or repackaging of this product is prohibited.

For the control of Horn Flies (including pyrethroid-resistant Horn Flies), Gulf Coast Ticks, and Spinose Ear Ticks on beef and non-lactating dairy cattle and as an aid to control Face Flies.

All mature animals in the herd should be tagged. For adequate control of Horn Flies attach one tag per animal. For optimum control of Horn Flies, Gulf Coast Ticks, and Spinose Ear Ticks, and as an aid in the control of Face Flies, attach one tag to each ear (two per animal). Replace as necessary. Co-Ral<sup>®</sup> Plus Insecticide Ear Tags have been proven to be effective against Horn Flies for three to five months.

Use 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. Co-Ral<sup>®</sup> Plus Insecticide Cattle Ear Tags contain the organophosphate insecticides coumaphos and diazinon.



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Bag (Rear)

**STORAGE AND DISPOSAL**

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

Pesticide Storage: Store in cool place in original container.

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. 67517-MO-1  
EPA Reg No. 11556-123

**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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[Notification]

Date: 05/28/2008  
Supersedes: 08/07/2007  
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Inner Box

**CO-RAL® PLUS**  
**INSECTICIDE CATTLE EAR TAG**

20 Tags – 0.5 oz per tag

	<u>Percent By Weight</u>
Active Ingredients:	
Coumaphos . . . . .	20%
Diazinon . . . . .	20%
Other Ingredients . . . . .	<u>60%</u>
Total . . . . .	100%

EPA Est. No. 67517-MO-1  
EPA Reg. No. 11556-123

**Keep Out of Reach of Children**

**CAUTION**

See Back of Bag For Additional Precautionary Statements and Full Labeling

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

*Via Federal Express 06/02/2008*

**Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501**

**Enclosure:**

- Application for Pesticide Notification for Co-Ral Plus Insecticide Ear Tag (EPA Reg. No. 11556-123)
- Five copies draft labeling
- One highlighted copy draft labeling

