

11556-23

8/26/2009

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

AUG 26 2009

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

Subject: Notification(s) for Label Revisions under PRN 97-4, 97-5, 98-10  
and 2007-4

Dear Dr. Spilker:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notices (PRN) 97-4, 97-5, 98-10 and 2007-4 dated, July 29, 2009 for:

**EPA Registration 11556-23**

**Co-Ral Emulsifiable Livestock Insecticide**

The Registration Division (RD) has conducted a review of the request(s) for applicability under PRN 97-4, 97-5, 98-10 and 2007-4 and finds that the label changes requested fall within the scope of PRN-97-4, 97-5, 98-10 and 2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

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

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

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

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 11556-23	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Emulsifiable Livestock Insecticide	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 _____ <b>AUG 26 2009</b>	

### 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.)

See attachment, dated 7/29/2009.  
email: doug.spilker.b@bayer.com

### Section - III

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

Signature 	3. Title Manager, EPA Regulatory Affairs	REC'D 8-19-09
Typed Name Douglas A. Spilker, Ph.D.	5. Date <u>29 July 2009</u>	

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ATTACHMENT FOR  
APPLICATION FOR PESTICIDE REGISTRATION - Notification  
July 29, 2009  
Co-Ral<sup>®</sup> Emulsifiable Livestock Insecticide (EPA Reg. No. 11556- 23)

Enclosed with this Application for Pesticide Notification is a draft label (5 copies) for Co-Ral<sup>®</sup> Emulsifiable Livestock Insecticide, dated July 28, 2009, which has been modified only to change those items (see highlighted copy) that fall under the scope of Pesticide Registration Notice (PRN) 97-4, PRN 97-5, PRN 98-10, PRN 2007-4 or may be accomplished as Non-notifications, and include:

1. Removal of "(coumaphos)" in close proximity of product name; this is not a part of the EPA accepted product name – Co-Ral<sup>®</sup> Emulsifiable Livestock Insecticide. See page 1.
2. Deletion of the long chemical name in the ingredient statement to only list common chemical name (coumaphos). This is allowed pursuant to PRN 97-5. See page 1.
3. Up-dating of our company name to Bayer HealthCare LLC, Animal Health Division. Please note there was no change in ownership.
4. Revision of the emergency telephone numbers; we are transitioning to another medical service, but the previous telephone numbers will remain in effect for some time. The customer service statement was also revised. This is allowed pursuant to PRN 97-4. See page 2.
5. Revision of the storage and disposal statements pursuant to PR Notice 2007-4. See page 7.
6. Revision of the CONDITIONS OF SALE and WARRANTY sections. See page 8.

*This notification is consistent with the provisions of PR Notices 97-4, 97-5, 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 of 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.*

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*Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146 and 156.156. No other changes have been made to 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 the amended label is not consistent with the requirements of 40 CFR §156.10, 156.140, 156.144, 156.146 and 156.156, 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.*

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Reason to Issue: Revise according to PRN 2007-4,  
and make other minor revisions.

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**RESTRICTED USE PESTICIDE: Due to Acute Oral Hazard.**  
For retail sale to and use only by Certified Applicators or persons under  
their direct supervision and only for those uses covered by the Certified  
Applicator's Certification

**Co-Ral®  
Emulsifiable Livestock Insecticide**

For Control of Horn Flies, Face Flies, Lice and Ticks

	Percent by Weight
Active Ingredient:	
coumaphos .....	11.6%
Other Ingredients* .....	88.4%
Total .....	100.0%

\*Contains aromatic petroleum distillates.

This product contains 1.0 lb coumaphos per gallon.

EPA Reg. No. 11556-23

EPA Est. No. TBD

**KEEP OUT OF REACH OF CHILDREN**

**DANGER --  -- POISON**

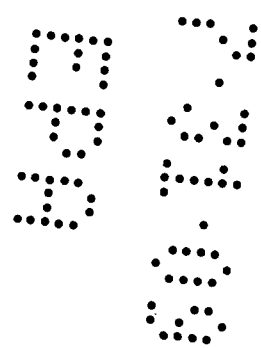
**PELIGRO**

Fatal if swallowed. Harmful if absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing.

**See Side Panel for First Aid and  
Other Precautionary Statements**

NET CONTENTS: 1 Quart (946 mL)

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



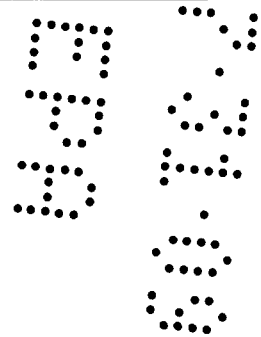
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**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

<b>FIRST AID</b>	
<b>Contains an organophosphate that inhibits cholinesterase.</b>	
<b>If swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give <u>any</u> liquid to the person.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If inhaled:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If on skin or clothing:</b>	<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>
<b>If in eyes:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>Note To Physician:</b> Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine. Contains petroleum distillate - vomiting may cause aspiration pneumonia.</p>	
<p><b>HOTLINE NUMBER:</b> 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.</p>	



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**DANGER --**  **-- POISON**  
**PELIGRO**

### **PERSONAL PROTECTIVE EQUIPMENT**

Some materials that are chemical-resistant to this product are barrier laminate and viton ( $\geq 14$  mils). If you want more options, follow the instructions for Category G on an EPA chemical-resistance category selection chart.

Mixers, loaders, and others exposed to the concentrate (such as during a spill or equipment breakdown) must wear long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron, and face shield or goggles.

Applicators and all other handlers exposed to the diluted product must wear long-sleeve shirt and long pants, chemical-resistant gloves, and chemical-resistant footwear plus socks.

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 the other laundry.

### **User Safety Recommendations**

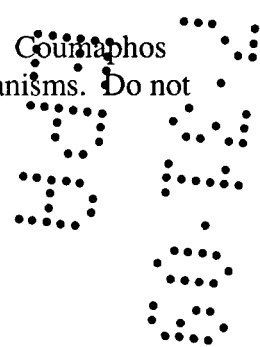
Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing 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 mammals, birds, fish and aquatic invertebrates. Coumatophos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not



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contaminate water when disposing of equipment washwater or rinsate. Apply this product only as specified on this label.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label and Conditions of Sale before using this product.

### **APPLICATION RESTRICTIONS**

Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase-inhibiting drugs or pesticides. Atropine sulfate by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

Do not apply in conjunction with oral drenches or other internal medications such as phenothiazine, nor with natural or synthetic pyrethroids or their synergists or with other organic phosphates.

For external insecticidal use only on specified animals.

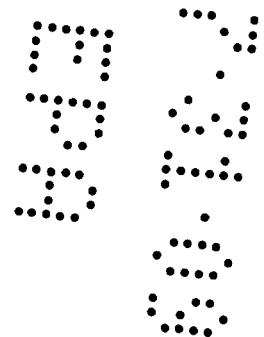
Do not apply as a spray at rates above 1¼ ounce of Co-Ral Emulsifiable Livestock Insecticide per 4 gallons of water to lactating dairy cattle or non-lactating dairy cattle within 14 days of freshening. If freshening should occur within the interval after spraying, do not use milk for human food for balance of 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old.

Do not spray animals for 10 days before or after shipping or weaning or after exposure to contagious and infecting diseases.

Do not spray in a confined, non-ventilated area.

Do not treat areas such as drinking cups, mangers, or troughs where livestock feed. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.





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Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.

Co-Ral Emulsifiable Livestock Insecticide mixes readily with water to form an emulsion which is easily applied with ordinary spray equipment. One spray treatment is highly effective for control of flies, lice and ticks and provides residual control for several weeks.

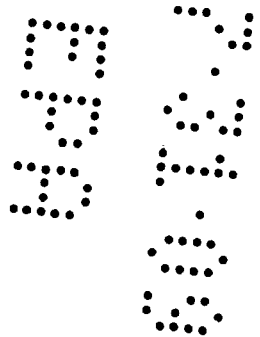
**Spray Treatment for Specified Ectoparasites:** Operate spray equipment so as to thoroughly penetrate the hair coat. Re-treatment will be necessary only when insects reappear and constitute a problem.

**Backrubber Application for Horn Flies and Face Flies:** Co-Ral Emulsifiable Livestock Insecticide has proved to be ideal for backrubber application. When properly mixed and applied, excellent control of horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. No. 2 furnace oil (fuel oil) or No. 2 diesel fuel oil is recommended for mixing with Co-Ral Emulsifiable Livestock Insecticide for use on backrubbers. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

**Entry Restriction:** Do not contact or allow others to contact treated animals until their coats are dry.

**NOTICE TO VETERINARIANS:** If the proper dosage of Co-Ral Emulsifiable Livestock Insecticide has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly probable that a host parasite reaction exists. Administer symptomatic treatment. Anti-inflammatory agents may be helpful. If necessary, relieve bloat by trocarization, as a stomach tube may traumatize a severely swollen esophagus. Do not administer atropine, as it is contraindicated in host parasite reactions. If toxicity should occur as a result of gross overdosage, atropine by injection is antidotal.

**ATTENTION  
CONTENTS MUST BE DILUTED BEFORE USE**



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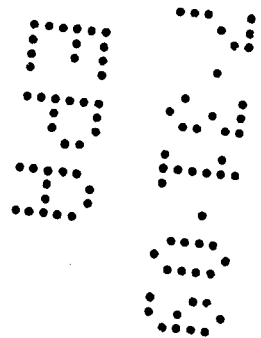
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**APPLICATION RATES**

Do not apply more than 5 ounces of Co-Ral Emulsifiable Livestock Insecticide per 4 gallons of water. For lactating dairy cattle do not apply more than 1 ¼ ounces Co-Ral Emulsifiable Livestock Insecticide per 4 gallons of water.

ANIMAL	PARASITE	Fl. oz. Co-Ral	REMARKS
Beef and Non-Lactating Dairy Cattle	Horn Flies Lice	2 ½	<b>SPRAY TREATMENTS:</b> Apply specified dosage in 4 gallons of water for a complete wetting to run-off. Repeat as necessary.
	Ticks	5	
Beef and Lactating Dairy Cattle	Horn Flies Face Flies	9 ¾	<b>CATTLE BACKRUBBERS:</b> Mix specified dosage in 1 gallon of No. 2 fuel oil or No. 2 diesel fuel. Saturate the fiber portion of the backrubber with this mixture. Place the backrubber where animals congregate or travel regularly. For dairy cattle suspend at a height that will prevent straddling. Resaturate backrubber as needed. <b>Note:</b> For most effective face fly control the rubber should be constructed so as to permit the animal to rub its face. No interval is required between treatment and slaughter or use of milk.
	Lice	1 ¼	<b>SPRAY TREATMENT(S):</b> Apply specified dosage in 4 gallons of water for a complete wetting to run-off. Repeat as necessary.

(Continued)



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ANIMAL	PARASITE	Fl. oz. Co-Ral	REMARKS
Horses  (Not intended for slaughter)	Horn Flies Lice	2 ½	<b>SPRAY TREATMENT(S):</b> Apply specified dosage in 4 gallons of water for complete wetting. Treat thoroughly all wounds and injuries. Repeat as necessary.
	Ticks	5	
Swine	Lice	2 ½	<b>SPRAY TREATMENT(S):</b> Apply specified dosage in 4 gallons of water for a complete wetting to run-off. Repeat as necessary.

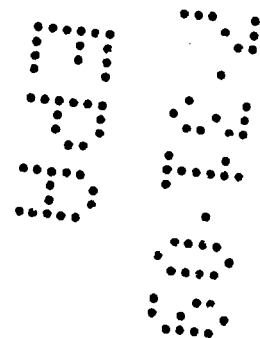
### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Do not allow to freeze. Keep from extreme heat.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Offer for reconditioning, if appropriate. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities.



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**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.

**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.

Co-Ral is a Reg. TM of the parent company Bayer AG, Leverkusen.

