

11556-98

09/18/2009

1/13



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 Div.  
P.O. Box 390  
Shawnee Mission, KS 66201-0390

SEP 18 2009

Subject: Label Notification(s) for Pesticide Registration Notices 2007-4, 98-10, 97-5, and 97-4

1. Updated address
2. Updated emergency telephone numbers
3. Relocation of Conditions of Sale section
4. Updated warranty statements
5. Other minor revisions

Dear Dr. Spilker:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4, 98-10, 97-5, and 97-4 dated June 30, 2009 for:

**EPA Registration 11556-98**

**Co-Ral Flowable Insecticide**

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 2007-4, 98-10, 97-5, and 97-4 and finds that the label changes requested falls within the scope of PR Notice 2007-4, 98-10, 97-5, and 97-4. 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. **Also, note that the container disposal statement must appear before the residue removal statement.**

If you have any questions, please contact me directly at 703-305-6249 or Nicole Williams of my staff at 703-308-5551.

---

Sincerely,




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

3/13

Please read instructions on reverse before completing form.

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

 United States <b>Environmental Protection Agency</b> 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 11556-98	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input type="checkbox"/> None <input checked="" type="checkbox"/> Restricted
4. Company/Product (Name) Co-Ral Flowable 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: EPA Reg. No. _____ Product Name _____	

### Section - II

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

NOTIFICATION  
 SEP 18 2009

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
 See attachment, dated 6/30/2009.  
 email: doug.spilker.b@bayer.com

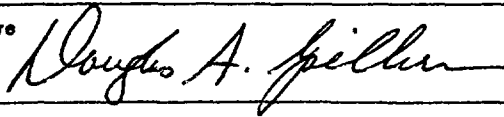
### Section - III

1. Material This Product Will Be Packaged In:			
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	2. Type of Container <input type="checkbox"/> Metal <input checked="" 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2 gallon jug	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

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
-----------------------------------	--	---

<b>Certification</b> 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  Typed Name Douglas A. Spilker, Ph.D.	3. Title Manager, EPA Regulatory Affairs 5. Date 30 June 2009

Reason to Issue: Minor Label Modifications  
[Notification]

Date: 06/29/09  
Supersedes: 01/09/01  
Page 1 of 10

4/13

**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

Use restricted to employees of the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) who are enrolled in the USDA-APHIS cholinesterase monitoring program.

**Co-Ral®**

**NOTIFICATION**

**SEP 18 2009**

**Flowable Insecticide**

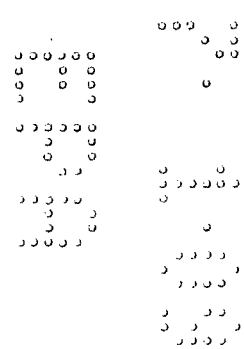
For Control of Scabies on Cattle and for Control  
of Horn Flies, Lice, Ticks and Screwworms on Beef  
and Non-Lactating Dairy Cattle and Horses

	<u>Percent by Weight</u>
Active Ingredient:	
coumaphos. ....	42%
Other Ingredients. ....	58%
TOTAL. ....	100%

Product contains 4.2 lbs of coumaphos per gallon.  
Shake Well Before Using

EPA Reg. No. 11556-98

EPA Est. No. TBD



Reason to Issue: Minor Label Modifications  
[Notification]

Date: 06/29/09  
Supersedes: 01/09/01  
Page 2 of 10

**STOP – Read Label before use.**

**KEEP OUT OF REACH OF CHILDREN**

**DANGER --  -- POISON**

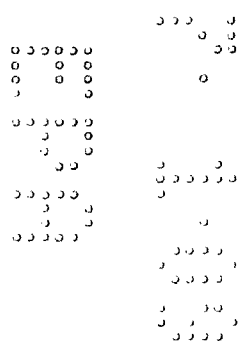
**PELIGRO**

Fatal if swallowed. Maybe fatal if inhaled. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Do not breathe spray mist.

**See Side Panel for Additional Precautionary Statements**

**NET CONTENTS: 2 GALLONS**

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



**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 poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</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>
<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.	
<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 information, call 1-800-422-9874. For customer service or to obtain product information, including MSDS, call 1-800-633-3796.	

**DANGER --  -- POISON**

**PELIGO**

**PERSONAL PROTECTIVE EQUIPMENT**

Wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter.

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

Mixers, loaders, applicators 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, 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.

Reason to Issue: Minor Label Modifications  
[Notification]

Date: 06/29/09  
Supersedes: 01/09/01  
Page 5 of 10

### ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, birds, fish and aquatic invertebrates. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

### DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

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

**CONDITIONS OF SALE:** The directions for use of this product were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions 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. 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.

Do not formulate this product into other end-use products.

**AVISO - Al Usuario:** Si usted no puede leer o entender ingles, no use este productohasta que la etiqueta le haya side 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.)

### 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 spray in 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.

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.

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

**FOR USE ON BEEF AND NON-LACTATING DAIRY CATTLE AND ON HORSES.**

Co-Ral Flowable has been especially developed to provide a highly concentrated formulation of coumaphos. The physical properties of the formulation allow for quick initial mixing and excellent suspension, as well as ease of resuspension where settling has occurred due to lack of regular use or overwintering.

As a liquid, the difficulties and inconvenience commonly associated with mixing of wettable powders are greatly reduced or eliminated. Because Co-Ral Flowable is a much more concentrated formulation of coumaphos than previously available, a smaller amount is needed to prepare any given volume of spray or dip suspension.

**DIP TREATMENT FOR ECTOPARASITES OF CATTLE LISTED BELOW:**

Charge dip vats with accurate concentration by using exact quantity of Co-Ral Flowable and volume of water specified. Mix suspension thoroughly before each use. Passage of animals through the vat does not change concentration of remaining suspension. Water lost by evaporation should be replaced. If water is added to the vat due to rainfall or replenishment, an appropriate amount of Co-Ral Flowable should also be added. Continue to use vat until accumulation of debris makes it unsuitable for further use.

NOTE. Be sure cattle have access to drinking water prior to dipping. Do not dip excessively thirsty animals.

---

---

**SPRAY TREATMENT FOR ECTOPARASITES OF CATTLE AND HORSES  
ARE LISTED BELOW:**

Co-Ral Flowable provides residual control of ectoparasites on livestock. Repeat applications will be necessary only when insects reappear and constitute a problem. Co-Ral Flowable mixes easily with water to form a suspension which is readily usable in spray equipment.

**HAZARDS TO DOMESTIC ANIMALS (CATTLE AND HORSES)**

Acute symptoms of overdosage in cattle and horses are: Frequent defecation and urination, watering of eyes and muscular twitching. Later the symptoms are: salivation, diarrhea and muscular weakness.

While no claims for control of cattle grubs are made for this product, host parasite reactions such as bloat, salivation, staggering and paralysis may sometimes occur when cattle are treated while the common cattle grub (*Hypoderma lineatum*) is in the gullet, or while the northern grub (*H. bovis*) is in the area of the spinal cord. Cattle should be treated either before or after these stages of grub development. Consult your veterinarian, extension livestock specialist or extension entomologist regarding the timing of the grub cycle for your cattle based on their origin and history.

Consult veterinarian at the first sign of adverse reaction.

**NOTE.** If it is impossible to determine the origin of the cattle, and thus the exact stage of the grubs is unknown, it is recommended that the cattle receive only a maintenance ration of low energy feed during the treatment period. This lessens the likelihood of severe bloat which may occur in cattle on full feed when the common grub is killed while in the gullet.

**NOTICE TO VETERINARIAN:** If the proper dosage of Co-Ral Flowable 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 sulfate by injection is antidotal.

**APPLICATION RATES**

Do not apply more than one (1) gallon of Co-Ral Flowable per 165 gallons of water as a dip or more than one (1) gallon of Co-Ral Flowable per 200 gallons of water as a spray.

No withdrawal interval is required between applications and use of meat as food.

PARASITE	GALLONS CO-RAL FLOWABLE	REMARKS
Scabies* ( <i>Psoroptes bovis</i> )	1	DIP TREATMENT: Mix specified amount in 165 gallons of water. Agitate dip suspension thoroughly prior to each use. Two treatments, 10 to 14 days apart, are necessary to control scabies. Do not dip more than twice per year.** Submerge each animal to assure complete coverage and thorough wetting of the skin.
Horn Flies Lice	¼  (1 quart)	SPRAY TREATMENT: Add specified amount to 200 gallons of water and mix thoroughly. Apply for complete wetting to run-off. Do not spray more than six times per year. Do not make applications less than 10 days apart.
Ticks*	½ - 1	DIP TREATMENT: Mix specified quantity of Flowable in 200 gallons of water. Agitate dip thoroughly prior to each use to assure uniform treatment. Do not dip more than twice per year.** Do not make applications less than 10 days apart.
Ticks*	½ - 1	SPRAY TREATMENT: Add specified amount of Flowable to 200 gallons of water and mix thoroughly. Apply for complete wetting to run-off. Do not spray more than six times per year. Do not make applications less than 10 days apart.
Screwworms*	1	SPRAY TREATMENT: Mix specified amount in 200 gallons of water and mix thoroughly. Apply as a high pressure spray to wet the skin, not just the hair. Do not spray more than six times per year. Do not make applications less than 10 days apart.

\* Approved as a "Permitted Pesticide" by Animal and Plant Health Inspection Service

---

(APHIS) of the U.S. Department of Agriculture for the control of Screwworms, Scabies and Ticks in Federal Eradication Programs when used according to the directions of APHIS Veterinary Service Regulations and/or Memoranda.

\*\* Animals should not be dipped more than twice per year unless additional treatments are required by APHIS Veterinary Services Regulations/Memoranda for Animals included in Federal Eradication Programs.

### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Not for storage in or around the home. Store in a cool, dry place.

**CATTLE DIP SOLUTION DISPOSAL:** The Agency requires that spent dip-vat solution be bioremediated, and recommends the bioremediation method developed by the USDA. The treated solution must be transferred to shallow, concrete-lined evaporation ponds for further degradation. The evaporation ponds must be constructed to prevent overflow or flooding during wet seasons and must be lined with reinforced concrete. Dried sludge generated in the evaporation ponds must not be applied to agricultural land and should be disposed according to solid waste disposal regulations established by your Local and/or State Environmental Control Agency. Questions concerning the disposal of spent solution should be directed to the waste representative at the nearest EPA Regional Office.

**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.

**Residue Removal:** Triple rinse as follows: Empty remaining contents into application equipment or mix tank and drain for 10 seconds after flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this process two more times.

**Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Reason to Issue: Minor Label Modifications  
[Notification]

Date: 06/29/09  
Supersedes: 01/09/01  
Page 10 of 10

13/13

---

## **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 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.