

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 23 1991

Dr. T. Bill Waggoner, PhD.  
Mobay Corporation  
Animal Health Division  
Box 390  
Shawnee Mission, KS 66201

Dear Dr. Waggoner:

Subject: Coumaphos Reregistration Standard - 2<sup>nd</sup> Round Review  
Revised Labeling and Confidential Statement of Formulas  
Co-Ral<sup>®</sup> Animal Insecticide 1% Shaker Can  
EPA Registration 11556-4  
Co-Ral<sup>®</sup> Animal Insecticide  
EPA Registration No. 11556-14  
Co-Ral<sup>®</sup> 1% Cattle Duster  
EPA Registration No. 11556-15  
Your Letter Dated September 10, 1990 and  
Your Revised Labeling Received April 4, 1991

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 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. For all above listed products, make the following revisions:

- a. Under **To Physician and Notice to Veterinarian**, add "by injection" to the phrase "atropine sulfate by injection is antidotal."
- b. Under **Storage and Disposal**, revise the **Pesticide Disposal Statement** in accordance to **ER Notice 83-3** as follows:

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

SYMBOL								
SURNAME	Waggoner							
DATE								

- 2. For EPA Reg. No. 11556-4, make the following changes:
  - a. Under the Hazards to Humans and Domestic Animals, add **"or clothing."** at the end of the sentence, **"Avoid contact with skin, eyes, or clothing."**
  - b. To the Use Restriction section, add the statement, **"Do not apply to sick, stressed, or convalescent animals."**

- 3. For EPA Reg. No. 11556-14, make the following changes:
  - a. Please note that the ingredient statement does not total to 100% but rather 100.5%.
  - b. The correct signal word for 1% dust products is **CAUTION** and not **WARNING**. Please make the correction as well as changing the precautionary statements under the Hazards to Humans and Domestic Animals section:

Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing dusts. Avoid contact with eyes, skin, and clothing.

- c. Add the following **Dust Bag Installation Instructions and Aid to Reduction of face fly populations** to the product label under the Directions for Use section as it appears on the label for Co-Ral® 1% Cattle Duster, EPA Reg. No. 11556-15.

- 4. For EPA Reg. No. 11556-15, make the following changes:
  - a. Please revise the **Hazards to Humans and Domestic Animals** section as follows:
 

Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing dusts. Avoid contact with eyes, skin, and clothing.

- b. Add as a footnote the following:
 

\* Note: 1 ox. of this material equals approximately three levels tablespoons.

- c. Add a (2) in front of the sentence beginning with **"The bags must be located..."** under the section on reducing face fly populations.

5. Submit five copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure

for a further description of final printed labeling.

6. The revised Confidential Statement of Formulas (CSFs) referred to above, submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable. A copy of each have been inserted in your file for the subject products.

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.

Sincerely yours,

George T. LaRocca  
Product Manager 13  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

Enclosure

Reason to Issue: 2nd Revision for Second Round Review/Rereg. Std.

Date: 1/16/91  
Page 1 of 4

(Front Panel)

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Co-Rale > 30

(coumaphos) > 30

ANIMAL INSECTICIDE - 24

1% BULK DUST - 24

Control of Horn Flies and Lice on Beef and Dairy Cattle, Reduction of Face Flies on Beef and Dairy Cattle, Control of Lice on Swine - 12

Use in Dust Bag, Shaker Can or Mechanical Dust Applicator - 12

Active Ingredients:

O,O-Diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate

1.0%

Inert Ingredients:

99.5%  
100.0%

EPA Est. No. 606-IL-1  
EPA Reg. No. 11556-14

KEEP OUT OF REACH OF CHILDREN - 14

Blue background

WARNING - 18

See Side Panel for Precautionary Statements and Treatments

NET WEIGHT 12.5 POUNDS

Manufactured for  
Mobay Corporation, Animal Health Division  
Box 390  
Shawnee Mission, Kansas 66201

23 '99

(Side Panel)

( Blue print on white throughout )

PRECAUTIONARY STATEMENTS/PRACTICAL TREATMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed, inhaled or absorbed through the skin. Avoid contact with skin or eyes. Avoid breathing dusts.

If swallowed - Call a physician or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Do not induce vomiting or give anything by mouth to an unconscious person.

If inhaled - Remove victim to fresh air. Apply artificial respiration if indicated. Get medical attention if victim displays signs of poisoning.

If on skin - Remove contaminated clothing and wash affected areas with soap and water.

If in eyes - Flush eyes with plenty of water. Call a physician immediately.

To Physician: Prolonged exposure will result in cholinesterase depression. Atropine sulfate is antidotal. 2-PAM is also antidotal and may be administered in conjunction with atropine.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate.

STORAGE AND DISPOSAL

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

STORAGE: Store in a cool, dry place.

Pesticide Disposal: Pesticide, spray mixture or rinse water that cannot be used according to label instructions must be disposed of according to applicable Federal, State or local procedures.

Container Disposal: Completely empty the container by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of bags in a sanitary landfill or by incineration if allowed by state and local authorities.

Reason to Issue: 2nd Revision for Second Round Review/Rereg. Std.

Date: 1/16/91 Page 3 of 4

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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.

CO-RAL 1% Bulk Dust may be used to fill cattle dust bags or it may be applied directly to cattle, swine or swine bedding by use of a shaker can or a suitable mechanical dust applicator. When used as recommended, C)-RAL 1% Dust controls horn flies and lice on beef and dairy cattle and lice on swine. CO-RAL 1% Dust will also reduce face fly populations on cattle; however, as face flies are able to travel over an area of several miles, best reduction of face fly populations is achieved when CO-RAL 1% Dust is used on an area-wide basis.

RECOMMENDED APPLICATIONS

ANIMAL	PARASITE	REMARKS
Beef and Dairy Cattle	Horn Flies Lice Face Flies	<p><u>DUST BAG:</u> Place contents of this package in any commercially available dust bag. Suspend bags in areas frequented by cattle or in gateways or lanes through which the animals pass daily for water, feed or minerals. Bags may also be suspended in loafing sheds or in front of protected and mineral feeders. For lactating dairy cows bags may be suspended in the exit through which cows <u>leave</u> the milking barn. In all cases the bags should be adjusted so that the bottom of the bag will hang four to six inches below the topline of the cattle. For reduction of face flies the bags must be located so the animals will be forced to use them daily and hung at a height to insure that the faces of the cattle will be dusted. <i>Manage the dispenser by so as not to apply more than 1 oz dust per animal per day</i></p> <p><u>DIRECT APPLICATION:</u> CO-RAL 1% Dust may be applied by use of a shaker can or by using a suitable mechanical duster applicat. Animals should be thoroughly dusted using not more than 2 oz.* (6 level tablespoonfuls) of dust per animal per treatment. Repeat as necessary; <i>but more often than once every 14 days</i></p>
	Horn Flies Lice	

BEST AVAILABLE COPY

(Back Panel)

Swine

Lice

DIRECT APPLICATION: Apply not more than 1 oz. \*(3 level tablespoonfuls) per head as a uniform coat to the head, shoulders and back by use of a shaker can or suitable mechanical dust applicator. Repeat as necessary but not more often than once every ten days.

BEDDING TREATMENT: Apply 2 oz. \*(6 level tablespoonfuls) uniformly over 30 square feet of fresh, dry bedding by use of a shaker can or a suitable mechanical dust applicator. Repeat as necessary but not more often than once every ten days.

DIRECT APPLICATION AND BEDDING TREATMENT: In severe infestations both individual animals and the bedding may be treated as directed above.

No interval is required between treatment and slaughter or between treatment and use of milk as feed.

\*Note: 1 oz. of this material equals approximately three level tablespoonfuls.

USE RESTRICTIONS

For external insecticidal use only on above-specified animals. Do not contaminate feed, troughs, water or water utensils. Provide thorough ventilation while dusting. Do not apply to sick, stressed or convalescent animals.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Mobay Corporation, Animal Health Division, warrants that this material conforms to the chemical description on the label. MOBAY CORPORATION, ANIMAL HEALTH DIVISION, MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY; and no agent of Mobay Corporation, Animal Health Division, 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.

CO-RAL® is a Reg. TM of the parent company of Farbenfabriken Bayer GmbH.