

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Confidential
9/23/91

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 - 2nd Round Review
Revised Labeling and Confidential Statement of Formulas
Co-Ral[®] Emulsifiable Livestock Insecticide
EPA Registration No. 11556-23 ✓
Co-Ral[®] Cattle Insecticide Pour On
EPA Registration No. 11556-25
Co-Ral[®] K·R·S· with Co-Ral[®] Spray Foam Insecticide
EPA Registration No. 11556-40
Your Letter Dated September 10, 1990 and
Your Revised Labels 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 label revisions:

a. Under the "To Physician", revise the statement to read: "Atropine sulfate by injection is antidotal."

3. For EPA Reg. No 11556-23, make the following changes:

a. Add a footnote in the ingredient statement indicating: *Contains aromatic petroleum distillates."

b. The complete Statement of Practical Treatment must appear on the front panel of the label for all pesticides that fall into Toxicity Category I on the basis of ~~concentration~~ concentration and dermal toxicity.

SYMBOL							
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c. Add the following sentence under **Use Restrictions**:

For external insecticidal use only on above-specified animals.

4. For EPA Reg. No. 11556-25, make the following changes:

a. Under the Statement of Practical Treatment, add the sentence, **"If possible, vomiting should be induced under medical supervision."**, before the "Drink one or two glasses of water...".

b. Add the following sentence under **Use Restrictions**:

For external insecticidal use only on above-specified animals.

5. For EPA Reg. No. 11556-40, make the following changes:

a. Delete the statement, **"This product contains the toxic inert ingredient, methylene chloride."**, from the ingredient statement since this inert is no longer a part of the formulation.

b. Change 130°C to 130°F under the Storage and Disposal Statement.

c. Also under Storage and Disposal, add the statement, **"Do not contaminate water, food or feed by storage and disposal."**

d. Add the following statement under **Use Restrictions**:

Do not apply to sick, stress or convalescent livestock or to animals less than 3 months of age.

6. 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.

7. 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.

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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

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RESTRICTED USE CLASSIFICATION - 18
Due to Acute Oral Hazards

For retail sale to and use only by Certified Applicators or persons under the direct supervision and only for those uses covered by the Certified Applicators Certification - 12

Co-Rate > 30

(coumaphos)

EMULSIFIABLE LIVESTOCK INSECTICIDE - 24

For Control of Grubs, Horn Flies, Face Flies, Lice and Ticks - 24

Active Ingredients:

O,O-Diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate 11.6%

Inert Ingredients:

88.4%
100.0%

This product contains 1.0 lb. O,O-Diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate per gallon.

(White on blue background)

KEEP OUT OF REACH OF CHILDREN - 14

DANGER --(skull & crossbones)-- POISON - 18 (Red)

STATEMENT OF PRACTICAL TREATMENT - 12

If swallowed:

Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

To Physician:

Administer atropine sulfate in therapeutic doses. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS/PRACTICAL TREATMENTS

NET CONTENTS 1 GALLON

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PRECAUTIONARY STATEMENTS/PRACTICAL TREATMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER --(skull & crossbones)-- POISON

Fatal if swallowed. May be fatal if inhaled. Do not breathe vapors or spray mist. Avoid contact with skin, clothing or eyes. Wash thoroughly with soap and warm water after handling. Wash contaminated clothing with soap and hot water before use.

If swallowed - Call a physician or Poison Control Center immediately. If possible, vomiting should be induced under medical supervision. Drink one or two glasses of water and induce vomiting by touching the back of throat with finger. 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: Administer atropine sulfate in therapeutic doses. Repeat as necessary to the point of tolerance. 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: 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: When the entire contents of the bag have been dispensed, dispose of bags in a sanitary landfill or by incineration, if allowed by state and local authorities.

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PROTECTIVE CLOTHING STATEMENT

USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE; long-sleeved shirt and long-legged pants; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots). In addition, mixers/loaders and dip tank workers must wear a chemical resistant apron and face shield or goggles and a NIOSH/MSHA approved respiratory protection device.

TIMING OF APPLICATIONS FOR CATTLE GRUB CONTROL:

Proper timing of treatment is important. For most effective results cattle should be treated as soon as possible after heelfly activity ceases. 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 treatment.

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.

For the most effective reduction of carcass damage and trim loss in cattle to be slaughtered, treatment should be applied at least six weeks before the expected appearance of grubs in the back.

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 is antidotal.

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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 Emulsifiable Livestock Insecticide mixes easily 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, Except Cattle Grubs: 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.

Spray Treatment for Cattle Grub Control: Spray treatment should be applied in such manner that the skin, not just the hair, becomes thoroughly wet. Spray pressures of 250 to 350 pounds per square inch are recommended. Operate box-type spray chutes at maximum pressure for thorough overall wetting and penetration. (See side panel for information on timing of grub treatment).

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RECOMMENDED APPLICATIONS

DO NOT APPLY MORE THAN 12 QUARTS OF CO-RAL EMULSIFIABLE LIVESTOCK INSECTICIDE PER 100 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART CO-RAL EMULSIFIABLE LIVESTOCK INSECTICIDE PER 100 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS CO-RAL	REMARKS
	Horn Flies Lice	2	SPRAY TREATMENTS: Apply specified dosage in 100 gallons of water for a complete wetting to run-off. Repeat as necessary.
	Ticks	4	
Beef and Non- Lactating Dairy Cattle	Screwworms	8	SPRAY TREATMENT(S): Apply specified dosage in 100 gallons of water as high pressure spray so as to wet the skin, not just the hair, of the animal. Repeat as necessary but not more often than every 14 days.
	Grubs	12	SPRAY TREATMENT: Apply specified dosage in 100 gallons of water as a high pressure spray so as to wet the skin, not just the hair, of the animal. See Directions for Use for proper timing of applications. Repeat as necessary but not more often than every 14 days.
Beef and Lactating Dairy Cattle	Horn Flies Face Flies	4	CATTLE BACKRUBBERS: Mix specified dosage in 13 gallons of No. 2 furnace 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. NOTE: 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.

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ANIMAL	PARASITE	QUARTS CO-RAL	REMARKS
Lactating Dairy Cattle (cont'd)	Lice	1	SPRAY TREATMENT(S): Apply specified dosage in 100 gallons of water for a complete wetting to run-off. Repeat as necessary. No interval is required between treatment and slaughter or use of milk.
Horses	Horn Flies Lice	2	SPRAY TREATMENT(S): Apply specified dosage in 100 gallons of water for complete wetting. Treat thoroughly all wounds and injuries. Repeat as necessary.
(Not intended for slaughter)	Ticks	4	
	Screwworms	8	
Swine	Lice	2	SPRAY TREATMENTS(S): Apply specified dosage in 100 gallons of water for a complete wetting to run-off. Repeat as necessary.

USE RESTRICTIONS

Do not apply as a spray at rates above 1 quart of CO-RAL Emulsifiable Livestock Insecticide per 100 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 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.

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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.

EPA Est. No. 11556-KS-1
EPA Reg. No. 11556-23

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