

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 30 1991

655-394118
19

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

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Dear Dr. Waggoner:

Subject: Coumaphos Reregistration Standard - 2nd Round Review
Revised Labeling and Confidential Statement of Formula
Co-Ral® (Coumaphos) Animal Insecticide
EPA Registration 11556-21
Your Letters Dated September 10, 1990 and March 26, 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. Make the labeling changes listed below before you release the product for shipment:

- a. Under To Physician and Notice to Veterinarian, add "by injection" to the phrase "atropine sulfate by injection is antidotal.
- b. Either explain or delete the word guarantee on the front panel.
- c. Revise the Container Disposal statement as follows:

Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

CONCURRENCES

SYMBOL	SURNAME	DATE					
	GA	10/27/91					

d. Delete the proposed dip vat solution disposal statement. As indicated in the August 12, 1991 letter to you from Allan S. Abramson, Acting Director, SRRD, a final proposed dip vat statement should be submitted after all environmental safety data is submitted.

3. 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.

4. The revised Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A copy has been inserted in your file for the subject product.

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 8

(Black on white background)

(Front Panel)

Co-Rate > 30

(coumaphos)

ANIMAL INSECTICIDE - 24

25% WETTABLE POWDER - 24

For Control of Specified Animal Parasites - 12

Guarantee

Active Ingredients:

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

25.0%

Related Organic Phosphates

1.3%

Inert Ingredients:

73.7%
100.0%

EPA Est. No. 10543-MO-1

EPA Reg. No. 11556-21

KEEP OUT OF REACH OF CHILDREN - 14

WARNING - 18

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See Side Panel for Precautionary Statements and Treatments - 8

Not for Manufacturing Use

NO COMMENTS with COMMENTS in EPA Letter Dated:

NET WEIGHT 4 POUNDS (48 Pounds)

OCT 30 1991 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide...

11536-21

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

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(Side Panel)

PRECAUTIONARY STATEMENTS/PRACTICAL TREATMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Do not breathe dust or spray mist. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing.

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 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.



(Side Panel)

Cattle Dip Vat Solution Disposal: Contact your Local and/or State Environmental Control Agency for specific recommendations for the geographical area where the dip vat is located. Used dip vat solutions should be transferred to lined, shallow evaporation ponds. Ponds should be constructed to prevent overflow or flooding during wet seasons and should be lined with compacted clay, reinforced concrete or flexible membrane liner. Contact your local/state authorities or the waste representative at the nearest EPA Regional Office for specifications of pond construction and lining materials. When evaporation of water has occurred, dried sludge should be removed from ponds, disposed of on land and plowed under to encourage degradation by soil microorganisms. Do not apply dried sludge to land used for raising crops for human consumption.

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.

USE RESTRICTIONS

- Do not apply as a spray to lactating dairy cattle at rates above 1 lb. of CO-RAL 25% Wettable Powder per 100 gallons of water.
- Do not treat sheep or goats within 3 days of slaughtering.
- Do not treat lactating dairy goats.
- Do not treat non-lactating dairy cattle at rates above 1 lb. of CO-RAL 25% Wettable Powder per 100 gallons of water within 14 days of freshening. If freshening should occur within 14 days after treatment at higher rates, do not use milk as human food for the balance of the 14-day interval.
- Do not treat non-lactating dairy goats within 14 days of freshening. If freshening should occur within 14 days of treatment, do not use milk as human food for the balance of the 14-day interval.
- Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old except in Federal or State eradication programs (Screwworms, Scabies, Cattle Fever Ticks) where immediate treatment of all animals in an infested herd is mandatory.
- Do not dip animals when they are over-heated.
- Do not spray in a confined, non-ventilated area.
- Do not apply in conjunction with oral drenches or other internal medications such as phenothiazine.
- 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, pesticides or chemicals. Atropine is antidotal. Consult veterinarian at first sign of adverse reaction.

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(Back Panel)

DIRECTIONS FOR USE

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

CO-RAL 25% Wettable Powder mixes easily with water to form a suspension which is readily usable in spray equipment. Maintain an adequate agitation in spray tank to insure uniform suspension during use.

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.

SPRAY TREATMENT FOR CATTLE GRUB CONTROL:

Spray treatment(s) should be applied in such a 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.

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

Date: 1/16/91
Page 5 of 8

(Back Panel)

SPRAY TREATMENT FOR ECTOPARASITES LISTED BELOW EXCEPT CATTLE GRUBS:

CO-RAL provides residual control of ectoparasites on livestock. Repeat applications will be necessary only when insects reappear and constitute a problem.

DIP TREATMENT FOR GRUBS, SCABIES, LICE, HORN FLIES, TICKS, KEDS AND FLEECEWORMS:

Charge dip vats with accurate concentration by using exact quantity of CO-RAL and volume of water specified. Mix suspension thoroughly before each use. Passage of animals through the vat does not change strength of remaining suspension. Merely replace evaporation with water or add appropriate amount of CO-RAL for rainfall or added water. Continue to use vat until accumulation of debris makes it unsuitable for further use. NOTE. Be sure free access to drinking water is available to animals prior to dipping. Do not dip excessively thirsty animals.

RECOMMENDED APPLICATIONS

Do not apply more than 16 pounds of CO-RAL 25% Wettable Powder per 100 gallons of water as a spray or more than 10 pounds of CO-RAL 25% Wettable Powder per 100 gallons of water as a dip. Do not apply more than 1 pound CO-RAL 25% Wettable Powder per 100 gallons of water as a spray to lactating dairy cattle.

ANIMAL	PARASITE	POUNDS CO-RAL 25%	REMARKS
	Grubs	12 to 16	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. Use the higher recommended rate in northern areas or for late fall applications when long hair coats make thorough wetting of the skin difficult. See Directions for Use for proper timing of application. Repeat as necessary but not more often than every 14 days.
Beef and	Screwworms*	8	SPRAY TREATMENT(S): 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. Repeat as necessary but not more often than every 14 days.

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

Date: 1/16/91 Page 6 of 8

(Back Panel)

ANIMAL	PARASITE	POUNDS CO-RAL 25%	REMARKS
	Grubs	8	DIP TREATMENT: Mix specified dosage per 100 gallons of water. Agitate dip suspension thoroughly prior to each use to assure uniform treatment. See Directions for Use for proper timing of application. Dip animals as needed but not more often than every 10 days.
Non-Lactating Dairy	Scabies* (Psoroptes bovis)	10	DIP TREATMENTS: Mix specified dosage per 100 gallons of water. Agitate dip suspension thoroughly prior to each use. Two treatments, 10 to 14 days apart, are necessary to control scabies. Submerge each animal to assure complete coverage and thorough wetting of the skin. Dip animals as needed but not more often than every 10 days.
	Horn Flies Lice	2	SPRAY OR DIP TREATMENT: Apply specified dosage in 100 gallons of water for complete wetting to run-off. Agitate dip suspension thoroughly prior to each use to assure uniform treatment. Repeat as necessary.
	Ticks	4	
	Ticks	4 to 8	DIP TREATMENT: Mix specified dosage in 100 gallons of water. Agitate dip suspension thoroughly prior to each use to assure uniform treatment. Dip animals as needed but not more often than every 10 days.
Beef and Lactating Dairy Cattle	Lice	1	SPRAY TREATMENT: Apply specified dosage in 100 gallons of water for a complete wetting to run-off. Repeat as necessary.

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(Back Panel)

ANIMAL	PARASITE	POUNDS CO-RAL 25Z	REMARKS
Sheep	Horn Flies Lice	2	<p>SPRAY OR DIP TREATMENT: Apply specified dosage in 100 gallons of water for complete wetting. Treat thoroughly all wounds and injuries. Repeat as necessary but not more often than every 14 days for spray treatments and every 10 days for dip treatments. Do not treat animals within 3 days of slaughter.</p>
	Fleeceworms		
	Keds Ticks	4	
	Screwworms*	8	

ANIMAL	PARASITE	POUNDS CO-RAL 25Z	REMARKS
Sheep (cont'd)	Scabies* (Psoroptes bovis)	8	<p>DIP TREATMENT: Mix specified dosage in 100 gallons of water. Agitate dip suspension thoroughly prior to each use. Two treatments, 10 to 14 days apart, are necessary to control scabies. Submerge each animal to assure complete coverage and thorough wetting of the skin. Do not treat more often than every 10 days and not within 3 days of slaughter.</p>
Goats	Horn Flies Lice	2	<p>SPRAY OR DIP TREATMENT: Apply specified dosage in 100 gallons of water for a complete wetting. Treat thoroughly all wounds and injuries. Repeat as necessary for spray treatments but not more often than every 14 days. Repeat as necessary for dip treatments but not more often than every 10 days. Do not treat animals within 3 days of slaughter.</p>
	Fleeceworms		
	Keds Ticks	4	
	Screwworms*	8	

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(Back Panel)

ANIMAL	PARASITE	POUNDS CO-RAL 25Z	REMARKS
Horses Swine	Horn Flies	2	SPRAY TREATMENT: Apply specified dosage in 100 gallons of water for complete wetting to run-off. Thoroughly treat all wounds and injuries. Repeat as necessary but not more often than every 14 days.
	Lice		
	Ticks	4	
	Screwworms*	8	

* 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 Program when used according to the directions of APHIS Veterinary Service Regulations and/or Memoranda.

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

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.

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