

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 30 1991

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

**BEST AVAILABLE COPY**

Dear Dr. Waggoner:

Subject: Coumaphos Reregistration Standard - 2<sup>nd</sup> Round Review  
Revised Labeling and Confidential Statement of Formula  
Co-RalU (Coumaphos) Flowable Insecticide  
EPA Registration 11556-98  
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. The Statement of Practical Treatment must appear in full format on the front panel for product which have a Toxicity Category I.
- c. 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

SYMBOL							
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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

(Black on white background)

(Front Panel)

RESTRICTED USE CLASSIFICATION -18  
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 -12

...COPY...  
with COMMENTS  
in EPA Letter Dated:

OCT 30 1991

Co-Rale

(coumaphos)

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide

FLOWABLE INSECTICIDE

11556-98 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 -14

Active Ingredients:

O,O-Diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate 42.0%

Inert Ingredients:

58.0%  
100.0%

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

EPA Reg. No. 11556-98

EPA Est. No. 3125-MO-1

(White on blue background)

KEEP OUT OF REACH OF CHILDREN -14

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

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. -8

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS/PRACTICAL TREATMENTS

NET CONTENTS 2 GALLONS

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background)

(Side Panel)

PRECAUTIONARY STATEMENTS/PRACTICAL TREATMENT  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER --(skull & crossbones)-- POISON

Fatal if swallowed or absorbed through the skin. Do not breathe spray mist. Do not get in eyes, on skin or on clothing. 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.

Keep out of reach of children.

This material contains a cholinesterase inhibitor. If poisoning should occur, obtain prompt medical aid.

HAZARDS TO DOMESTIC ANIMALS (CATTLE AND HORSES)

Acute symptoms of over dosage 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.

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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 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.

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. Not for storage in or around the home.

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: Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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.

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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.

#### DIRECTIONS FOR USE

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

AVISO - Al Usuario: Si usted no puede leer o entender ingles, no use este producto hasta que la etiqueta le haya sido 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.)

IMPORTANT: Read this entire label including the Limited Warranty and Limitation of Damages provision, before using.

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.

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SPRAY TREATMENT FOR ECTOPARASITES OF CATTLE AND HORSES 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.

RECOMMENDED APPLICATIONS

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 application and use of meat as food.

PARASITE	GALLONS CO-RAL FLOWABLE	REMARKS
Scabies* (Psoroptes bovis)	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. Submerge each animal to assure complete coverage and thorough wetting of the skin. Repeat as necessary but not more often than every 10 days.
Horn Flies	$\frac{1}{4}$ (1 quart)	DIP TREATMENT: Add specified quantity of Flowable to 200 gallons of water. Agitate dip suspension thoroughly prior to each use to assure uniform treatment. Repeat as necessary but not more often than every 10 days.
Lice	$\frac{1}{4}$ (1 quart)	SPRAY TREATMENT: Add specified amount to 200 gallons of water and mix thoroughly. Apply for complete wetting to run-off. Repeat as necessary.

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PARASITE	GALLONS CO-RAL FLOWABLE	REMARKS
Ticks*	1/2 - 1	DIP TREATMENT: Mix specified quantity of Flowable in 200 gallons of water. Agitate dip thoroughly prior to each use to assure uniform treatment. Repeat as necessary but not more often than every 10 days.
Ticks*	1/2 - 1	SPRAY TREATMENT: Add specified amount of Flowable to 200 gallons of water and mix thoroughly. Apply for complete wetting to run-off. Repeat as necessary but not more often than every 14 days.
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, of the animal. Repeat as necessary but not more often than every 14 days.

\* 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.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

We warrant that at the time of manufacture of this product was true to label and reasonably fit for the purposes described in its labeling. However, there are numerous factors beyond our control, e.g. storage, diagnosis, dosage, differences among individual animals, etc. which make it impossible to eliminate all risks associated with the use of this product, even if the directions are followed.

This statement is made in lieu of any other warranty, either express or implied, including any warranty of merchantability or fitness, and no representative or agent of this company is authorized to vary the terms of this warranty or the contents of the labeling of this product except by printed notice from the company's Shawnee, Kansas head office. In the event of damages arising from our breach of this warranty, damages shall be limited to direct damages, and shall not include consequential commercial damages such as loss of profit or values, etc.

Co-Ral® is a Reg. TM of the Parent Company of Farbenfabriken Bayer, GmbH, Leverkusen.

