PM 13 11556-25

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

23100

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

Dear Dr. Waggoner:

Coumaphos Reregistration Standard - 2nd Round Review Subject: 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 V

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)(T)(A), is acceptable provided that you:

- Submit/cite all data required 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 reregisteation of your product under FIFRA section 4.
- For <u>all</u> above listed products make the following label 2. revisions:
 - Under the "To Physician", revise the statement to a. "Atropine sulfate by injection antidotal."
 - 3. For EPA Reg. No 11556-23, make the following changes:
 - Add a footnote in the ingredient statement a. 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 oragecutatusation and dermal toxicity.											
SYMBOL)		ne	asis of C								
SURNAME)	16.0	************		1	*****						
DATE											
OFFICIAL SUE CORY											

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

 For external insecticidal use only on abovespecified animals.
- 4. For EPA Req. 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 abovespecified 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.
 - 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.

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: 1/17/91

Page 1 of 5

(Front Panel)

(Blue on white background except where indicated)

Co-Rals > 30

(coumaphos)

CATTLE INSECTICIDE

-14

POUR ON

For Control of Cattle Grubs

(Red print) - 12

Active Ingredients:

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

4.0%

Inert Ingredients:

96.0% 100.0%

This product contains 0.4 lbs. 0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1benzopyran-7-yl) phosphorothioate

EP. Est. No. 10543-MO-1 EPA Reg. No. 11556-25

KEEP OUT OF REACH OF CHILDREN -/ 0

- (Red print)

See Side Panel for Precautionary Statements and Treatments

NET CONTENTS 1 GALLON

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

OCT 2 3 1991

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

Date: 1/17/91 Page 2 of 5

(Side Panel)

PRECAUTIONARY STATEMENTS/PRACTICAL TREATMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS

(Red print)

WARNING

May be fatal if swallowed or inhaled. Do not breathe vapors or spray mist.

Avoid contact with skin, clothing or eyes. Causes moderate eye irritation.

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 artifical 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 cholinsterase depression. Atropine sulfate is antidotal. 2-PAM is also antidotal and may be administered in conjunction with atropine.

ENVIRONMENTAL HAZARDS

(Red print)

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

STORAGE AND DISPOSAL

(Red print)

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 disposed, 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: 1/17/91 Page 3 of 5

(Back Panel)

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 inconsistant with its labeling.

CO-RAL Pour-On Cattle Insecticide is a ready-to-use preparation that requires no further dilution. A single application placed on the backline of an animal gives highly effective control of cattle grubs. A reduction of lice may also be obtained. If reinfestation of lice occurs, use CO-RAL 25% Wettable Powder Animal Insecticide in accordance with label directions.

'MOUNT TO USE:

Apply CO-RAL Pour-On solution at a rate of $\frac{1}{2}$ fluid ounce per 100 pounds of body weight. Measure the correct amount to use in relation to the animal's weight.

THIS CONTAINER WILL TREAT:

Weight of Animal (lbs.)	200	300	400	500	600	700	800	900	1000
Number of Animals	128	85	64	51	42	36	32	28	25

HOW TO APPLY:

Pour the correct amount of solution uniformly along the animal's back. The CO-RAL solution may be dipped from any clean bucket or pail.

NOTE. If used at time of branding, this product can be ignited by a hat branding iron.

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

Date: 1/17/91 Page 4 of 5

(Back Panel)

WHEN TO APPLY FOR 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 Pour On has been applied and adverse reactions, such as bloat, excessive salivation and posterior paralysis occur, it is highly robable 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.

USE RESTRICTIONS

Do not treat lactating dairy animals, animals less than 3 months old, sick, convalescent or stressed livestock.

Do not treat non-lactating dairy animals within 14 days of freshening. If freshening should occur within 14 days after treatment, do not use milk for the balance of 14 day interval.

Do not treat animals for 10 days before or after shipping or weaning or after exposure to contagious or infectious diseases.

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.

Animals may be treated as needed but not more often than every 14 days.

Reason to Issue: 2nd Revision for Second

Round Review/Rereg. Std.

Date: 1/17/91 Page 5 of 5

(Back Panel)

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.