

PM 03

11556-21

10/29/97

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~~6557-532-138~~
17/102

Mr. F. Terry McNamara
Bayer Corporation
P.O. Box 390
Shawnee Mission, KS 66201-0390

OCT 29 1997

Dear Mr. McNamara:

Subject: Amendment- label changes
Co- Ral Animal Insecticide Wettable Powder
EPA Registration Number 11556-21
Your submission dated October 3, 1997

This amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable, provided that you:

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. The protective clothing statements must specify chemical resistant footwear.

3. Submit two (2) 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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 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,

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

Enclosure

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Co-Ral®

(coumaphos)

ANIMAL INSECTICIDE

25% WETTABLE POWDER

For Control of Specified Animal Parasites

Active Ingredients:

0,0-Diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate	25.0%
Related Organophosphates	1.3%

Inert Ingredients:	<u>73.7%</u>
	100.0%

EPA Est. No. 10543-MO-1
EPA Reg. No. 11556-21

KEEP OUT OF REACH OF CHILDREN

WARNING

See Side Panel for Statements of Practical Treatment and Other Precautionary Statements

Not for Manufacturing Use

NET WEIGHT 4 POUNDS
(48 Pounds)

Manufactured for
Bayer Corporation
Agriculture Division
Animal Health
Shawnee Mission, KS 66201 U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated

OCT 29 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 11556-21

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PRECAUTIONARY STATEMENTS
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.

STATEMENTS OF PRACTICAL TREATMENT

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 by injection 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. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate.

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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: 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.

CATTLE DIP SOLUTION DISPOSAL: Contact your Local and/or State Environmental Control Agency for specific recommendations or details for the geographical area where the dip vat is located. The Agency recommends that spent dip-vat solution be bioremediated in accordance with a method developed by USDA. The treated solution can then be transferred to lined, shallow evaporation ponds or incorporated into the soil to encourage further degradation. If an evaporation pond is used it should be constructed to prevent overflow or flooding during wet seasons and should be lined with the compacted clay, reinforced concrete or flexible membrane liner. Questions concerning the disposal of the spent solution should be directed to the waste representative at the nearest EPA Regional Office. Details are available concerning the bioremediation procedure and ultimate disposition of the remediated solution. Do not apply dried sludge or the bioremediated/treated solution to land used for raising crops for human consumption.

PROTECTIVE CLOTHING STATEMENT

Applicators and handlers exposed to the concentrate or participating in dip vat operations must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, chemical resistant footwear plus socks, chemical resistant apron, face shield or goggles. All other handlers must wear long sleeve shirt, long pants, chemical-resistant gloves such as barrier laminate or butyl rubber \geq 14 mils, chemical resistant footwear plus socks.

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Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Follow manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

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 this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

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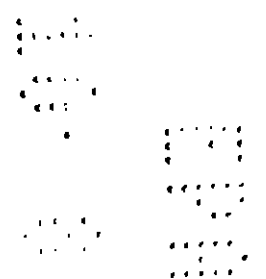
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Co-Ral is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase inhibiting drugs or pesticides. Atropine sulfate by injection is antidotal. Consult veterinarian at first sign of adverse reaction.

Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.



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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 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.

Entry Restriction: Do not contact treated animals until their coats are dry.

TIME 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 heel fly 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 Emuslifiable 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 sulfate by injection is antidotal.

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SPRAY TREATMENT FOR ECTOPARASITES LISTED BELOW

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 8 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
Beef and Non-Lactating Dairy Cattle	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 once per year.

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ANIMAL	PARASITE	POUNDS CO-RAL 25%	REMARKS
Beef and Non-Lactating Dairy Cattle	Scabies* (<i>Psoroptes bovis</i>)	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. Do not dip more than twice per year.** Submerge each animal to assure complete coverage and thorough wetting of the skin.
	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. Do not spray more than six times or dip more than twice per year.** Do not make applications less than 10 days apart.
	Ticks	4	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. Do not spray more than six times or dip more than twice per year.** Do not make applications less than 10 days apart.
	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. Do not dip more than twice per year.** Do not make applications less than 10 days apart.

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ANIMAL	PARASITE	POUNDS CO-RAL 25%	REMARKS
Beef and Lactating Dairy Cattle	Lice	1	SPRAY TREATMENT: Apply specified dosage in 100 gallons of water for a complete wetting to run-off. Do not spray more than six times per year. Do not make applications less than 10 days apart.
Sheep	Horn Flies Lice	2	SPRAY OR DIP TREATMENT: Apply specified dosage in 100 gallons of water for complete wetting. Treat thoroughly all wounds and injuries. Do not spray more than six times or dip more than twice per year.** Do not make applications less than 10 days apart. Do not treat animals within 3 days of slaughter.
	Fleeceworms Keds Ticks	4	
Goats	Horn Flies Lice	2	SPRAY OR DIP TREATMENT: Apply specified dosage in 100 gallons of water for a complete wetting. Treat thoroughly all wounds and injuries. Do not spray more than six times or dip more than twice per year.** Do not make applications less than 10 days apart. Do not treat animals within 3 days of slaughter.
	Fleeceworms Keds Ticks	4	

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ANIMAL	PARASITE	POUNDS CO-RAL 25%	REMARKS
Horses Swine	Horn Flies Lice	2	SPRAY TREATMENT: Apply specified dosage in 100 gallons of water for complete wetting to run-off. Thoroughly treat all wounds and injuries. Do not spray more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	

* 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 Memorandum.

** Animals should not be dipped more than twice per year unless additional treatments are required by APHIS Veterinary Services Regulations/Memoranda for Animals included in Federal Eradication Programs.

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

Premise Precautions: Do not spray in a confined, non-ventilated area. Do not treat areas such as feed bunks, mangers, or troughs where livestock feed or drink. Do not contaminate water, food, feedstuffs, food or feed handling equipment or milk or meat handling equipment.

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LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer Corporation, Agriculture Division warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer Corporation 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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