



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 17, 2017

Mr. J. Todd Frank
Regulatory Affairs Consultant
Animal Health Division
Bayer HealthCare LLC
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Label Amendment – Removing Diesel Fuel and Furnace Oil References
Product Name: Co-Ral Fly and Tick Spray
EPA Registration Number: 11556-115
Application Date: December 21, 2016
Resubmission Date: March 7, 2017
Decision Number: 524874

Dear Mr. Frank:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

SEE NEXT PAGE

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Rebecca Whalen by phone at (703) 347-8228, or via email at whalen.rebecca@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Walsh", written in a cursive style.

Michael Walsh
Product Manager 11
Invertebrate & Vertebrate Branch 2
Registration Division
Office of Pesticide Programs

Attachment

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Co-Ral®

Fly and Tick Spray

For Control of Horn Flies, Face Flies, Lice and Ticks

	<u>Percent by Weight</u>
ACTIVE INGREDIENT:	
Coumaphos.	6.15%
OTHER INGREDIENTS*:	93.85%
.	
Total	<u>100.0%</u>

*Contains aromatic petroleum distillates.

This product contains 0.25 lb coumaphos per half gallon.

EPA Reg No. 11556-115

EPA Est. No. TBD

**KEEP OUT OF REACH OF CHILDREN
WARNING**

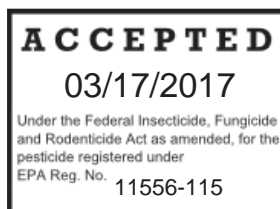
**See Back and Side Panels for First Aid
and Other Precautionary Statements**

NET CONTENTS: 0.50 gallon (1.892 L)

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 U.S.A.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

WARNING. May be fatal if swallowed. Harmful if absorbed through skin or inhaled.
Causes moderate eye irritation. Avoid contact with eyes, skin or clothing.



FIRST AID	
Contains an organophosphate that inhibits cholinesterase.	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give <u>any</u> liquid to the person. • Do not give anything by mouth to an unconscious person.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Note To Physician: Atropine sulfate by injection is antidotal. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered in conjunction with atropine. Contains petroleum distillate - vomiting may cause aspiration pneumonia.	
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment call 1-800-422-9874.	

WARNING

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders, applicators, handlers, and all others exposed to this product (such as during a spill or equipment breakdown) must wear:

- Long-sleeve shirt and long pants
- Chemical resistant gloves made of barrier laminate or Viton \geq 14 mils

- Chemical-resistant footwear plus socks
- Chemical-resistant apron
- Face shield or goggles.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

User Safety Recommendations

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 PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, 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.

DIRECTIONS FOR USE

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

Read entire label and Conditions of Sale before using this product.

APPLICATION RESTRICTIONS

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 by injection is antidotal. Consult veterinarian at the first sign of adverse reaction.

For external insecticidal use only on specified animals.

Do not apply as a spray at rates above 1 quart of Co-Ral Fly and Tick Spray per 50 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 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.

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 ½ maximum label rate, etc.

Co-Ral Fly and Tick Spray 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.

Spray Treatment for Specified Ectoparasites: 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 Fly and Tick Spray is ideal for backrubber application. When properly mixed and applied, effective control of

horn flies and face flies will be achieved. Best control is obtained when backrubbers are strategically located and properly treated. Mix with any backrubber oil approved for use on livestock. Do not mix with home furnace oil (fuel oil) or diesel fuel. Use of other oils may result in sludge formation that will prevent proper distribution in the reservoir-type backrubber.

Entry Restriction: Do not contact or allow others to contact treated animals until their coats are dry.

NOTICE TO VETERINARIANS: If the proper dosage of Co-Ral Fly and Tick Spray 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 overdose, atropine by injection is antidotal.

APPLICATION RATES

DO NOT APPLY MORE THAN 4 QUARTS OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER. FOR LACTATING DAIRY CATTLE DO NOT APPLY MORE THAN 1 QUART OF CO-RAL FLY AND TICK SPRAY PER 50 GALLONS OF WATER.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Beef and Non- Lactating Dairy Cattle	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.
	Ticks	4	10	
Lactating Dairy Cattle	Lice Flies	1	2½	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run-off. Treat no more than six times per year. Do not make applications less than 10 days apart.

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ANIMAL	PARASITE	REMARKS
Backrubber for Beef and Lactating Dairy Cattle	Horn Flies Face Flies	Mix 4 quarts Co-Ral in 13 gallons (or 9 ¾ oz Co-Ral per gallon) of any backrubber oil approved for use on livestock. Do not mix with home furnace oil (fuel oil) or 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.

ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Horses (Not intended for slaughter)	Horn Flies Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for complete wetting.
	Ticks	4	10	Treat thoroughly all wounds and injuries. Treat no more than six times per year. Do not make applications less than 10 days apart.

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ANIMAL	PARASITE	QUARTS PER 50 GALLONS OF WATER	OUNCES PER 4 GALLONS OF WATER	REMARKS
Swine	Lice	2	5	SPRAY TREATMENT(S): Apply specified dosage for a complete wetting to run- off. Treat no more than six times per year. Do not make applications less than 10 days apart.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE 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: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Offer for reconditioning, if appropriate. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, 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.

Conditions of Sale: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer HealthCare LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

Limited Warranty and Limitation of Damages: Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, and no agent of Bayer is

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authorized to make or modify any warranties beyond those contained herein. To the extent consistent with applicable law, any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use of handling of this product.

For customer service or to obtain product information, including the MSDS, call 1-800-633-3796.