



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

June 4, 2025

J. Todd Frank
Sr. Regulatory Affairs Consultant
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

Subject: Label Amendment - Registration Review Mitigation for Coumaphos
Product Name: Co-Ral Fly & Tick Spray
EPA Registration Number: 11556-115
Application Date: September 22, 2021
Decision Number: 578619
Case Number: 00479491

Dear J. Todd Frank:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Coumaphos Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. 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 12 months from the date of this letter. After 12 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.

If you have any questions about this letter, please contact Michelle Nolan by phone at (202) 566-2237, or via email at nolan.michelle@epa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "Kevin Costello". The signature is written in a cursive, flowing style.

Kevin Costello, Branch Chief
Risk Management and Implementation Branch 2
Pesticide Re-Evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

NOTE TO REVIEWER: Brace “{ }” indicate notes to reviewer. Brackets “[]” indicate optional language.

Co-Ral Fly & Tick Spray

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

COUMAPHOS	GROUP	1B	INSECTICIDE
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{Box will be in the upper right corner of front panel.}

{{Optional marketing pictos appearing at the end of the document}}

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

*Contains aromatic petroleum distillates.

This product contains 0.25 lb coumaphos per half gallon.

EPA Reg No. 11556-115

EPA Est. No. _____

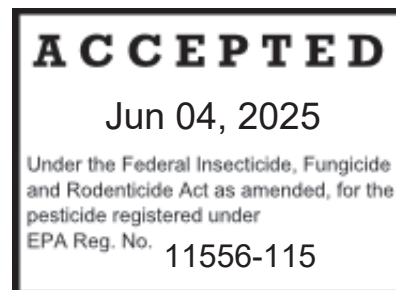
KEEP OUT OF REACH OF CHILDREN

WARNING

See [label location] for [Directions for use], [First Aid], [Precautionary Statements], and [Storage and Disposal.]

NET WEIGHT [CONTENTS]: _____
Lot No.:

Manufactured For:
Elanco US Inc
450 Elanco Circle
Indianapolis, IN 46221 [U.S.A.]



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 product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 1-800-428-4441.] [or CHEMTREC at 1-800-424-9300],] [24 hours per day, 7 days per week.]	

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.

Respirator fit testing, medical qualification, and training:

Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is:

- Fit-tested and fit-checked,
- Trained, and
- Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn.

A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a

questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements.

PERSONAL PROTECTIVE EQUIPMENT [(PPE)]

All exposures	Long-sleeve shirt, long pants, shoes, and socks
Mixers/loaders – all application methods	All of the above PLUS <ul style="list-style-type: none"> • Wear barrier laminate, nitrile rubber (>14 mils), neoprene rubber (>14 mils) or Viton gloves (>14 mils), and • Chemical-resistant footwear plus socks.
Mixers/loaders – all spray methods of application Applicators - handheld sprayer*	All of the above PLUS <ul style="list-style-type: none"> • Coveralls over long-sleeved shirt and long pants, and • Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any R or P filter; <u>OR</u> a NIOSH-approved powered air purifying respirator with HE filters.
Mixers, loaders, and others exposed to the concentrate (such as during a management of a spill or equipment breakdown)	All of the above PLUS <ul style="list-style-type: none"> • Wear a chemical-resistant apron and face shield or goggles.
* For application via vehicle-mounted sprayer: Handlers must use closed mixing/loading systems when mixing/loading. Handlers must use closed cabs while applying spray materials.	

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:

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

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.

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

This product may ONLY be used in accordance with the use directions/instructions on this label. All other uses and application methods are prohibited.

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.

Removable chemical extraction probes (also known as “stingers”) used in suction/extraction systems must be rinsed within the pesticide container prior to removal.

For handheld spray applications, mixers, loaders, and applicators must limit the amount handled to 10 gallons per day.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, Co-Ral Fly & Tick Spray contains a Group 1B insecticide. Any insect population may contain individuals naturally resistant to Co-Ral Fly & Tick Spray and other Group 1B insecticides. The resistant individuals may dominate the insect population if this group of insecticides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

APPLICATION RESTRICTIONS

Co-Ral Fly & Tick Spray 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 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.

For handheld spray applications, mixers, loaders, and applicators must limit the amount handled to 10 gallons per day.

Co-Ral Fly & 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.

Use of Vehicle-Mounted Sprayers: For Use on Animal Feeding Operations (AFOs) or Small Cattle Operations (<100 head of cattle) Only. Only apply to cattle in an open-air, fenced area such as a corral. Applications may be made by ATV or tractor only. Sprayers must be directed toward the intended application site while spray is active.

Backrubber Application for Horn Flies and Face Flies: Co-Ral Fly & 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 & 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 overdosage, atropine by injection is antidotal.

APPLICATION RATES

Beef and Dairy Cattle - Applications via Vehicle-Mounted Sprayers and Backrubbers

Pest	Application Equipment	Max. Application Rate	Max. Number of Applications per Year	Minimum Retreatment Interval
Horn Flies Lice Ticks	Vehicle-mounted spray equipment (e.g., boom sprayer)	0.005 lbs ai/gallon	6	Do not make applications less than 10 days apart. Re-treat only when insects reappear.
Directions and Restrictions				
Mix 1 gallon of Co-Ral Fly & Tick Spray per 100 gallons of water in tank. The droplet size of the sprayer nozzles should be greater than 1 mm. For Use on Animal Feeding Operations (AFOs) or Small Cattle Operations (<100 head of cattle) Only. Only apply to cattle in an open-air, fenced area such as a corral. Applications may be made by ATV or tractor only. Sprayers must be directed toward the intended application site while spray is active.				
Pest	Application Equipment	Max. Application Rate	Max. Number of Applications per Year	Minimum Retreatment Interval
Horn Flies Face Flies	Cattle backrubbers	NA	NA	NA
Directions and Restrictions				
Mix 9.75 oz. (95 mL) of Co-Ral Fly & Tick Spray per 1 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.				

Horses - Applications via Handheld Sprayer

Pest	Max. Number of Applications per Year	Minimum Retreatment Interval	Use Directions
Horn Flies Lice	6	No less than 10 days apart	Add 1.25 oz. Co-Ral Fly & Tick Spray per gallon of water and mix thoroughly. For example: 5 oz. spray with 4 gallons of water 12.5 oz. spray with 10 gallons of water
Ticks	6	No less than 10 days apart	Add 2.5 oz. Co-Ral Fly & Tick Spray per gallon of water and mix thoroughly. For example: 10 oz. spray with 4 gallons of water 25 oz. spray with 10 gallons of water
Directions and Restrictions			
Apply for complete wetting to run-off.			

Not for use on horses intended for slaughter.
Do not apply more than 10 gallons per day via handheld sprayer.

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 $\frac{1}{4}$ 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 Elanco US Inc. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

LIMITED WARRANTY AND LIMITATIONS OF DAMAGES

Elanco US Inc warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO 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 Elanco is 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.

{[Optional Marketing pictograms appearing on any location:]}



{QR code added to package due to Spanish translation requirements}

Escanee el código QR
para etiqueta en español

{QR Code will be inserted here}