



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

June 20, 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 Animal Insecticide 1% Bulk Dust
EPA Registration Number: 11556-14
Application Date: September 22, 2021
Decision Number: 578604
Case Number: 00474412

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™ Animal Insecticide 1% Bulk Dust

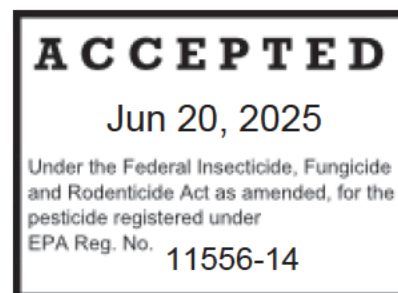
Control of Horn Flies and Lice on Beef and Dairy Cattle, Reduction of Face Flies on Beef and Dairy Cattle

{Alternate Brand Name(s) are listed at the end of the document}
{if ABN is used, to replace primary brand name throughout document}

Use in Dust Bag

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

[Contains:]
[Contains refillable dispenser bag]
[Two 12.5 lb. bags of dust]



COUMAPHOS	GROUP	1B	INSECTICIDE
-----------	-------	----	-------------

{Box will be in the upper right corner of front panel.}

ACTIVE INGREDIENT:	<u>% by Weight</u>
Coumaphos.....	1%
OTHER INGREDIENTS:	99%
TOTAL	100%

EPA Reg. No. 11556-14

EPA Est. No. _____

KEEP OUT OF REACH OF CHILDREN

CAUTION

Harmful if swallowed, absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, and clothing.

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

NET [WEIGHT][CONTENTS]: [12.5 POUNDS], [Two 12.5 Pounds]

[Lot No.:]

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

FIRST AID	
If Swallowed:	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • 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: 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.	
HOTLINE NUMBER Contains an organophosphate that inhibits cholinesterase. 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

CAUTION

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)]

For establishments with 100 or fewer cattle: Mixers, loaders, applicators, and other handlers must wear	<ul style="list-style-type: none"> • Long-sleeved shirt and long pants, • Wear barrier laminate, nitrile rubber (>14 mils), neoprene rubber (>14 mils), or Viton gloves (>14 mils), and • Chemical resistant footwear plus socks, • Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R or P filter; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any N, R or P filter; <u>OR</u> a NIOSH-approved powered air purifying respirator with HE filters.
For establishments with 100 to 350 cattle: Mixers, loaders, applicators, and other handlers must wear	All of the above PLUS <ul style="list-style-type: none"> • Coveralls over long-sleeved shirt and long pants
For establishments with over 350 cattle: Mixers, loaders, applicators, and other handlers must wear	All of the above with the exception of the respirator which needs to be <ul style="list-style-type: none"> • NIOSH-approved full face respirator with an N, R, or P 99 or 100 filter.
Mixers, loaders, and others exposed to the concentrate (such as during 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.
* Wear the appropriate respirator as shown above for the size of establishment.	

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 the other laundry.

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.

Co-Ral Animal Insecticide 1% Bulk Dust may be used to fill cattle dust bags. When used as recommended, Co-Ral Animal Insecticide 1% Bulk Dust controls horn flies and lice on beef and dairy cattle. Co-Ral Animal Insecticide 1% Bulk Dust will also reduce face fly populations on cattle; however, as face flies are able to travel over an area of several miles, best reduction of face fly populations is achieved when Co-Ral Animal Insecticide 1% Bulk Dust is used on an area-wide basis.

Maximum Application rate for dust bag applications is 0.00125 lbs. ai/animal.

Individuals must not treat more than 100 animals per day.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, Co-Ral Animal Insecticide 1% Bulk Dust contains a Group 1B insecticide. Any insect population may contain individuals naturally resistant to Co-Ral Animal Insecticide 1% Bulk Dust 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.

Contact your local extension specialist advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific pest problems in your area.

APPLICATION RESTRICTIONS

The use of mechanical dusters is prohibited.

For external insecticidal use only on specified animals. Do not contaminate feed, troughs, water or water utensils. Provide thorough ventilation while dusting. Do not apply to sick, stressed or convalescent animal.

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.

Do not treat areas such as drinking cups, mangers, or troughs where livestock feed. Do not contaminate food, feedstuffs, food or feed handling equipment or milk or meat handling equipment.

Entry Restriction: Do not enter treated areas or allow contact with treated animals until dusts have settled.

INSTALLATION OF DUST BAGS:

Suspend the bags by inserting rope, chain or wire through the grommets at the top of the bag and attaching to an overhead structure or by hooking the grommets into hooks fastened to a stationary overhead 2 x 4 board at heights recommended for louse and horn fly or face fly control. In areas of frequent or heavy rainfall the cattle duster should be protected from the weather.

Install as many cattle dusters as necessary to lanes or other openings to ensure proper dusting of the animals. After the bags are in place, pull the rip cord to allow the insecticide to fall into the bottom of the bag. When dust bags are provided on a free-choice basis, allow one 12.5-pound Co-Ral Animal Insecticide 1% Bulk Dust cattle duster per 100 animals.

APPLICATION RATES

Beef and Dairy Cattle

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

Pest	Application Equipment	Max. Application Rate	Max. Number of Applications per Year	Minimum Retreatment Interval
Horn Flies Face Flies Lice	Dust Bag	0.00125 lbs. ai/animal	NA	NA

Use Directions and Limitations

Place contents of this package in any commercially available dust bag. Suspend bags in areas frequented by cattle or in gateways or lanes through which the animals pass daily for water, feed or minerals. Bags may also be suspended in loafing sheds or in front of protected mineral feeders.

For lactating dairy cows bags may be suspended in the exit through which cows leave the milking barn. In all cases the bags should be adjusted so that the bottom of the bag will hang four to six inches below the topline of the cattle.

For reduction of face flies: (1) The bottom of the bags should be 18 to 24 inches from the ground to ensure that the faces of the cattle will be dusted. (2) The bags must be located so the animals will be forced to use them daily.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Completely empty the container by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Offer for recycling, if available. Dispose of bags in a sanitary landfill or by incineration if allowed by state and local authorities.

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 LIMITATION 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. 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 Claims appearing on any location:}

1. Control of [Horn Flies] [and] [Lice] on [Beef] [and] [Dairy] Cattle
2. Reduction of Face Flies on [Beef] [and] [Dairy] Cattle

{Optional Marketing pictograms appearing on any location:}



{Alternate Brand Names}

1. Co-Ral 1% Livestock Dust

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

Escanee el código QR
para etiqueta en español

{QR Code will be inserted here}