



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 26, 2024

Todd Frank
Senior Regulatory Affairs Consultant, Pesticides and General Product Support, R&D
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

Subject: Label Amendment – Additional label changes in accordance with the
Coumaphos Interim Decision
Product Name: Corathon
EPA Registration Number: 11556-148
Application Date: November 2, 2022
Decision Number: 578601

Dear Todd Frank:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product. The Agency has concluded that your submission 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 by the Agency. 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.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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) lists 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

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substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

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 Alex McKee at 202-566-1939 or at mckee.alex@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Dana L. Friedman". The signature is written in a cursive, flowing style.

Dana L. Friedman, Chief
Risk Management and Implementation Branch 1
Pesticide Re-Evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

Enclosure

CC: Tamica Cain, Registration Division, PM10

Reason to Issue: Add ESA statement and resistance management information. Add pictograms and other minor revisions. Date: 10/31/2022

Supersedes: 03/31/2009

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

Corathon

Insecticide Cattle Ear Tag for use on Beef and Non-Lactating Dairy Cattle to Control Horn Flies [including pyrethroid-, [and] chlorinated hydrocarbon- [and avermectin-] resistant horn flies], Face Flies, Gulf Coast Ticks, and Spinose Ear Ticks for up to 5 Months.

For Use with Allflex® Universal Total Tagger with red pin and black clip. With FyberTek™

[Selected optional claims bulleted from OPTIONAL MARKETING CLAIMS from pages 5-6]

[Selected pictograms/pictures from page 5]

ACTIVE INGREDIENTS:	% by Weight
Coumaphos	15%
Diazinon.....	35%
OTHER INGREDIENTS:	50%
TOTAL	100%

Net Contents: [2 pouches] [of] [10 Tags] 0.5 oz (14 grams) per tag

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EPA Est. No. TBD

COUMAPHOS	GROUP	1B	INSECTICIDE
DIAZINON	GROUP	1B	INSECTICIDE

{Note to reviewer: box will be in the upper right corner of front panel.}

STOP – Read the label before [each] use.

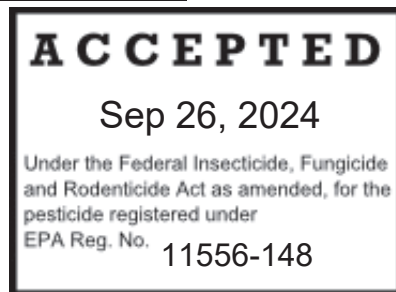
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See [location on package] for [First Aid] [Directions for Use] [and] Precautionary Statements

[Refer to accompanying manufacturer’s recommendations for complete directions for use and precautions.]

PRECAUCION AL USUARIO: Si usted no puede leer o entender inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read or understand English, do not use this product until the label has been fully explained to you.)



FIRST AID	
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.
If Swallowed:	<ul style="list-style-type: none"> • Call a 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 or convulsing person.
HOT LINE NUMBER	
<p>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 1-800-428-4441. For customer service or to obtain product information, including the SDS, call 1-800-428-4441.] [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.]</p>	
<p>Note to Physician: This product contains cholinesterase inhibitors. If symptoms of cholinesterase inhibition are present, atropine sulfate, by injection, is antidotal. 2-PAM is also antidotal and may be administered, but only in conjunction with atropine.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some people. Wash thoroughly with soap and water after handling and before eating, drinking chewing gum, using tobacco, or using the toilet. Wear chemical-resistant gloves made of rubber or any waterproof material (thickness equal to or greater than 14 mils) when applying tags.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long sleeved shirt and long pants
- shoes and socks
- chemical-resistant gloves made of rubber or any waterproof material (thickness equal to or greater than 14 mils)

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE 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.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds, fish, and wildlife. Do not apply directly to water. Do not contaminate water when disposing of used tags.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in possession of the user at the time of pesticide application.

IMPORTANT: Read the entire Directions for Use, Conditions of Sale and Disclaimer of Limited Warranty and Limitations of Damages 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.

Endangered Species Protection Requirements:

It is a Federal offense to use any pesticide in a manner that results in an unauthorized “take” (e.g., kill or otherwise harm) of an endangered species and certain threatened species under the Endangered Species Act section 9. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. You must obtain a Bulletin no earlier than six months before using this product. To obtain Bulletins, consult <http://www.epa.gov/espp/>, call 1-844-447-3813, or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product.

Reporting Ecological Incidents: To report ecological incidents, including mortality, injury, or harm to plants and animals, call 1-800-428-4441.

RESISTANCE-MANAGEMENT RECOMMENDATIONS

For resistance management, Corathon contains a Group 1B insecticide. Any insect population may contain individuals naturally resistant to Corathon 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.

To delay insecticide resistance, take the following steps:

- Rotate the use of Corathon or other Group 1B insecticides, with different groups that control the same pests.
- Adopt an integrated pest management program for insecticide/acaricides use that includes scouting, uses historical information related to pesticide use, crop rotation, record keeping, and which considers cultural, biological and other chemical control practices.
- Monitor after application for unexpected target pest survival. If the level of survival suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.
- [For further information or to report suspected resistance contact Elanco US Inc at 1-800-428-4441.]
[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.]

For the control of horn flies (including pyrethroid-, [and] chlorinated hydrocarbon- [and avermectin-] resistant horn flies), face flies, Gulf Coast ticks, and spinose ear ticks on beef and non-lactating dairy cattle.

For adequate control of horn flies, face flies, Gulf Coast ticks, and spinose ear ticks attach one tag per mature animal. For optimum control of horn flies, face flies, Gulf Coast ticks, and spinose ear ticks, attach one tag to

each ear (two per animal) per mature animal. For calves apply one tag per animal. Replace as necessary. Corathon has been proven to be effective against horn flies and face flies for up to five months.

Use the Allflex Universal Total Tagger with the red pin and black clip to apply tags to cattle.

Apply as indicated (Figures 1-4). Remove tags at end of fly season or prior to slaughter.

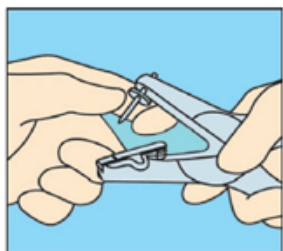


Figure 1. Disinfect pliers prior to use. Place male button onto pin.



Figure 2. Slide tag under the clip of the pliers by depressing the lever.

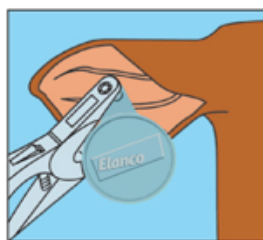


Figure 3. Position tag in the center portion of the front side of the ear.

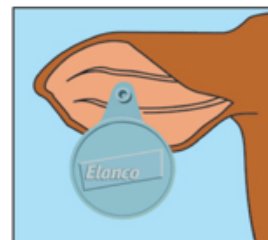



Figure 4. Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids, organophosphates, chlorinated [or] hydrocarbons [or avermectin]) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. Corathon contains the organophosphate insecticides coumaphos and diazinon.

CORATHON [insecticide cattle ear tags] QUICKFACTS	
[Selected optional label claims bulleted here from pages 5-6]	
WHERE TO APPLY	<ul style="list-style-type: none"> • Beef and Non-Lactating Dairy Cattle
HOW TO APPLY	<ul style="list-style-type: none"> • Use Allflex Universal Total Tagger with red pin and black clip to apply tags to cattle.
COVERAGE	<ul style="list-style-type: none"> • [All mature animals in the herd should be tagged.] • [For optimum control of horn flies, face flies, Gulf Coast ticks, and spinose ear ticks, attach one tag to each ear (two tags per animal) per mature animal.] • [Use one ear tag per calf] [for face fly control.] • [For adequate control of horn flies, face flies, Gulf Coast ticks, and spinose ear ticks, attach one tag per mature animal.]
RE-APPLY	<ul style="list-style-type: none"> • [Corathon has been proven to be effective against horn flies and face flies for up to five months.] • [Replace as necessary.] • [Remove tags at end of fly season or prior to slaughter.]
QUESTIONS? 	<ul style="list-style-type: none"> • For questions or comments, call toll-free 1-800-428-4441.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) 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. Dispose of empty pouch in a sanitary landfill or by 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.

Reformulation or repackaging of this product is prohibited.

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. 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.

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140 [U.S.A.]

{{Optional/Alternative Marketing Claims appearing on any location:}}

1. [[Effective against] [Controls]] [horn flies [including pyrethroid-, [and] chlorinated hydrocarbon- [and avermectin]- resistant horn flies] [Gulf Coast ticks] [face flies] [and] [spinose ear ticks] for up to 5 months.
2. [[Effective against] [Controls]] face flies - mechanical vector of *Moraxella bovis* bacteria causing "pink eye" of cattle for up to 5 months.
3. [[Effective against] [Controls]] horn flies and face flies
4. [[Effective against] [Controls]] Gulf Coast ticks and spinose ear ticks
5. Contains two [organophosphate] insecticides [Coumaphos and Diazinon]
6. Contains 50% [[active ingredient] [organophosphate insecticides]]
7. Use in rotation with [Elanco's] CyGuard™ [insecticide cattle ear tags]
8. Use in rotation with pyrethroid, [or] chlorinated hydrocarbon [or avermectin] cattle ear tags
9. [[Green] [grey] [brown]] color [ear tag]
10. [Cellulose] fiber [technology] [for [[dependable] [effective]] [fly and tick] control]]
11. Maximum insecticide [holding] capacity [[tag] [technology] [matrix]]
12. Contains insecticide holding [cellulose] fibers
13. Fiber [[technology] [tag] [matrix]] effectively kills flies and ticks
14. [[FiberTech] [FiberCell] [FyberTek™]] matrix: [[effective] [dependable] [long lasting]] [fly and tick] control [for up to 5 months]
15. Fiber [[technology] [tag] [matrix]] [FyberTek™] allows for maximum insecticide holding capacity and provides even dispersion of insecticide
16. Fiber [[technology] [tag] [matrix]] [FyberTek™] provides even dispersion of insecticide
17. [[Controls] [prevents]] horn fly and face fly feeding and irritation

18. [[Cellulose] [fiber]] technology holds 25% more insecticide than [Elanco's] Co-Ral Plus Insecticide Cattle Ear Tags
19. [[Cellulose] [fiber]] technology holds 25% more [organophosphate] insecticide
20. [Fiber] technology [[holds] [contains]] [25%] more [[organophosphate insecticide] [active ingredient]] than [Elanco's] Co-Ral Plus Insecticide Cattle Ear Tag
21. Fiber [[technology] [tag] [matrix]] holds more insecticide

{{Optional marketing pictograms and images appearing on any panel:}}

