



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

November 13, 2023

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 – Label changes based on the 2022 National Marine Fisheries Service Biological Opinion on Diazinon and Coumaphos Interim Decision
Product Name: Co Ral Plus Cattle Ear Tag
EPA Registration Number: 11556-123
Application Date: October 24, 2022
Decision Numbers: 588386, 578602

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 in connection with the Diazinon 2022 Biological Opinion and Coumaphos Interim Decision. 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

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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.

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 style with a large, stylized 'D'.

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.

Date: 10/19/2022

Supersedes: 05/28/2008
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Bag (Front)

CO-RAL PLUS

INSECTICIDE CATTLE EAR TAG

For use with Allflex® Universal Total Tagger with red pin and black clip.

For use on Beef and Non-Lactating Dairy Cattle to control Horn Flies (including pyrethroid-resistant horn flies), Gulf Coast Ticks, Spinose Ear Ticks, And As An Aid To Control Face Flies.

		Percent By Weight
Active Ingredients:	Coumaphos	20%
	Diazinon	20%
Other Ingredients	60%
Total	100%

Keep Out of Reach of Children

CAUTION

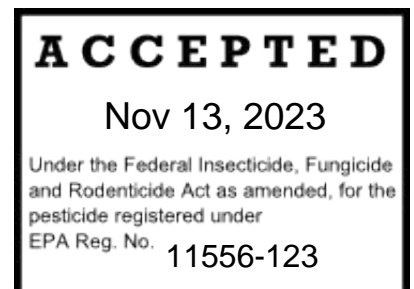
See Back of Bag For Additional Precautionary Statements and Full Labeling

COUMAPHOS	GROUP	1B	INSECTICIDE
DIAZINON	GROUP	1B	INSECTICIDE

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

Net Contents: 20 Tags - 0.5 oz per tag

Elanco US Inc.



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2500 Innovation Way
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Bag (Rear)

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.

User Safety Recommendation: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID	
Contains organophosphates that inhibits cholinesterase.	
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 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 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 instructed to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious or convulsing person.

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

Bag (Rear)

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handles 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. Users should remove clothing/PPE 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 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 the possession of the user at the time of pesticide application.

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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, Co-Ral Plus Insecticide Cattle Ear Tag contains Group 1B insecticides. Any insect population may contain individuals naturally resistant to Co-Ral Plus Insecticide Cattle Ear Tag 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 Co-Ral Plus Insecticide Cattle Ear Tag 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.]

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Reformulation or repackaging of this product is prohibited.

For the control of Horn Flies (including pyrethroid-resistant Horn Flies), Gulf Coast Ticks, and Spinose Ear Ticks on beef and non-lactating dairy cattle and as an aid to control Face Flies.

All mature animals in the herd should be tagged. For adequate control of Horn Flies attach one tag per animal. For optimum control of Horn Flies, Gulf Coast Ticks, and Spinose Ear Ticks, and as an aid in the control of Face Flies, attach one tag to each ear (two per animal). Replace as necessary. Co-Ral[®] Plus Insecticide Ear Tags have been proven to be effective against Horn Flies for three to five months.

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

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)

Figure 1

(Illustration)

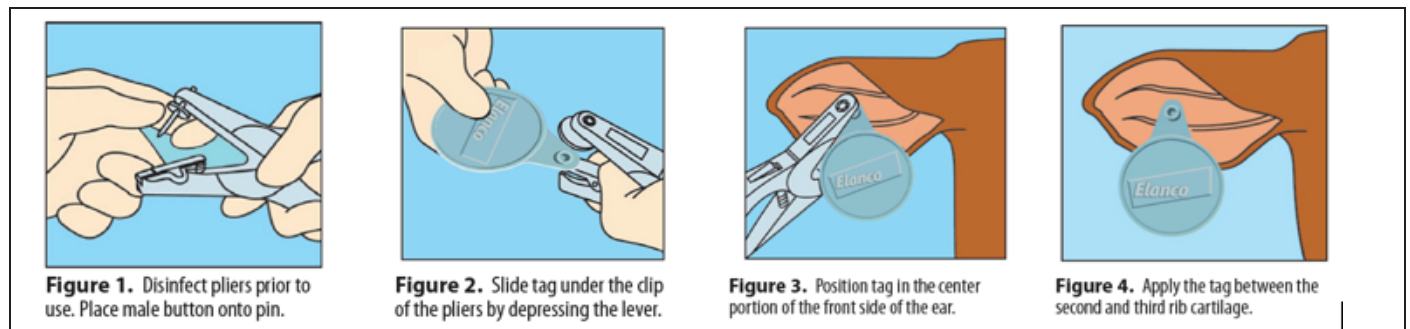
Figure 2

(Illustration)

Figure 3

(Illustration)

Figure 4



Continual exposure of Horn Flies to a single class of insecticide (e.g. pyrethroids or organophosphates) 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. Co-Ral[®] Plus Insecticide Cattle Ear Tags contain the organophosphate insecticides coumaphos and diazinon.

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Bag (Rear)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in cool place in original container.

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: 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.

EPA Est. No. XX-XX-XX

EPA Reg No. 11556-123

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 EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Elanco 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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Inner Box

CO-RAL[®] PLUS
INSECTICIDE CATTLE EAR TAG

20 Tags – 0.5 oz per tag

		<u>Percent By Weight</u>
Active Ingredients:		
	Coumaphos	20%
	Diazinon	20%
Other Ingredients	<u>60%</u>
Total	100%

EPA Est. No. XX-XX-XX
EPA Reg. No. 11556-123

Keep Out of Reach of Children

CAUTION

See Back of Bag For Additional Precautionary Statements and Full Labeling

Manufactured for:
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140