

PM 03

68451-1

11/17/98

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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NOV 17 1998

John J. Lauber
Hoechst Roussel Vet
Agent for Hoechst Roussel Vet S.A.
30 Independence Blvd.
P.O. Box 4915
Warren, N.J. 07059

Subject: Deltamethrin 4% Collar
EPA Registration No. 68451-1
Amendment dated June 4, 1998

Dear Mr. Lauber:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you:

1. Make the following changes to your label:

a. Based on the submitted studies, the addition of the claims for "deer ticks" is acceptable. Black-legged ticks is also acceptable. However, if a species name specific claim is made, then only *Ixodes scapularis* and/or *Ixodes pacificus* may be used in addition to the terms above. *Ixodes sp.* is not acceptable, and should be removed from the label and the above species names should replace it.

b. The label claim for mosquitoes reads: "Collar kills and repels mosquitoes and prevents them from feeding." The data submitted do not support these claims and for the following reasons they should be removed from the label:

1) The data do not show that this product is an efficacious repellent. The study results demonstrate a reduction in blood-feeding but this reduction is insufficient to support repellent claims. The maximum reduction in feeding between the control and treated groups is 84.4% with a range of 15.9% to 84.4%. In addition, there was no statistically significant difference in landings between treated and control groups.

2) The data do not support the "kill" claim for mosquitoes. The range was 69% - 91.1%. The 91.1% mortality result was for one data point only. All other measurements of mortality were below 50%. This is less than the 95% required by

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2. Submit two copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records. I have also enclosed copies of the reviews for your records. If you have any questions about this letter, please contact Beth Edwards at (703) 305-5400.

Sincerely yours,

Beth Edwards

for

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosures

CONCURRENCES

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DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

ACCEPTED
with COMMENTS
in EPA Letter Dated

NOV 17 1998

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
68451-1

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
 INERT INGREDIENTS	 96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Side Panel for additional Precautionary Statements

EPA Reg. No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 1.1 oz

Hoechst Roussel Vet SA
102 route de Noisy
93235 Romainville, France

495

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID

IF SWALLOWED: Call a physician or poison control center. ~~Drink one or two glasses of water and induce vomiting by touching back of throat with finger.~~ Do not induce vomiting or give anything by mouth to an unconscious person.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

EMERGENCY PHONE NUMBERS:

FOR HUMAN, FIRE, ENVIRONMENTAL:

1-800-228-5635, ext. 132

FOR ANIMALS: 1-800-345-4735, EXT. 104

Collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*) and deer tick (*Ixodes sp.*) which may carry the Lyme disease. Collar kills and repels mosquitoes (*Aedes aegypti*) and prevents them from feeding. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. Deltamethrin 4% Collar may be used in addition to a lead or constriction collar. Use only one Deltamethrin collar at a time.

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STORAGE AND DISPOSAL: Store in original, unopened container, away from children. Do not reuse container or used collar. Wrap in newspaper and put in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. HOECHST ROUSSEL VET S.A. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to HOECHST ROUSSEL VET S.A., and user assumes the risk of any such use. HOECHST ROUSSEL VET S. A MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall HOECHST ROUSSEL VET S.A. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of HOECHST ROUSSEL VET S.A.

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Part No. XXXXX

Universal Product Code Number (Bar Code)

