68451-1

2/9/2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Micah T. Reynolds Intervet, Inc. (d/b/a Merck Animal Health) 556 Morris Avenue Summit, New Jersey 07901

Subject: Label Amendment – Removal of Repellency Claims for Ticks Product Name: Deltamethrin 4% Collar EPA Registration Number: 68451-1 Submission Date: January 10, 2014 Decision Number: 487212 FEB 0 4 2014

Dear Mr Reynolds:

The label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is <u>acceptable</u>.

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.

Products released for shipment after 18 months from the date on this notice or the next printing of the master label whichever occurs first, must bear the new revised label. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA. Amended labeling will supersede all previously accepted labels. Your release for shipment of this product constitutes acceptance of these conditions. As required by 40 CFR 156.10(6), you must submit one copy of the final printed label before the product is released for shipment. If you have any questions please contact Carlyn Petrella by phone at (703) 347-0439 or via email at "petrella.carlyn@epa.gov".

Sincerely,

Michael Walsh Acting Product Manager (13) Insecticide Branch Registration Division (7505P) Office of Pesticide Programs

Enclosure

page: 1 of 5 revision date: 01-09-14

DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Dog Collar for Flea and Tick Control SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs SCALIBOR® 6-Month Flea and Tick Collar for Dogs SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Six Month Collar for Dogs SCALIBOR® Six Month Flea and Tick Collar for Dogs SCALIBOR® Six Month Flea & Tick Collar for Dogs SCALIBOR® Collar with Deltamethrin SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Long Lasting Collar for Dogs SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® Protector Band for Dogs

ACCEPTED

FEB 0 4 2014 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	<u>96.0%</u>	
Total	100.0%	

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements See Back for additional Precautionary Statements

Adjustable - One Size Fits All

EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar NET WT. 0.9 oz

Intervet Inc (d/b/a Merck Animal Health) Summit, NJ 07901

Product of France

page: revision date:

2 of 5 01-09-14

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON 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 products 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.

This 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.

FIRST AID		
If swallowed	 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 on skin or clothing	 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	 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. 	
For incidents in x	or incidents involving HUMANS , call 1-800-680-9206 nvolving ANIMALS , call 1-800-224-5318 EST between the hours of ex and xxx. Evenings and week-ends call 800-345-4735 for container or label with you when calling a poison control center or doctor, or going for treatment	

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

Wipe the collar with a damp cloth prior to application. 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. Maximum effectiveness may not occur for 2-3 weeks after collar placement. 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 constraint collar. Use only one Deltamethrin 4% Collar at a time. This collar should be worn continuously. Reapply a new collar every 6 months.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product in a cool, dry place away from children and pets. **Pesticide and Container Disposal:** Do not reuse container or used collar. Dispose of in trash.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France

page: revision date:

01 - 09 - 14

OPTIONAL/ALTERNATE LABEL TEXT

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology.

Fleas (Ctenocephalides sp.) on the dog will be killed and those present in the dog's environment that may infest your pet will be killed.

Collar will kill ticks for up to 6 months including: Lone Star tick (Amblyomma americanum), Brown dog tick (Rhipicephalus sanguineus), American dog tick (Dermacentor variabilis), and deer ticks (Ixodes scapularis and Ixodes pacificus) which may carry the Lyme disease.

Kills fleas and ticks for up to 6 months

Long lasting protection for up to 6 months

Protects your dog from (fleas) and (ticks) for up to 6 months

Continuous protection

Kills ticks (including deer ticks which may transmit *Lyme disease*)

Kills ticks (which may transmit Rocky Mountain Spotted Fever)

Kills ticks (which may transmit anaplasmosis, babesiosis, ehrlichiosis, tularemia, Lyme disease and Southern Tick-Associated Rash Illness (STARI)

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

page: 5 of 5 revision date: 01-09-14

OPTIONAL/ALTERNATE LABEL TEXT (cont'd)

Not affected by water

Water resistant

Repels mosquitoes for up to six months.

Reduces mosquito bites for up to six months.

Reduces blood feeding by mosquitoes for up to six months.

Protects against mosquito bites for up to six months.