

68451-1

3/21/2012

1/6



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MAR 21 2012

Ms. Heather R. Bjornson  
Technology Sciences Group Inc.  
1150 18<sup>th</sup> Street, NW, Suite 1000  
Washington, D.C. 20036

Subject: Label Amendment to Add Efficacy Claims

EPA Reg. No. 68451-1  
Deltamethrin 4% Collar

Your Submission Dated October 31, 2012

Dear Ms. Bjornson;

The labeling referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below.

1. The mosquito claims are acceptable provided you agree to submit additional data (Guideline 810.3400), as specified on the enclosed Efficacy Review Memo (Sweeney, March 21, 2012). Such data should be submitted to the Agency by March 2013, one year from the date of this Memo.
2. Repellency claims for ticks are not acceptable based on the submitted data, therefore, delete the claims throughout the label.

Your release for shipment of the product bearing amended labeling 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(e). A stamped copy of the label is enclosed for your records. Two (2) copies of the final printed labeling must be submitted prior to releasing the product for shipment.

If you have questions regarding this action, please contact Olga Odiott at (703) 308-9369.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez".

Mark Suarez  
Product Manager 13  
Insecticide Branch  
Registration Division (7505P)

Enclosure

2/6

## 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® Collar with Deltamethrin  
SCALIBOR® Collar with 4% Deltamethrin

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

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

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® 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® Protector Band 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

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
**MAR 21 2012**  
**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

**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.

<b>FIRST AID</b>	
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Call poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<p><b>For incidents involving HUMANS, call 1-800-680-9206</b> For incidents involving <b>ANIMALS</b>, call 1-800-224-53181 EST between the hours of xxx and xxx. Evenings and week-ends call 800-345-4735 Have the product container or label with you when calling a poison control center or doctor, or going for treatment</p>	

**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

**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 and repel 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

6/6

Deltamethrin 4% Collar  
EPA Reg. No: 68451-1

page: 5 of 5  
revision date: 10-25-11

**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.