

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 12, 2016

Micah T. Reynolds Intervet, Inc. c/o Technology Sciences Group, Inc. 2 Giralda Farms Madison, New Jersey 07940

Subject: Notification per PRN 98-10 – Addition of ABNs & Marketing Claims Product Name: Deltamethrin 4% Collar EPA Registration Number: 68451-1 Application Date: 16-Dec-2015 Decision Number: 512457

Dear Mr. Reynolds:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

The alternate brand names "Activyl Flea and Tick Collar for Dogs, Activyl Flea & Tick Collar for Dogs, Activyl Collar with Deltamethrin, Activyl Collar with 4% Deltamethrin, Activyl Long Lasting Collar for Dogs, Activyl Deltamethrin Collar for Dogs, Activyl Protector Band for Dogs, Activyl Tick and Flea Collar for Dogs, Activyl Tick & Flea Collar for Dogs, Activyl Collar for Dogs, Activyl 6-Month Collar for Dogs, Activyl 6-Month Flea and Tick Collar for Dogs, Activyl 6-Month Flea & Tick Collar for Dogs, Activyl 6-Month Tick and Flea Collar for Dogs, Activyl 6-Month Tick & Flea Collar for Dogs, Activyl Six Month Collar for Dogs, Activyl Six Month Flea and Tick Collar for Dogs, Activyl Six Month Flea & Tick Collar for Dogs, Activyl Six Month Tick and Flea Collar for Dogs, Activyl Six Month Tick & Flea Collar for Dogs, Activyl Dog Collar for Tick and Flea Control, Activyl Dog Collar for Tick & Flea Control, Activyl Dog Collar for Flea and Tick Control, Activyl Dog Collar for Flea & Tick Control" have been added to the product record.

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

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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.

If you have any questions, you may contact Letu Kassa at 703-347-0462 or via email at <u>kassa.letu@epa.gov</u>.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

# **DELTAMETHRIN 4% COLLAR** FLEA & TICK COLLAR FOR DOGS

[Note: One of the following "brands" may be used with subsequent callout text of			Formatted: Font: 10 pt, Not Bold, Italic
Alternate Brand Names: "SCALIBOR <sup>®</sup> ", "BandGuard <sup>®</sup> ", "Activ	<u>yl</u>		Formatted: Superscript
<u>"Alternate Brand Name" Flea and Tick Collar for Dogs</u>		10	Formatted: Superscript
"Alternate Brand Name" Flea & Tick Collar for Dogs		$(\cdot, \cdot)$	Formatted: Superscript
"Alternate Brand Name" Collar with Deltamethrin			Deleted: ¶
"Alternate Brand Name" Collar with 4% Deltamethrin	NOTIFICATION		~
"Alternate Brand Name" Long Lasting Collar for Dogs	68451-1		
"Alternate Brand Name" Deltamethrin Collar for Dogs	The applicant has certified that no		
"Alternate Brand Name" Protector Band for Dogs	changes, other than those reported to		
"Alternate Brand Name" Tick and Flea Collar for Dogs	the Agency have been made to the		
"Alternate Brand Name" Tick & Flea Collar for Dogs	labeling. The Agency acknowledges		
"Alternate Brand Name" Collar for Dogs	this notification by letter dated:		
<u>"Alternate Brand Name" 6-Month Collar for Dogs</u> "Alternate Brand Name" 6-Month Flea and Tick Collar for Dogs	02/12/2016		
"Alternate Brand Name" 6-Month Flea & Tick Collar for Dogs			
"Alternate Brand Name" 6-Month Tick and Flea Collar for Dogs			
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"Alternate Brand Name" Six Month Tick and Flea Collar for Dogs			
"Alternate Brand Name" Six Month Tick & Flea Collar for Dogs			
"Alternate Brand Name" Dog Collar for Tick and Flea Control			
"Alternate Brand Name" Dog Collar for Tick & Flea Control			
"Alternate Brand Name" Dog Collar for Flea and Tick Control			
"Alternate Brand Name" Dog Collar for Flea & Tick Control			
			Deleted: SCALIBOR <sup>®</sup> Flea and Tick Collar for
			Dogs SCALIBOR <sup>®</sup> Collar with Deltamethrin¶ SCALIBOR <sup>®</sup> Flea & Tick Collar for Dogs
ACTIVE INGREDIENT: Percentage by Weight			SCALIBOR <sup>®</sup> Collar with 4% Deltamethrin
Deltamethrin			SCALIBOR <sup>®</sup> Dog Collar for Flea and Tick Control SCALIBOR <sup>®</sup> Long Lasting Collar for
INERT INGREDIENTS <u>96.0%</u>			Dogs
Total 100.0%			SCALIBOR <sup>®</sup> Dog Collar for Flea & Tick Control SCALIBOR <sup>®</sup> Deltamethrin Collar for
			Dogs¶

**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	A11
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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) 2 Giralda Farms, Madison, NJ 07940,

Product of France

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Dogs .

Dogs¶

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Dogs¶ SCALIBOR<sup>®</sup> Collar for Dogs

Protector Band for Dogs¶ SCALIBOR® 6-Month Collar for Dogs ..... SCALIBOR® Tick and Flea Collar for

SCALIBOR<sup>®</sup> 6-Month Flea and Tick Collar for Dogs . SCALIBOR<sup>®</sup> 6-Month Flea & Tick Collar ¶ SCALIBOR<sup>®</sup> Tick & Flea Collar for Dogs . Dogs . .

SCALIBOR®

for

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# READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

[Product Name] 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.

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FIRST AID				
If swallowed	ed • 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	• Take off contaminated clothing.			
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.			
F	For incidents involving HUMANS, call 1-800-680-9206			
For incidents i	nvolving ANIMALS, call 1-800-224-5318 EST between the hours of			
Х	xx and xxx. Evenings and week-ends call 800-345-4735			
Have the produ	act container or label with you when calling a poison control center or doctor,			
	or going for treatment			

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**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. [Product Name] may be used in addition to a lead or constraint collar. Use only one [Product Name] 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.

#### IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. 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 the 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 INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use of 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 INTERVET INC.

Part No. xxxxx

Universal Product Code Number (Bar Code)

Product of France

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### **OPTIONAL/ALTERNATE LABEL TEXT**

[Product Name], 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 fleas

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) 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.

Deltamethrin 4% Collar EPA Reg. No: 68451-1	page: 6 of 6 revision date: <u>12-14-2015</u>	<b>Deleted:</b> 4-28-2014
<b>OPTIONAL/ALTERNATE LABEL TEXT (cont</b> )	<u>d)</u>	
(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit b	pabesiosis.	
(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may transmit a	naplasmosis.	
Patented insecticide-release technology		
Wetting will not impair the collar's effectiveness or the pet's protection 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.		
Flea [and] [&] Tick Collar for Dogs		
Collar with [4%] Deltamethrin		
Long Lasting Collar for Dogs		
Deltamethrin Collar for Dogs		
Protector Band for Dogs		
[Tick] [and] [&] [Flea] Collar for Dogs		
[Six] [6] Month [Tick] [&] [and] [Flea] Collar for Dogs		
Dog Collar for [Tick] [and] [&] [Flea] Control	+	Formatted: Tab stops: 3.25", Centered
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