

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 19, 2018

Michelle Foster Associate Manager Regulatory Affairs Virbac AH, Inc. 3200 Meacham Blvd Fort Worth, TX 76137

Subject: Label Amendment – Removal of veterinarian restriction on label

Product Name: Preventic Tick Collar for Dogs

EPA Registration Number: 2382-104

Application Date: 6/9/2017 Decision Number: 530999

Dear Ms. Foster:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 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. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 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, 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.

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

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with FIFRA section 6. If you have any questions, please contact Jacquelyn Herrick by phone at 703-347-0559, or via email at herrick.jacquelyn@epa.gov.

Sincerely,

Gene Benbow, Product Manager 7 Invertebrate & Vertebrate Branch 3 Registration Division (7505P)

Su to

Office of Pesticide Programs

Enclosure

#### MASTER LABEL

[Optional text appears in brackets. The final label may include some or all of the optional text on the front, back, or side panels.]

#### **Front Panel**

#### PREVENTIC® TICK COLLAR FOR DOGS

April 8, 2010 generic pouch ABN [Tick Collar for Dogs over 60 lbs] or [Tick Collar for Dogs up to 60 lbs]

[Note to reviewer- the first two statements have been moved below KOOROC]

[FITS NECKS UP TO 18"] or [FITS NECKS UP TO 25"]

[KILLS AND DETACHES TICKS FOR 3 MONTHS]

[ADJUSTABLE-ONE SIZE FITS MOST DOGS] or [ADJUSTABLE-FOR DOGS OVER 60 LBS] or [ADJUSTABLE- FOR DOGS UP TO 60 LBS]

[TICK COLLAR FOR DOGS]

[90 DAY TICK COLLAR FOR DOGS]

[KILL TICKS FOR 3 MONTHS]

[KILL TICKS FOR 90 DAYS]

[THE ONE THAT KILLS AND DETACHES TICKS]

[FOR DOGS UP TO 60 LBS] or [FOR DOGS OVER 60 LBS]

[SIX [6] MONTHS OF TICK PREVENTION {I.E. FOR CARTONS CONTAINING TWO COLLARS}]

[EACH COLLAR] [PROVIDES][THREE [3] MONTHS OF TICK PREVENTION]

[EACH] [COLLAR] [KILLS TICKS FOR 3 MONTHS]

[INDIVIDUAL COLLARS NOT TO BE SOLD SEPARATELY]

[ADJUSTABLE - FOR DOGS UP TO 60 LBS] or [ADJUSTABLE - FOR DOGS OVER 60 LBS]

[18" COLLAR AVAILABLE FOR DOGS UP TO 60 LBS (NOTE: ON THE 25" COLLAR IFC)] or [25" COLLAR AVAILABLE FOR

DOGS OVER 60 LBS (NOTE: ON THE 18" COLLAR IFC)]

[18]["] [Collar] or [25]["] [Collar]

#### **ACTIVE INGREDIENT**

Amitraz	9.0%
OTHER INGREDIENTS	<u>91.0%</u>
TOTAL	100.0%

## ACCEPTED

01/19/2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 2382-104

# KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BACK PANEL FOR FIRST AID, ADDITIONAL
PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE
DO NOT ALLOW CHILDREN TO PLAY WITH THE COLLAR
DO NOT OPEN UNTIL READY TO USE
USE ONLY ON DOGS



#### DO NOT USE ON CATS

NET CONTENTS: ONE 18" COLLAR - NET WT. 0.652 OZ. (18.5g)
NET CONTENTS: 2 (TWO) 18" COLLARS - NET WT. 1.304 OZ. (37g)
NET CONTENTS: ONE 25" COLLAR - NET WT. 0.97 OZ. (27.5g)
NET CONTENTS: 2 (TWO) 25" COLLARS - NET WT. 1.94 OZ. (55g)

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## MASTER LABEL Back Panel or Front Panel

## READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS. DO NOT USE ON CATS

FIRST AID		
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.	
Have product container or label with you when calling a poison control center or doctor, or going for treatment.		
You may also contact 1	800-338-3659 for emergency medical treatment information.	

**NOTE TO VETERINARIAN:** If a dog ingests this collar and exhibits intoxication (primary sign is severe depression), induce vomiting, administer non-oily laxative, activated charcoal or enema. Provide supportive therapy until collar fragments are voided. If dog cannot be roused, Yohimbine, 0.1mg/kg by intravenous injection is antidotal. Repeat as needed.

# Back Panel PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

**HAZARDS TO HUMANS:** Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. This collar is for use as an acaracide generator and is not to be taken internally by man or animal. Not for use on humans. Do not allow children to handle or play with this collar. Some humans may develop skin irritation through contact with collared pet. Remove collar, shampoo pet and consult physician if irritation persists.

#### HAZARDS TO DOMESTIC ANIMALS: FOR USE ON DOGS ONLY, DO NOT USE ON CATS.

Do not use on puppies under 12 weeks of age. Consult a veterinarian before using on debilitated, aged, medicated, pregnant or nursing animals. Do not treat collared dogs with other monoamine oxidase inhibitors, or with tricyclic antidepressants, selective serotonin reuptake inhibitors, or pressor agents. Consult a veterinarian before using this product on dogs on any other medication.

Sensitivities may occur after using ANY pesticide product for pets. Remove collar at first sign of irritation or adverse reaction, bathe dog with mild soap or non-pesticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

**DO NOT APPLY TO CATS.** There is a risk of collar breakage and ingestion if collar is worn by unattended dogs that play by mouthing each other in the neck area. If collar is missing from a dog, search for, retrieve and recover the entire collar. Immediately consult a veterinarian if dog is depressed or if ingestion is suspected.

**NOTICE:** This product contains an ingredient known to the State of California to cause birth defects or other reproductive harm. Wash hands thoroughly after applying this product. Dispose of as instructed below.

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## MASTER LABEL Back Panel or Front Panel

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this collar in a manner inconsistent with its labeling.

#### RESTRICTIONS

- -Do not place more than one collar on a dog at a time.
- -Do not allow children to handle or play with the collar.
- -Do not use on puppies under 12 weeks of age.
- -Do not use this collar with other on-animal tick control products unless directed by a Veterinarian.
- -Do not use on cats.



**APPLICATION INSTRUCTIONS:** Place this collar around the dog's neck, adjust for proper fit and buckle in place. The collar must be snug enough to contact skin and so that the dog cannot remove it. A properly fitted collar will allow two fingers to be placed between the collar and the dog's neck. Adjust periodically for growing dogs. Cut off and dispose of excess length. Do not allow dogs to play with cut-off excess.

Activity against ticks starts within 24 hours and continues as long as the collar is worn (up to 90 days). Ticks present in the dog's environment that may reappear on the dog will not attach and will be killed in less than 24 hours. Replace collar when effectiveness diminishes. The effectiveness of the collar is not diminished by normal wetting such as rainfall, however, it is suggested that the collar be removed before bathing. This product does not control fleas.

#### **Back Panel or Bottom Panel**

#### STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container in locked storage area. Store away from food and pet food.

**Pesticide Disposal and Container Handling:** Do not reuse empty pouch or box. Wrap pouch and put in trash collection. When discarding cut-off end and used collar, wrap in newspaper and place in trash collection.

#### **Back Panel, Side Panel or Bottom Panel**

#### **[LIMITED WARRANTY AND DISCLAIMER**

VIRBAC warrants this product only if it is used, stored and handled in accordance with the label instructions. The buyers and users are solely responsible for all risks of use and handling of this product when such use and handling are contrary to or differ from the label instructions. To the extent permitted by applicable law, any damages arising from a breach of this warranty shall be limited to direct damages only and shall not include any type of consequential damages.]

#### **Back Panel**

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EPA Est. No. [2382-FRA-1] [79975-IL-2] [86169-MO-1]

Made in France Manufactured for Virbac AH, Inc. P.O. BOX 162059 Fort Worth, TX 76161 (800) 338-3659

(lot number on pouch ) (label revision number) (product number)[UPC Code] EPA Reg. No. 2382-104 January 10, 2018 Page 3 of 4

# MASTER LABEL Front Panel, Back Panel, Side Panel or Bottom Panel

[Optional images appear below. The final label may include some or all of the optional images on the front, back, or side panels.]







