



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 6, 2018

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

Subject: Notification per PRN 98-10 – Update the placement of text on label
Product Name: Preventic Tick Collar for Dogs
EPA Registration Number: 2382-104
Application Date: 2/26/2018
Decision Number: 539013

Dear Ms. Foster:

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.

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.

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

Sincerely,

A handwritten signature in black ink that reads "Gene Benbow for".

Gene Benbow, Product Manager 07
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

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]

[KILLS TICKS FOR 3 MONTHS]

[KILLS 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.....91.0%

TOTAL.....100.0%

NOTIFICATION

2382-104

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/06/2018

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)

EPA Reg. No. 2382-104

January 10, 2018 February 22, 2018

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 CLOTHING	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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.

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 ~~V~~yeterinarian.
- 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, Side 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, Side Panel or Bottom Panel

EPA Reg. No. 2382-104

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~~ February 202, 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.]

