

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



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 8, 2010

Nikita S. Mapp
Virbac AH, Inc.
3200 Meacham Blvd.
Ft. Worth, TX 76137

Dear Ms. Mapp,

Subject: Notification of Alternate Brand Names per Pesticide Registration Notice 98-10

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10, dated April 8, 2010, for the product "Preventic Tick Collar for Dogs," EPA Registration Number 2382-104.

The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The information submitted with the application has been stamped "Notification" and will be placed in our records. The alternate brand names "Tick Collar For Dogs Over 60 lbs." and "Tick Collar For Dogs Up To 60 lbs." have been added to the record.

If you have any questions, please contact me directly at 703-308-8735 or email me at chao.julie@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Julie A. Chao".

Julie A. Chao
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs



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SUBMITTED VIA EMAIL ONLY PER EPA REQUEST

April 8, 2010

NOTIFICATION

APR - 8 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTENTION: Julie Chao

Subject: NOTIFICATION OF (alternate brand name) PER PR NOTICE 98-10
PREVENTIC TICK COLLAR FOR DOGS
EPA Reg. No.: 2382-104 (Contains 9% Amitraz)

Dear Ms. Chao:

In accordance with 40 CFR 156 and 152.46, Virbac AH, Inc. submits herewith an application for pesticide notification for an alternate brand name for subject product.

The purpose of this submission is to allow for the use of generic pouch labels: Tick Collar for Dogs Up to 60 lbs. and Tick Collar for Dogs Over 60 lbs.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

The contents and attachments to this notification include the following:

- 1) Cover Letter
- 2) Application for Pesticide Notification (EPA FORM 8570-1)
- 3) Alternate Brand Name Labels: Tick Collar for Dogs Up to 60 lbs. and Tick Collar for Dogs Over 60 lbs.

If there are any questions concerning this notification, please contact me at 314-291-6767 x110 or by fax at 314-447-2003 or by email at nikitamapp@virbacus.com

Sincerely,

Nikita S. Mapp
Regulatory Affairs Manager

Enclosures

3200 Meacham Blvd., Fort Worth, TX 76137 • Telephone: (817) 831-5030 • Fax: (817) 831-8327

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Generic label without "Preventic" in name

Tick Collar

For Dogs Over 60 lbs.

25" COLLAR • Net Wt. 0.97 oz. (27.5g)

**KEEP OUT OF REACH OF CHILDREN
DO NOT ALLOW CHILDREN TO PLAY WITH THE COLLAR
DO NOT OPEN UNTIL READY TO USE**

CAUTION: See back panel for additional precautionary statements and directions.

ACTIVE INGREDIENT:
Amitraz CAS# 33089-61-1 9.0%

OTHER INGREDIENTS 91.0%

TOTAL 100.0%

EPA Reg. No. 2382-104 EPA Est. No. 2382-FR-1

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

DO NOT APPLY TO CATS.

APPLICATION INSTRUCTIONS: Place this collar around the dog's neck, adjust for proper fit and buckle in place. Cut off and dispose of excess length. Do not allow dogs to play with cut-off excess. The collar must be worn tightly enough to contact skin and so that the dog cannot remove it. 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.

800556-03

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

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 or using tobacco. This collar is intended for use as an acaricide generator and is not to be taken internally by man or animal. Not intended 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, malnourished, 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. Sensitivities may occur after using ANY pesticide product for pets. Remove at first sign of irritation or adverse reaction, bathe dog with a 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.

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 emetic. 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.

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.

FIRST AID:

| | |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. |
| 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. |

HOT LINE NUMBER

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact 1-800-345-4735 for emergency medical treatment information.

STORAGE AND DISPOSAL: Storage: Store in original container in locked storage area. Disposal: 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.

EPA Reg. No. 2382-104
EPA Est. No. 2382-FR-1
Lot no. located on pouch.

Made in France

Manufactured for:
Virbac AH, Inc.
P.O. Box 162059
Fort Worth, Texas 76161
(800) 338-3659

800556-03

SIGNOFF & FILE INFO

Virbac ANIMAL HEALTH Colors: Black

| | | | |
|----------------|---------------------------------|-----------------|---------------------------------|
| Product Name: | Generic (25") Tick Collar Pouch | File Name: | Generic(25)Tick Collar Pouch.ai |
| Product Size: | 25" Collar | Trim Size: | W: 4-1/4" x H: 4-3/8" |
| Component No.: | 800556 | Corner Radius: | N/A |
| Revision No.: | 03 | Material: | Sealed Pouch |
| Product Nos.: | 0002186, 609525, 609540 | Material Specs: | |
| Product UPC: | N/A | Colors | 1 Flat Color |
| UPC 14: | N/A | Date: | 10/21/08 |
| Country: | USA | | |

Disposition Orders:

PROOF ONE

Unwind Format for Labels: N/A

THIS WAY
1

AWAY FROM YOU
2

THIS WAY
3

AWAY FROM YOU
4

THIS WAY
5

AWAY FROM YOU
6

THIS WAY
7

AWAY FROM YOU
8

SIGN WITHIN 24 HOURS

OR PASS ON TO ANOTHER PERSON ON LIST.

| | |
|-----------------------|-------|
| Product Manager: | Date: |
| Marketing Director: | Date: |
| Regulatory: | Date: |
| R&D: | Date: |
| Business Development: | Date: |
| Formulations: | Date: |
| Manufacturing: | Date: |
| Quality Assurance: | Date: |
| Translation: | Date: |
| Project Manager: | Date: |

Rev. 07/08

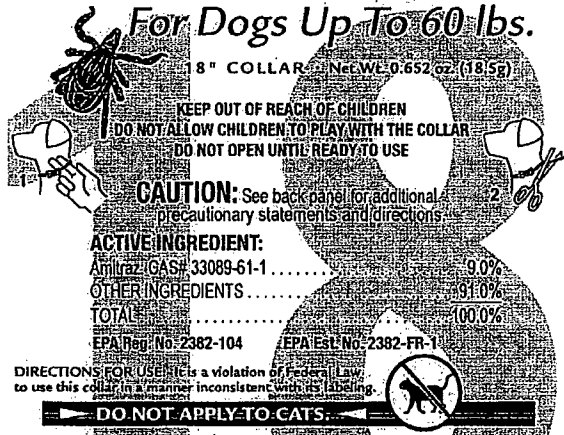
NOTIFICATION

APR - 8 2010

Generic label without "Preventic" in name

Tick Collar

For Dogs Up To 60 lbs.



18" COLLAR Net Wt. 0.652 oz. (18.5g)

**KEEP OUT OF REACH OF CHILDREN
DO NOT ALLOW CHILDREN TO PLAY WITH THE COLLAR
DO NOT OPEN UNTIL READY TO USE**

CAUTION: See back panel for additional precautionary statements and directions

ACTIVE INGREDIENT:

Amfraz (CAS# 33089-61-1) 9.0%

OTHER INGREDIENTS 91.0%

TOTAL 100.0%

EPA Reg. No. 2382-104 EPA Est. No. 2382-FR-1

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

DO NOT APPLY TO CATS.

APPLICATION INSTRUCTIONS: Place this collar around the dog's neck, adjust for proper fit and buckle in place. Cut off and dispose of excess length. Do not allow dogs to play with cut-off excess. The collar must be worn tightly enough to contact skin and so that the dog cannot remove it. 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 reattach to 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. 800555-03

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON CATS.
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 or using tobacco. This collar is intended for use as an acaricide generator and is not to be taken internally by man or animal. Not intended 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.
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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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 • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
 • Call a Poison Control Center or doctor for treatment advice.
 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.

HOT LINE NUMBER
 Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact 1-800-345-4735 for emergency medical treatment information.

STORAGE AND DISPOSAL: Storage: Store in original container in locked storage area.
 Disposal: 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.

EPA Reg. No. 2382-104
 EPA Est. No. 2382-FR-1
 Lot no. located on pouch.
 Made in France

Manufactured for:
 Virbac AH, Inc.
 P.O. Box 162059
 Fort Worth, Texas 76161
 (800) 338-3659

Virbac
 800555-03

| SIGNOFF & FILE INFO | | | |
|----------------------------------|--------------------------------|------------------|---------------------------------|
| Virbac ANIMAL HEALTH | | Colors: | |
| Product Name: | Generic (18) Tick Collar Pouch | File Name: | Generic(18)Tick Collar Pouch.ai |
| Product Size: | 18" Collar | Trim Size: | W: 4-1/4" x H: 4-3/8" |
| Component No.: | 800555 | Corner Radius: | N/A |
| Revision No.: | 03 | Material: | Sealed Pouch |
| Product Nos.: | 002185, 609526, 609541 | Material Specs: | |
| Product UPC: | N/A | Colors: | 1 Flat Color |
| UPC 14: | N/A | Date: | 10/21/08 |
| Country: | USA | | |
| Disposition Orders: | | PROOF ONE | |
| Unwind Format for Labels: N/A | | | |
| | | | |

| SIGN WITHIN 24 HOURS | |
|---------------------------------------|-------------|
| OR PASS ON TO ANOTHER PERSON ON LIST. | |
| Product Manager: | Date: _____ |
| Marketing Director: | Date: _____ |
| Regulatory: | Date: _____ |
| R&D: | Date: _____ |
| Business Development: | Date: _____ |
| Formulations: | Date: _____ |
| Manufacturing: | Date: _____ |
| Quality Assurance: | Date: _____ |
| Translation: | Date: _____ |
| Project Manager: | Date: _____ |

NOTIFICATION
APR - 8 2010