



004691-00150-062599

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Systems Integration Group, Inc.

PM 03

4691-150

6/25/99

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (H7505C)401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number

4691-150

Date of Issuance

JUN 25 1999

NOTICE OF PESTICIDE:

__ Registration

☒ Reregistration

under FIFRA, as amended.

Term of Issuance: Unconditional

Name of Pesticide Product:

Americare™ Rabon® Flea and
Tick Collar for Dogs

Name and Address of Registrant (include ZIP Code):

Boehringer Ingelheim Vetmedica, Inc.

2621 North Belt Highway

St. Joseph, MO 64506-2002

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by other.

Based on your response to the Reregistration Eligibility Documents, EPA has reregistered the product listed above. This action is taken under the authority of section 4 (g) (2) (c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for control reassessment of pesticides. EPA may require submission of data at anytime to maintain the registration of your product.

- 1) The correct chemical name for your product should be listed as the following, which is the more specific isomer designation (please revise your active ingredients statement accordingly):

“Tetrachlorvinphos: (Z)-2chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate”.

- 2) The word “CAUTION” should appear after your statement “Do not let children play with this collar”, not before.
- 3) Per PR Notice 96-6, please place your company or Animal Poison Control Center telephone number on your label. This number should be a resource for consumers in the event of an emergency or to receive information concerning the proper use of your product. Additionally, please put your EPA establishment number directly beneath your EPA Reg. No.

Signature of Approving Official

George T. L. Brown
George T. L. Brown

Date

JUN 25 1999

- 4) Please rename your "Statement of Practical Treatment" to read "First Aid". It should be located under your "Precautionary Statements" and state the following:

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

- 5) Your product is also required to have a "Note to Physicians and Veterinarians". This should be located directly below your Statement of Practical Treatment and should contain the following information:

- Technical information on symptomatology;
- Use of supportive treatments to maintain life functions;
- Medicine that will counteract the specific physiological effects of the pesticide;
- Company telephone number to specific medical personnel who can provide specialized medical advice.
- Information for veterinarians.

- 6) Please revise your "Hazards to Humans" heading to read "Hazards to Humans and Domestic Animals". It should read the following:

CAUTION

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

- 7) Your product is subject to PR Notice 96-6 (Pet Pesticide Product Label Statements). Please add the following precautions to your label:

- a) The following statement should be inserted at the top of the rear or side panel in bold, all caps.

"READ ENTIRE LABEL BEFORE EACH USE."

Please follow this statement with the type of animal your product may be used on:

"USE ONLY ON (DOGS, CATS, or DOGS OR CATS)."

- b) If your product has certain precautions or incidents associated with it, follow this statement with the specific breeds that your product should not be used on:

"Do not use on...(specific breed)"

- c) Delete the sentence that states "It is not advisable to use this collar or similar pesticides on puppies less than 6 weeks of age". Please state only: "Do not use on puppies under 6 weeks of age".

- d) Please state the following:

"Consult a veterinarian before using this product on debilitated, aged, or medicated animals. If used on pregnant or nursing dogs, do not replace collar until the puppies are at least 6 weeks old"

- e) Please put the following statement after your precautionary statements.

"Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur remove collar and bathe your pet with mild soap and rinse with large amounts of water."

- f) Please delete the statement "For continuous flea and tick protection under normal conditions replace the collar every 5 months. Under conditions where dogs are exposed to severe flea or tick infestations it may be necessary to replace the collar more frequently". The second sentence of this statement is ambiguous and does not provide the consumer with the minimum acceptable amount of time between applications. Please replace the above with this statement: "For continuous flea and tick protection under normal conditions replace the collar every 5 months. Under conditions where dogs are exposed to severe flea or tick infestations it may be necessary to replace the collar more frequently, however do not replace the collar more frequently than every _____ months" (the minimum duration between collar changes should be based on your efficacy and domestic animal safety data).
- g) Please add the following statement: "Do not use this product on animals simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals. Flea and tick collars may be immediately replaced with new collars."
- 8) Enclosed is a copy of your label stamped "Accepted with Comments". Please submit two (2) copies of your final printed label for before your release the product for shipment. Please refer to the A-79 enclosure for a further description of final printed labeling.

If you have any questions regarding this action, please contact Tracy Keigwin of my team at (703) 305-6605.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

AMERICARE™ RABON® FLEA & TICK COLLAR FOR DOGS

Kills For 5 Months

ACTIVE INGREDIENT:

Tetrachlorvinphos: 2-Chloro-1-(2,4,5-trichloro-phenyl) vinyl dimethyl phosphate 13.7%

INERT INGREDIENTS: 86.3%

TOTAL 100.0%

CAUTION:

Do not let children play with this collar

CONTENTS: 1 COLLAR,
NET WT. 0.85 oz 24 g

EPA Reg. No. 4691-150

Boehringer Ingelheim Animal Health Inc.
St. Joseph, MO 64506-2002

PRECAUTIONARY STATEMENTS

Hazards to Humans

Caution

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Wash thoroughly with soap and water after handling. This product may cause skin sensitization reactions in certain individuals.

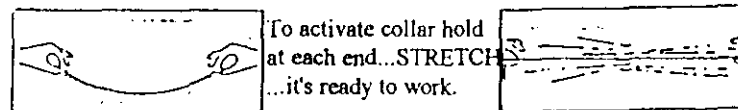
STATEMENT OF PRACTICAL TREATMENT

If in eyes - Flush with plenty of water. If irritation persists, seek medical attention.

DIRECTIONS FOR USE

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

REMOVE COLLAR FROM PACKAGE, UNROLL AND STRETCH TO ACTIVATE INSECTICIDE GENERATOR



It is not advisable to use this collar or similar pesticides on puppies less than 6 weeks of age. Do not unroll collar until ready to use. Place the Americare Rabon Flea & Tick Collar around the dog's neck, adjust for proper fit, and secure in place. The collar must be worn loosely to allow for growth of the dog and to permit the collar to move about the neck. Generally, a properly fitted collar is one that when fastened will snugly slide over the dog's head. Leave 2 or 3 inches on the collar for extra adjustment and cut off and dispose of the extra length. Some animals may become irritated by any collar if it is applied too tightly. If this occurs, loosen the collar. If irritation continues, remove the collar from the animal. This collar is intended for use only as an insecticide generator.

Kills fleas and ticks common to dogs. The Americare Rabon Flea & Tick Collar will begin to kill fleas and ticks immediately. Its full protection against harder to kill ticks will be built up within a few days after being placed on the pet. For continuous flea and tick protection under normal conditions replace the collar every five months. Under conditions where dogs are exposed to severe flea or tick infestations it may be necessary to replace the collar more frequently. Wetting will not impair the collar's effectiveness or pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar. The Americare Rabon Flea & Tick Collar may be worn with a regular collar.

DISPOSAL - Do not use empty pouch. Dispose in trash collection.

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