

2596-84

5/14/2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Robert Rosenwasser
Director, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

MAY 14 2009

RE: Notification for addition of Optional Marketing Statements
EPA Registration Number: 2596-84
Submission Dated: March 19, 2009

Dear Mr. Rosenwasser:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated, March 19, 2009, for the product, Hartz 2 in 1 Plus 7 Month Collar for Dogs with Rabon. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested does not clearly fall within the scope of PRN 98-10 and will require additional administrative review of the related files. A summary of our findings include:

1. Per a conversation with Product Manager, the claim "safety" will require evaluation as an amendment.

Therefore, the RD has determined that this action is denied and will be further processed as a fast track amendment and our records have been updated accordingly. The label submitted with the application is considered proposed drafts and has been forwarded to Richard Gebken, PM 10 for further processing.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely yours,

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

2009

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-84	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ 2 In1 Plus 7 Month Collar For Dogs with Rabon	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

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Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Addition of Optional Marketing Statements per PR Notice 98-10"

"This notice is consistent with the provisions of PR Notices 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 FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Robert Rosenwasser	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) 201-271-4800, ext. 7202
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Director, Regulatory Affairs	
4. Typed Name Robert Rosenwasser	5. Date 3/19/09	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

March 19, 2009

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

Attention: Mr. Richard Gebken (PM # 10)
RE: HARTZ 2 In 1 Plus 7 Month Collar for Dogs with Rabon
EPA Reg. No. 2596-84
Addition of Optional Marketing Statements Per PR Notice 98-10

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this notification to add an additional marketing statement to the product.

This product serves two valuable functions for the dog owner. The formulation itself contains tetrachlorvinphos, an insecticidal active which offers properties to kill and repel fleas and ticks.

The second property of this dog collar is the inclusion of Reflective Technology through the use of a reflective strip that allows the dog's collar to become visible for up to 300 feet when headlights shine on the collar itself. This important characteristic provides a degree of safety to the dog when the collar is made visible allowing the dog to be seen by a driver who comes within 300 feet of the dog on a path, road or street.

This safety characteristic of the collar itself is vital to the incorporation of the Reflective Technology and in no manner implies safety of the collar in terms the use of the active ingredient as an insecticide when used on the dog. Any reference to safety is strictly related to the reflective strip on the collar and does not connote safety in terms the product formulation. There is no implied safety claim relating to the insecticidal component of the product. It is important to Hartz to make our customers aware of this non-pesticidal property of the product. Many animals are killed each year on the highways and this technology provides a tool for the physical safety of the dog at night when walking along roads.

Handwritten marks and symbols at the bottom right of the page, including several rows of small circles and dashes.

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Hartz® 2 in 1® Plus Seven Month Collar for Dogs

3/16/09

EPA Reg. No.: 2596-84

MASTER LABEL BASED ON 10/7/08 EPA STAMPED APPROVED LABEL

Hartz® 2 in 1® Plus Seven Month Collar for Dogs

Alternate Brand Name(s)

- Hartz® UltraGuard™ Flea (&) (and) Tick Collar for (Dogs) (&) (and) Puppies
- Hartz® UltraGuard™ Flea (&) (and) Tick Collar for Small Dogs
- Hartz® UltraGuard™ Flea (&) (and) Tick Collar for Large Dogs
- Hartz® UltraGuard™ Reflecting Flea (&) (and) Tick Collar for Dogs (&) (and) Puppies
- Hartz® UltraGuard™ Reflecting Flea (&) (and) Tick Collar for Small Dogs
- Hartz® UltraGuard™ Reflecting Flea (&) (and) Tick Collar for Large Dogs
- Hartz® UltraGuard™ Reflecting Flea (&) (and) Tick Collar for Puppies

- Hartz® Advanced Care™ 2 in 1® 7 Month Flea and Tick Collar for Dogs
- Hartz® Advanced Care™ 2 in 1® 7 Month Flea and Tick Collar for Large Dogs
- Hartz® Advanced Care™ 2 in 1® 7 Month Flea and Tick Collar for Puppies
- Hartz® Advanced Care™ 2 in 1® Reflecting 7 Month Flea and Tick Collar for Dogs
- Hartz® Advanced Care™ 2 in 1® Reflecting 7 Month Flea and Tick Collar for Large Dogs
- Hartz® Advanced Care™ 2 in 1® Reflecting 7 Month Flea and Tick Collar for Puppies
- Hartz® Advanced Care™ 2 in 1® Collar for Dogs
- Hartz® Advanced Care™ 2 in 1® Collar for Large Dogs
- Hartz® Advanced Care™ 2 in 1® Collar for Puppies
- Hartz® Advanced Care™ 2 in 1® Reflecting Collar for Dogs
- Hartz® Advanced Care™ 2 in 1® Reflecting Collar for Large Dogs
- Hartz® Advanced Care™ 2 in 1® Reflecting Collar for Puppies

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- Hartz® 2 in 1® Collar for Dogs
- Hartz® 2 in 1® Collar for Large Dogs
- Hartz® 2 in 1® Collar for Puppies
- Hartz® 2 in 1® Reflecting Collar for Dogs

ACTIVE INGREDIENT:

Tetrachlorvinphos14.55%

OTHER INGREDIENTS85.45%

TOTAL100.00%

CAUTION: Do not let children play with this collar.

See (side) (back) panel(s) for additional precautionary statements.

NET CONTENT(S): 1 (white) (pink) (orange) (blue) (yellow) (purple) (red) (grey) (hunter green)(green)(black)(silver)(gold)(reflecting)(reflective) COLLAR, (NET. WT.) *(Range from 19 g to 32 g depending on size of animal)*

EPA Reg. No. 2596-84

EPA Est. No. 2596-NJ-1

Hartz® 2 in 1® Plus Seven Month Collar for Dogs

3/16/09

EPA Reg. No.: 2596-84

MASTER LABEL BASED ON 10/7/08 EPA STAMPED APPROVED LABEL

Made (in the U.S.A.) by
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094 (U.S.A.)

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS.**

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

If Swallowed: Call a 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 a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

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.

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 the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact 1-800-275-1414 for emergency medical treatment information.

Note to Physicians and Veterinarians: This product contains tetrachlorvinphos (an organophosphate) which is a cholinesterase inhibitor. Cholinergic symptoms may include salivation, miosis, incoordination, muscle fasciculation and/or weakness, vomiting and diarrhea. Atropine is antidotal. 2-PAM may be effective as an adjunct to atropine. Call 1-800-275-1414 or your local Poison Control Center for further information.

DIRECTIONS FOR USE

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

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Hartz® 2 in 1® Plus Seven Month Collar for Dogs

3/16/09

EPA Reg. No.: 2596-84

MASTER LABEL BASED ON 10/7/08 EPA STAMPED APPROVED LABEL

REMOVE COLLAR FROM PACKAGE, UNROLL AND STRETCH TO ACTIVATE INSECTICIDE GENERATOR. As the collar begins to work, a fine white powder will appear on the surface.

Do not use on puppies under 6 weeks of age. Do not unroll collar until ready to use. Place the (brand name) (collar) around the dog's neck, adjust for proper fit, and buckle 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.

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. Sensitivity may occur after using ANY pesticide product for pets. 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 dog. If signs of sensitivity occur, remove the collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Do not use this product on dogs simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea and tick collars may be immediately replaced.

This collar is intended for use only as an insecticide generator.

(Kills fleas and ticks common to dogs, including the Deer tick, which may carry Lyme disease, and the Rocky Mountain wood tick, which may carry Rocky Mountain spotted fever.) The 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 seven months. The collar kills ticks for 5 months and aids in their control an additional 2 months. Under conditions where dogs are exposed to severe flea and tick infestations it may be necessary to replace the collar more frequently; however, do not replace the collar more frequently than every 5 months. 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. The (brand name) (collar) may be worn with a regular collar. It is recommended that the pet's bedding or sleeping quarters be treated for flea and tick control with a product registered for this use such as (brand name).

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product in a cool, dry place that is inaccessible to children.

Pesticide Disposal: If empty: Nonrefillable container. Do not refill or reuse this container. Offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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Hartz® 2 in 1® Plus Seven Month Collar for Dogs

3/16/09

EPA Reg. No.: 2596-84

MASTER LABEL BASED ON 10/7/08 EPA STAMPED APPROVED LABEL

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

For Dogs
For Puppies
For Dogs (&) (and) Puppies

With deodorant

(Clean) (Fresh) (deodorant) scent
Powerful Results When You Need (it)(them)

EASY ACTIVATION - To activate collar, hold at each end ... STRETCH ... and it's ready (to work) (to kill fleas & ticks) (for your dog to wear).

The Hartz® (brand name) provides an added dimension of nighttime (visibility) (safety) for you and your pet. The collar will reflect (up to 300 feet) when light shines directly on (onto) the reflecting strip.

Water resistant

Fits up to (range from 15" to 26") necks

For (dogs) (and) (&) (puppies) with necks up to (range from 15" to 26")

Reflects Direct Light up to (200 ft.) (250 ft.) (300 ft.) (400 ft.) (450 ft.) (500 ft.) (550 ft.) (600 ft.)

White Collar with Reflecting Technology

White Collar with Reflective Technology

Visible (in) (to) headlights

Important: Consumer information and pet I.D. tag offer printed on inside of package.

Hartz® (brand name) products are designed to complement each other in an integrated program for flea (and)(&) tick management. To assure proper treatment, we recommend use of only Hartz® (brand name) products.

To learn more about treating current infestations and preventing future outbreaks please visit our website (www.hartz.com)(www.hartzultraguard.com)

To learn more visit (www.hartz.com)(www.hartzultraguard.com)

(PLEASE) VISIT OUR WEBSITE (AT) (www.hartz.com)(www.hartzultraguard.com)

Hartz recommends that you visit your veterinarian twice a year.

Be sure to read full directions and precautions on the label of every product you use.

Remember to always read each product label and follow the directions carefully.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

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