2596-125



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

AUG 2.4 2007

RE: Addition of Optional Marketing Statements EPA Registration Number: 2596-125 Date of Submission: July 23, 2007

Dear Mr. Rosenwasser:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated July 23, 2007, for the product Hartz 2 in 1 Flea and Tick Pump for Dogs II. 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 label submitted with the application has been stamped "Notification" and will be placed in our records.

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

Sincerely,

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

| ase read instructions on reverse before completing form | n. Form Approved. OMB | Hq No. 2070-0060, Approvel expires 2-28-9 |
|--|---|--|
| United St Environmental Prote Washington, D | ection Agency | istration ^{OPP Identifier Number} endment |
| Appli | cation for Pesticide - Section I | |
| 1. Company/Product Number 2596-125 | 2. EPA Product Manager R. Gebken | 3. Proposed Classification |
| 4. Company/Product (Name) HARTZ 2 In 1 Flea and Tick Pump for Dogs II | РМ# 10 | |
| 5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 | (b)(i), my product is similar or to: EPA Reg. No | cordance with FIFRA Section 3(c)(3) identical in composition and labeling |
| | Product Name Section - II | |
| Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. | Final printed labels in rep Agency letter dated "Me Too" Application. Other - Explain below. | AUG 2 4 2007 |
| Explanation: Use additional page(s) if necessary. (For s "Addition of optional marketing statements per PR Notice 98- "This notice is consistent with the provisions of PR Notices 98 labeling or the Confidential Statement of Formula of this produ- to EPA. I further understand that if this notification is not cons FIFRA and I may be subject to enforcement action and penalt | 10" 3-10 and EPA regulations at 40 CFR 152.46, and no o uct. I understand that it is a violation of 18 U.S.C. Sec. istent with the terms of PR Notice 98-10 and 40 CFR | . 1001 to willfully make any false statement |
| | Section - III | |
| 1. Material This Product Will Be Packaged In: | | |
| Child-Resistant Packaging Yes No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No Ves No | Pres No. per | De of Container Metal Plastic Glass Paper Other (Specify) |
| 3. Location of Net Contents Information 4. Size(s Label Container | s) Retail Container 5. Location o | f Label Directions |
| 6. Manner in Which Label is Affixed to Product | _ithographOther Paper glued Stenciled | · |
| | Section - IV | · |
| 1. Contact Point (Complete items directly below for identif | fication of individual to be contacted, if necessary, | to process this application.) |
| Name Robert Rosenwasser | Title Director, Regulatory Affairs | Telephone No. (m.ciude Area Code) 201-271-4800, ^c ext. 7202 |
| Cert I certify that the statements I have made on this form I acknowledge that any knowlinglly false or misleadir both under applicable law. | tification n and all attachments thereto are true, accurate an ng statement may be punishable by fine or imprisor | d complete. wnentrol to |
| 2. Signature | 3. Title Director, Regulatory Affairs | |
| 4. Typed Name Robert Rosenwasser | 5. Date 7/23/07 | |

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

'n

Yellow - Applicant Copy

Hartz[®] 2 in 1[®] Flea & Tick Pump for Dogs II

Alternate Brand Names

Hartz[®] Advanced CareTM 2 in 1[®] Flea & Tick Dog Spray Hartz[®] 2 in 1[®] Flea & Tick Dog Spray Hartz[®] UltraGuardTM Flea (&) (and) Tick Spray for Dogs

| ACTIVE INGREDIENT: | (BY WEIGHT) (NOM.) |
|--|--------------------|
| Tetrachlorvinphos [CAS#22248-79-9] | |
| OTHER INGREDIENTS | <u>98.92%</u> |
| (TOTAL | |
| Note: CAS # may or may not be shown on label | |

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements. See (side) (back) panel for ingredients and additional precautions

fl. oz. mL

EPA Reg. No. 2596-125 EPA Est. No. 2596-NJ-1

[Made (by Hartz[®]) in (the) U.S.A. (by)] ©The Hartz Mountain Corporation Secaucus, NJ 07094 (U.S.A.) (and St. Thomas, Ontario N5P 3W7 Canada)

(U.S. Patent No. 5,595,749)

Note: Optional/alternate text in parentheses or brackets

7/23/07

NOTIFICATION

AUG 2 4 2007

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands and exposed skin thoroughly with soap and water after handling.

Do not use on puppies under 6 weeks old. Consult a veterinarian before using this product on debilitated, aged, or medicated animals. Sensitivity may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Do not use near birds, fish or foodstuffs. If used on pregnant or nursing dogs, do not retreat until the puppies are at least 6 weeks old. Do not use this product 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 after use.

FIRST AID: Contains an organophosphate that inhibits cholinesterase.

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.

Note to Physicians and Veterinarians: This product contains an organophosphate and may cause cholinesterase inhibition. Cholinergic symptoms may include salivation, missis, 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.

SHAKE WELL BEFORE USE

- 1. Hold bottle upright 6 inches from pet. Direct spray towards pet and spray entire coat, pressing dispenser with quick short strokes. Move bottle to get even coverage of coat (until tips of hair are moist).
- 2. Apply lightly and rub into animal's coat. For longhaired dogs, ruffle hair for spray to reach skin.
- 3. Recommended dosage: Spray 25-30 strokes for a small dog (e.g. Terrier). Spray 30-40 strokes for a medium dog (e.g. Spaniel). Spray 40-70 strokes for a large
- dog (e.g. Labrador). More spray may be needed for longhaired dogs.
- 4. Ticks are tough—spray directly.

Hartz[®] 2 in 1[®] Flea & Tick Pump for Dogs II EPA Reg. No.: 2596-125 MASTER LABEL

- 5. After 10 minutes, dry dog with towel.
- 6. Comb and brush coat.
- 7. Repeat once a week. Use on bedding and other areas as needed.

STORAGE AND DISPOSAL

Storage: Store at room temperature.

Disposal: If empty: Do not re-use this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information (or help at any step,) call our flea and tick experts at 1-800-275-1414 weekdays, 9am-5pm (E.S.T.) (Eastern Time).

OPTIONAL/ALTERNATE LABEL TEXT

(Kills) (&) (and) (Repels) (Fleas) (&) (and) (Ticks)

Actively (Kills) (&) (and) (Repels) (Fleas) (&) (and) (Ticks)

Actively (Kills) (Fleas) (&) (and) (Ticks)

(Kills) (&) (and) (Repels) (Fleas) (&) (and) (Ticks) on Contact

(Kills) (Fleas) (&) (and) (Ticks) on Contact

Starts Working on Contact

Powerful Results When You Need It

Clean Fresh Scent

Patented formula

[All **bolded** text below represents one label statement with any selected line bulleted.]

When your dog has fleas and ticks, your family and pet may be exposed to:

(Fleas that may cause)

Flea allergy dermatitis

Flea bite anemia

Tapeworm infestation

(Deer ticks which may carry Lyme disease)

Lyme disease

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

To learn more visit <u>www.hartz.com</u>

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. Kills Fleas

Kills Ticks

Kills the Deer tick which may carry Lyme disease

Kills and repels fleas and ticks

Fast acting

Hartz[®], 2 in 1[®], Flea & Tick Pump for Dogs II (this product) (alternate brand name) (actually) prevents fleas and ticks from living on your pet. This spray may also be used to kill any fleas and ticks already on your dog. Once sprayed, fleas will be killed within 5 to 10 minutes.

Important

The ABC's of Flea & Tick Management

(Control Pet Care System) (alternate brand name) products are designed to work together. in a complete insecticidal system. For elimination of fleas and ticks, it is necessary to treat not only the pet but also its surrounding environment. Use (Control Pet Care System) (alternate brand name) products and follow these simple ABC's to get rid of fleas and ticks on your pet and around your home.

6 1-6 6 6 6 6 7 7/23/07

OPTIONAL/ALTERNATE LABEL TEXT, cont'd.

STEP A—TREAT YOUR PET with one of the (Control) (alternate brand name) such as Conditioning Shampoo, Dip, Powder or Spray. Use a (Control) (alternate brand name) product containing vIGRen[®], an insect growth regulator (IGR) to also stop hatching flea eggs from developing into biting adults.

STEP B—PROTECT YOUR PET with a (Control) (alternate brand name) repellent or flea and tick collar to keep fleas and ticks from reinfesting your pet. The (Control Pet Care System Ultimate Flea Collar) (alternate brand name) will also prevent flea eggs from hatching.

STEP C—TREAT YOUR HOME both indoors and outdoors with (Control Pet Care System) (alternate brand name) Home Flea & Tick Killer or Fogger with vIGRen[®], and (Control Pet Care System) (alternate brand name) Yard and Kennel Spray to protect your entire home and guard against reinfestation. The (Control Pet Care System) (alternate brand name) Flea Trap will also serve to help break the flea life cycle by killing fleas in hard to reach areas in your home. Be sure to read full directions and precautions on the label of each product you use.

The Stress-Free System For Controlling Fleas & Ticks

On Animal Protection

Relief for your pet

Use (Releve Pet Protection System) (alternate brand name) Conditioning Shampoo, Dip, Spray, or Powder to kill fleas and ticks living on your pet.

Repellent

Keep fleas and ticks off your pet

Prevent any more fleas and ticks from coming onto your pet by spraying your pet with (Releve Pet Protection System Repellent for Dogs or Repellent for Cats) (alternate brand name).

Continuous Protection

Long-term protection for your pet

Keep fleas and ticks from reinfesting your pet with (Releve Pet Protection System 7-Month Flea & Flea Egg Collar with vIGRen[®]) (alternate brand name), which will prevent flea eggs from hatching and Rabon[®] to kill adult fleas and ticks.

Home & Yard

Protect your home and yard

Kill fleas and ticks around your home with (Releve Pet Protection System) (alternate brand name) Carpet Powder, Yard and Kennel Spray, Home Flea & Tick Killer and Home Fogger.

7/23/07

OPTIONAL/ALTERNATE LABEL TEXT, cont'd.

Remember to always read each product label and follow the directions carefully. Rabon[®] is a registered trademark for tetrachlorvinphos. vIGRen[®] is a registered trademark of Wellmark Intl.

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT:

Deodorizing Formula Deodorizes Deodorizing Water-based (formula) Fine Mist Spray In addition to controlling fleas and ticks, this product leaves your pet's coat soft, glossy, and manageable.

Rabon[®] is the Hartz[®] trademark for tetrachlorvinphos Hartz[®] Every Pet's Best FriendTM VISIT OUR WEBSITE <u>www.hartz.com</u> For full precautions and directions for use, peel back here

(Unconditional) Money back guarantee (by Hartz[®])

Hartz[®] and other trademarks are trademarks of the Hartz Mountain Corporation

Note: Optional/alternate text in parentheses or brackets

.



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

July 23, 2007

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 Flea & Tick Pump for Dogs II, EPA Reg. No. 2596-125

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 optional marketing statements for the product.

The Hartz Mountain Corporation is submitting the following information:

- A completed application (EPA Form 8570-1);
- Three copies of the proposed label.

"This notice 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."

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or mailto:<u>rrosenwasser@hartz.com</u>.

Sincerely

Kobert Rosenwasser Director, Regulatory Affairs