2596-79

10/1/2008



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

October 1, 2008

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

## Subject: Amended Labeling, Incorporation of Previously Rescinded Notification Language Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea and Tick Powder for Dogs, EPA Reg. No. 2596-79 Your Submission Dated July 2, 2008

Dear Mr. Rosenwasser:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following provision(s):

General Statement:

1. Delete all text throughout the label marked with "strikethrough."

Precautionary Statements section, Hazards to Humans and Domestic Animals subsection comment(s):

2. Replace the 5<sup>th</sup> sentence in paragraph #1 with: "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."

First Aid Statement section, Note to Physicians and Veterinarians subsection comment(s):

- 3. It is important to note that the "1-800-275-1414" phone number should be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.
- 4. In the **"Note to Physicians and Veterinarians:**" subsection, replace the 1<sup>st</sup> sentence with: "This product contains tetrachlorvinphos (an organophosphate), which is a cholinesterase inhibitor."

#### Storage and Disposal Statement section comment(s):

5. To facilitate inclusion of language from PR Notice 2007-1, you should replace this section with:

#### 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 reuse or refill this container. Offer for recycling, if available. **If partly filled:** Call your local solid waste agency [or toll free number or website which meets the criteria in paragraph II.E., P.R. Notice 20007-1] for disposal instructions. Never place unused product down any indoor or outdoor drain. Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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 section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists 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 be 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours, ichand lech

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments" 002596-00079 D397436

7/1/08

# Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea and Tick Powder for Dogs

<u>Alternate Brand Names</u> Hartz<sup>®</sup> UltraGuard<sup>TM</sup> Flea & Tick Powder for Dogs Hartz<sup>®</sup> Advanced Care<sup>TM</sup> 2 in 1<sup>®</sup> Flea and Tick Powder for Dogs

# **ACTIVE INGREDIENT:**

Tetrachlorvinphos (CAS #22248-79-9)	3.3%
OTHER INGREDIENTS	<u>96.7%</u>
TOTAL	100.0%

Note: CAS numbers may or may not be included in ingredient statement

# **KEEP OUT OF REACH OF CHILDREN**

# CAUTION

See back panel-for-additional precautionary statements. See (back) (side) panel(s) for (ingredient) (and) additional precautionary statements. [Ingredient statement on the back of 4 oz package only]

**NET CONTENT** oz. (

EPA Reg. No. 2596-79 EPA Est. No. 2596-NJ-1

Made (in the USA) by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

> ACCEPTED with COMMENTS In EPA Letter Dated

Under the Federal Insectic

Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA\_Reg. No. New text is highlighted; optional/alternate text is shown in (parentheses) or [brackets]

# 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. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Not for use on puppies less than 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or medicated animals. Sensitivity may occur after using ANY pesticide product on 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 this product on animals 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.

FIRST AID – Contains an organophosphate that inhibits cholinesterase.

If swallowed •Call 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 the 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 an organophosphate and may cause cholinesterase inhibition. Cholinergic symptoms may include salivation, miosis, incoordination, muscle fasciculation and/or weakness, vomiting and diarrhea. Atropine is antidotal only if symptoms of cholinesterase inhibition are present. 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.

### **READ ENTIRE LABEL BEFORE EACH USE**

# USE ONLY ON DOGS

To kill fleas, ticks and lice, and to reduce itching and scratching due to insect bites, dust entire dog beginning at head and working back. Make sure that the powder gets down to the skin. Take care to treat feet and legs.

To kill fleas and ticks:

1. Dust entire dog beginning at head and working back.

2. Make sure that the powder gets down to the skin.

3. Take care to treat feet and legs.

4. Lightly dust dog's bedding with approximately the same amount of powder. 5. Repeat treatment of dog and bedding at weekly intervals if necessary.

Recommended Dosage: Use approximately ½ ounce of powder for a small dog (e.g. Terrier). Use approximately 1 ounce of powder for a medium dog (e.g. Spaniel). Use approximately 1.¼ ounce of powder for a large dog (e.g. Labrador). More powder may be needed for longhaired dogs. There is sufficient powder in this container to treat a small dog 8 times.

To control Sarcoptic Mange – a problem often encountered by dogs. Lesions which form are usually characterized by loss of hair, redness and possible open sores. Hartz 2 in 1 Flea and Tick Powder will kill the mite which causes this problem. To treat the dog, apply the powder as directed above, making sure that all sores and lesions are covered. Repeat application weekly for at least 3 treatments. More advanced lesions may require further weekly treatments. The area-will begin to heal-immediately, but complete healing, including hair growth, may take several weeks. If irritation persists, consult your veterinarian.

To control Sarcoptic Mange

1. Apply the powder as directed above, making sure that all sores and lesions are covered.

2. Repeat application weekly for at least 3 treatments.

3. More advanced lesions may require further weekly treatments.

The area will begin to heal immediately, but complete healing, including hair growth, may take several weeks. If irritation persists, consult your veterinarian

New text is highlighted; optional/alternate text is shown in (parentheses) or [brackets]

# STORAGE AND DISPOSAL

If empty. Do not reuse this container. Place in trash or 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.

# **OPTIONAL/ALTERNATE LABEL TEXT**

Kills fleas

Kills ticks

Kills fleas and ticks, including the deer tick which may carry LYME DISEASE KILLS LICE WHEN A PROBLEM FAST ACTING LASTS 7 DAYS KILLS INSECTS WHICH MAY CAUSE ITCHING AND SCRATCHING CONTROLS SARCOPTIC MANGE Kills (Fleas) (Ticks) (Lice) Kills (Fleas) (&) (and) (Ticks) (through contact) (Immediately) starts to kill (Fleas) (&) (and) (Ticks) (through contact) Kills fleas which may cause (flea bite anemia) (flea allergy dermatitis) Kills fleas that may transmit tapeworm Kills (and repels) (fleas) (ticks) (Starts) Killing (through) contact Kills (through) contact Flea and tick control

X Day Protection

# NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Direct treatment With Rabon\* \*Rabon is the Hartz® trademark for Tetrachlorvinphos Unaffected by water Water Resistant For more information call our (flea and tick) experts at 1-800-275-1414 weekdays, 9am-5pm (E.S.T.) (Eastern Time). Visit (our website) (www.hartz.com ) (www.hartzultraguard.com) Hartz® — every pet's best friend Made in the USA (by) ©The Hartz Mountain Corporation Secaucus, NJ 07094 (and St. Thomas, Ontario N5P 3W7, Canada) Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation. For more information, call our experts at xxx-xxx-xxxx

New text is highlighted; optional/alternate text is shown in (parentheses) or [brackets]

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.

As with all flea and tick products, they are most effective when used as part of a total program aimed at reducing fleas and ticks in the (dog's) (cat's) (pet's) environment A single female flea can lay [an average of] 25 eggs per day [on average]

Complete your preventative program with products that kill both adult and pre-adult fleas.

(Complete your defense against fleas with) (two) ingredients targeted at (killing fleas) (breaking the life cycle)

Be sure to treat the animal's bedding and surroundings with product registered for these uses, such as Hartz (brand name) line (products)