



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

October 7, 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Amended Labeling, Incorporation of Previously Rescinded Notification Language Hartz $^{\otimes}$  2 in 1 $^{\otimes}$  Flea & Tick Dip for Dog and Cats with Pyrethrin, EPA Reg. No. 2596-86 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):

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

- 1. Replace the 3<sup>rd</sup> sentence with: "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
- 2. Replace the 5<sup>th</sup> sentence starting with "Do not use on puppies ..." with: "Do not apply to pets (puppies or kittens) less than twelve (12) weeks old."

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

 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.

#### Environmental Hazards section comment(s):

4. To facilitate inclusion of language from the Reregistration Eligibility Decision (RED) document for pyrethrins, replace this section with: "This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment wash water or rinsate. See Directions of Use for additional precautions and requirements."

#### Physical or Chemical Hazards section comment(s):

- 5. The section title should be changed from "Physical Hazards:" to "Physical or Chemical Hazards:"
- 6. Replace this section with: "Combustible. Do not use or store near heat or open flame."

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

7. 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.

The Hartz Mountain Corporation should note that a notice of availability of EPA's RED for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). In addition, EPA's RED for products containing piperonyl butoxide was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42385-42386). As a result, additional data and/or labeling changes may be required for products containing pyrethrins and/or piperonyl butoxide.

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.

Richard J. Gebken Product Manager (10)

Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments" 002596-00086 D397475

7/1/08

### Hartz® 2 in 1® Flea & Tick Dip for Dogs and Cats with **Pyrethrin**

#### Alternate Brand Names

Hartz<sup>®</sup> UltraGuard<sup>TM</sup> Flea & Tick Dip for Dogs & Cats Hartz<sup>®</sup> Advanced Care<sup>TM</sup> 2 in 1<sup>®</sup> Flea & Tick Dip Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Dip

| ACTIVE INGREDIENTS:  | (By Weight)   |
|--|---------------|
| ACTIVE INGREDIENTS: Pyrethrins (CAS# 121-29-9)                       | 0.33%         |
| Piperonyl butoxide, technical* (CAS # 51-03-6)                       | 0.67%         |
| N-octyl bicycloheptene dicarboximide (CAS# 113-48-4)                 | 1.11%         |
| OTHER INGREDIENTS  | 97.89%        |
| TOTAL  | 100.00%       |
| *Equivalent to 0.54% (butylcarbityl)(6-propylpiperonyl) ether and    | 0.13% related |
| compounds. Contains petroleum distillate.                            |               |
| 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 additional precautionary statements.

ACCEPTED with COMMENTS In EPA Letter Dated

Under the Federal Insecticide. Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

NET CONTENT \_\_\_fl. oz. (\_\_\_ ml)

EPA Reg. No. 2596-86 EPA Est. No. 2596-NJ-1

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

EPA Reg. No.: 2596-86

MASTER LABEL BASED ON 10/14/04 EPA STAMPED APPROVED LABEL

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid contact with skin or eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Do not contaminate food or feedstuffs with this concentrate or dip. Do not use on puppies or kittens under (less than) twelve (12) weeks of age.

#### FIRST AID

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.

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.

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 Physician: Contains petroleum distillate. Vomiting may cause aspiration pneumonia.

ENVIRONMENTAL HAZARDS: Toxic to fish. Do not contaminate any body of water with this concentrate or dip.

PHYSICAL HAZARDS: Do not use, pour, spill, or store near heat or open flames.

#### **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 AND CATS MUST BE DILUTED (Note: may also appear on front panel)

For control of fleas, lice, and ticks on dogs and cats, dilute 4 ounces of (Hartz 2 in 1 Elea & Tick-Dip) (this product) (alternate name) with 1 gallon of water. Dip animal into solution, making sure hair is thoroughly wet to the skin. The area around the ears should

#### MASTER LABEL BASED ON 10/14/04 EPA STAMPED APPROVED LABEL

be sponged thoroughly. Avoid contact of material with eyes and mouth of animal. Do not rinse. Towel dry. Repeat weekly (if necessary) for control. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing 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.

- 1. Dilute 4 ounces of this product with 1 gallon of water-
- 2. Dip animal into solution, making sure hair is thoroughly wet to the skin.
- 3. The area around the ears should be sponged thoroughly. Avoid contact of material with eyes and mouth of animal.
- 4. Do not rinse.
- 5. Towel dry.
- 6. Repeat weekly (if necessary)

Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing 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.

#### 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

Kills fleas and ticks, including the Deer tick, which may carry Lyme disease

Kills Deer ticks, which may carry Lyme disease

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

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

#### NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

For Dogs

For Cats

For Dogs and Cats

Concentrated- Makes (x) gallons

Concentrated- Makes three gallons

Hartz®-Every Pet's Best Friend™

Visit (our website) (www.hartz.com) (www.hartzultraguard.com)

Money back guarantee (by Hartz<sup>®</sup>)

Hartz<sup>®</sup> and other trademarks are trademarks of The Hartz Mountain Corporation

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

[For more information (about flea and tick problems and how to solve them) (or in an emergency) call (our flea and tick experts at) 1-800-275-1414 (weekdays.) 9am-5pm (Eastern Time) (E.S.T.)]

For more information, call our experts at xxx-xxx-xxxx

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)