

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Amended Labeling, Incorporation of Previously Rescinded Notification Language Hartz[®] 2 in 1[®] Flea & Tick Killer for Dogs with Pyrethrin, EPA Reg. No. 2596-94 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):

<u>Ingredient Statement section comment(s):</u>

1. On the footnote for Piperonyl butoxide, technical, replace the numeration "0.96%" with "0.096%"

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

- 2. Replace the 3rd sentence starting with "Do not use on puppies ..." with: "Do not apply to pets (puppies) less than twelve (12) weeks old."
- 3. Replace the 8th sentence 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):

4. 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.

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.

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"

Hartz[®] 2 in 1[®] Flea & Tick Killer for Dogs with **Pyrethrin**

Alternate Brand Names Hartz® UltraGuard Dog Spray

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

Hartz® Advanced Care TM 2 in 1® Flea and Tick Killer

Hartz®-Control Pet Care System®-Flea and Tick Killer for Dogs

Pet's Defense Pet Protection Plan Flea & Tick Killer for Dogs

Hartz® 2 in 1® Flea & Tick Killer

ACTIVE INGREDIENTS:	(By Weight)
Pyrethrins (CAS# 121-29-9)	0.060%
Piperonyl butoxide, technical* (CAS # 51-03-6)	0.120%
N-octyl bicycloheptene dicarboximide (CAS# 113-48-4)	0.200%
OTHER INGREDIENTS	<u>99.620%</u>
TOTAL	100.00%

^{*}Equivalent to 0.96% (butylcarbityl)(6-propylpiperonyl) ether and 0.024% 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

October 7, 2008 Under the Federal Insecticide, Fungicide, and Rodenticide Act.

NET CONTEN	T fl. oz.	(ml	l) 8 fl. oz - 20 fl. oz (236 mL -	-591-mL)

EPA Reg. No. 2596-94 EPA Est. No. 2596-NJ-1

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

MASTER LABEL BASED ON 3/31/04 EPA STAMPED APPROVED LABEL

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Do not use near birds, fish or foodstuffs. Do not spray in eyes or face of dog. Do not use on puppies under 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, pregnant, or 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. Wash hands thoroughly after use.

FIRST AID

If inhaled •Move person to fresh air. •If person is not breathing, call 941 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible •Call a poison control center or doctor for further treatment advice

It 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 •floid 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 of 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.

DIRECTIONS FOR USE

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

- 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 long haired dogs, ruffle hair for spray to reach skin.

MASTER LABEL BASED ON 3/31/04 EPA STAMPED APPROVED LABEL

- 3. After 10 minutes, dry dog with towel.
- 4. Comb and brush coat
- 5. Repeat once a week for fresh, glossy coat. Use on bedding and other areas as needed.
- 6. Kills fleas in 5 to 10 minutes. Ticks are tough—spray directly.
- 12. Hold bottle upright about 6 inches from pet.
- 2. Spray lightly until the tips of hair are moist. Keep spray out of pet steves
- Rub spray into animal s coat. For longhaired dogs ruffle fur-to allow the spray to reach skin.
- 4 After 10 minutes, dry dog with towel.
- Comb and brush coat.
- 6. Repeat once a week.
- 7: If you see a tick, spray it directly
- 8. Use on pet bedding as needed

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 or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

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

Repels flies gnats and mosquitoes

Kills fleas lice and ticks including the Deer tick, carrier of Lyme disease

Kills (and):(&) (Repels) (flies) (gnats) (and) (mosquitoes)

Kills fleas

Kills lice

Kills ticks, including the Deer tick, carrier of Lyme disease

Repels (flies) (gnats) (and) (mosquitoes)

Repels flies and gnats

Repels flies

Repels gnats

Repels mosquitoes

Kills (Fleas) (&) (and) (Ticks) (through contact)

(Immediately) starts to kill (Fleas) (&) (and) (Ficks) (through contact)

Kills fleas which may cause (flea bite anemia) (flea allergy dermatitis)

Kills fleas that may transmit tapeworm

(Starts) Killing (through) contact

Kills (through) contact

Flea and tick control

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

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

Unconditional Money-Back-Guarantee by Hartz

Made in U.S.A.

©The Hartz Mountain Corporation

Secaucus, NJ 07094 (U.S.A.)

For more information call our (flea and tick) experts at xxx xxxx (1-800-275-1414 weekdays, 9am-5pm E.S.T.)

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

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 nek-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)

Optional/alternate text in parentheses or brackets, new text is highlighted

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