

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 8, 2009

Ms. Heather Masch, Regulatory Affairs Associate The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688

Subject:

Amended Labeling, Response to PR Notices 2001-1 & 2007-4

Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Killer for Carpets, EPA Reg. No. 2596-138

Your Submission Dated April 22, 2009

Dear Ms. Masch:

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 label revision provision(s):

## **General Statement:**

- 1. Delete all text throughout the label marked with "strikethrough."
- 2. Revise all instances of the word "Kittens," "(kittens)," "Puppies," or "(puppies)," to read "Kittens (Over 12 Weeks of Age)," "(kittens over 12 weeks of age)," "Puppies (Over 12 Weeks of Age)," or "(puppies over 12 weeks of age),"

## Alternate Brand Name (ABN) section comment(s):

3. Delete the newly added ABNs. The use of the words "UltraGuard" imply heightened efficacy.

#### Ingredient Statement comment(s):

4. As per Chapter VII, Section 4.6 of the Agency's LRM, within the text immediately following the Ingredient Statement, revise the shaded language to read: "See back panel for additional precautionary statements." since this statement should only appear on the back panel of this label.

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

5. To facilitate inclusion of language from the REDs for pyrethrins and piperonyl butoxide, replace this section with: "Harmful if inhaled, swallowed or absorbed through skin. Avoid breathing of dust. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with plenty of soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Obtain medical attention if irritation persists. Avoid contamination of food or feedstuffs. Apply this product only as specified on this label. Do not apply to (use on) kittens less than twelve (12) weeks old."

## Environmental Hazards section comment(s):

6. To facilitate inclusion of language from the REDs for pyrethrins and piperonyl butoxide, replace this section with: "Environmental Hazards: This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment wash-waters or rinsate. See Directions for Use for additional precautions and restrictions."

## First Aid section (table) comment(s):

7. To facilitate inclusion of language from the acute toxicity review completed for this product, replace this section (table) with:

FIRST AID		
If Inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>	
If on Skin or Clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
If in Eyes:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
If Swallowed:	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	
treatment. For ad	container or label with you when calling a poison control center or doctor, or going for ditional information on this pesticide product (including health concerns, medical esticide incidents), you may call 1-800-275-1414.	

## <u>Directions for Use section comment(s)</u>:

- 8. Add the statement "**READ ENTIRE LABEL BEFORE EACH USE**" immediately following the statement "It is a violation of..." This statement must be must be in bold, all caps.
- 9. Add the following as a new subsection at the beginning of this section, immediately following the statement in Item #8 above. This information must be placed in a text box as follows:

### **General Precautions and Use Restrictions**

- Apply this product only as specified on this label.
- Do not enter or allow adults, children or pets to enter the treated area until dusts have settled.
- Except when applying directly to pets, do not apply this product in a way that will contact adults, children or pets, either directly or through drift.
- Do not apply to pets less than 12 weeks old.
- Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant or nursing animals.
- Sensitivities 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.
- Remove pets, birds and cover fish aquariums before spraying application.
- Remove and cover exposed food and drinking water before application.
- Remove or cover dishes, utensils, food processing equipment and food preparation surfaces, or wash them before use.
- Keep children and pets off carpet and upholstered furniture during treatment and until area is vacuumed.

<sup>&</sup>lt;sup>1</sup> Please note that the "1-800-275-1414" number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

## <u>Directions for Use section, FOR USE ON CARPETS subsection comment(s):</u>

10. Replace numerical point #7 in this subsection with: "Reapply every 7 days (if necessary)."

## Directions for Use section, USE ONLY ON (CATS) (&) (DOGS) subsection comment(s):

- 11. In the 2<sup>nd</sup> sentence of the 1<sup>st</sup> paragraph, replace the words "dead fleas, ticks and lice" with the words "remaining product."
- 12. Replace numerical point #3 in this subsection with: "Reapply every 7 days (if necessary)."
- 13. Delete the 3<sup>rd</sup> paragraph in this subsection as this text was revised and re-inserted into this label in the new subsection in Item #9 above.

## <u>Directions for Use section, FOR PET LIVING QUARTERS subsection comment(s):</u>

14. Replace numerical point #4 in this subsection with: "Reapply every 5 to 7 days (if necessary)."

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

15. Revise the subsection header "Pesticide Disposal:" to read "Container Disposal:"

### Optional/Alternate Text section comment(s):

- 16. Delete the 2<sup>nd</sup> optional/alternate claim as it implies false and misleading statements regarding heightened efficacy.
- 17. Delete all repellency claims throughout this section of the label.

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 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,

40P

Richard J. Gebken Product Manager (10) Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments" 002596-00138 D409317

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## Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Killer for Carpets

## Alternate Brand Names

- -Harz@lUtraChard@lilea & Fok Dog Powdor
- Hartz® UltraGuard® Dog Powder-
- Hartz® UltraGuard® Flea & Tick Cat Powder-
- Hartz® UltraGuard® Cat Povder-
- Hartz® UltraGuard® Flea & Tick Carpet Powder
  Hartz® 2 in 1™ Rid Flea Carpet Powder

ACTIVE INGREDIENTS:	(By Weight)
Pyrethrins	0.10%
Piperonyl butoxide, technical*	1.00%
OTHER INGREDIENTS	
TOTAL	100.00%
*Equivalent to 0.080% (butylcarbityl)(6-propylpiperonyl) ether and 0 compounds.	.020% related

# KEEP OUT OF REACH OF CHILDREN CAUTION

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

## NET CONTENTS \_\_\_\_oz (\_\_\_g)

EPA Reg. No. 2596-138 EPA Est. XXXX-XX-XXX

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

With COMMENTS
In EPA Letter Dated:
July 8, 2009
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:
2596-138

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EPA Reg. No.: 2596-138 MASTER LABEL

BACK PANEL

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid breathing of dust and contact with eyes, skin or clothing. Wash thoroughly with soap and warm water after handling and before eating or smoking. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Flush eyes with plenty of water. If irritation persists, get medical attention. Do not contaminate food, water or feed. Do not use in food serving areas while food is exposed. Food processing surfaces and utensils should be covered or thoroughly washed after treatment. Cover aquariums before use.

## **ENVIRONMENTAL HAZARDS**

Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

FIRST AID If Swallowed: Call a physician or Poison Control Center immediately. Induce vomiting by giving victim 1 or 2 glasses of water and touching back of throat with finger. Never give anything by mouth to an unconscious person. If in EYES: Flush eyes with plenty of water. Get medical attention if irritation persists. If on Skin: Wash with soap and warm water.

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 poison control center or doctor for treatment advice?

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 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 treatment information.

## **DIRECTIONS FOR USE**

**MASTER LABEL** 

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

## SHAKE WELL BEFORE USING

## PUNCH PLASTIC SEAL

## KEEP CHILDREN AND PETS OFF CARPETING DURING TREATMENT AND UNTIL THE AREA IS VACUUMED

Directions: FOR USE ON CARPETS\* hold upside down and shake powder to penetrate carpet fibers. Wait 60 minutes, then vacuum. (Use new vacuum cleaner bag.) For severe problems or where ticks are known to be hiding, wait 2-3 hours before vacuuming. If powder adheres to a spot, brush it out and vacuum immediately. Apply to dry surfaces only. Do not allow powder to become wet. Remove bag from vacuum cleaner. Wrap securely in several layers of newspaper and diseard in trash. To repeat a second generation from flea eggs in the carpet, repeat treatment in 7 days.

- 1. Apply to dry surfaces only. Do not allow powder to become wet.
- 2. If powder adheres to a spot, brush it out and vacuum immediately.
- 3. Hold can upside down and shake powder onto carpet.
- 4. Wait 60 minutes and then vacuum (using a new vacuum bag).
- 5. For severe problems, wait 2-3 hours before vacuuming.
- 6. Remove bag from vacuum cleaner and immediately discard in the trash.
- 7. Repeat once a week (if necessary).

\*Test on hidden surface of carpet before using. If texture or color is affected, do not use. Clean carpets after using Rid Flea Carpet Powder. Keep children and pets off carpeting during treatment and until entire area is vacuumed.

\*Test on hidden surface of carpet before using to ensure texture or color is not affected.

## FLEA CONTROL FOR (CATS) (&) (DOGS)

Read entire label before each use. Use only on (dogs) (and) (cats). Punch plastic seal. Hold can upside down and sprinkle powder over animal's back, head to tail, around the neck and ears, the underbelly, the legs, the base of the tail and where fleas are seen, keeping out of pets eyes and face. Rub against the lay of the hair until powder penetrates to skin. Repeat once weekly if necessary. It is not advisable to use this or similar pesticides on (puppies) or (kittens) under 12 weeks of age. Consult a veterinarian before

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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.

## -READ ENTIRE LABEL BEFORE EACH USE.

## **USE ONLY ON (DOGS) (AND) (CATS).**

NOTE: Apply to your pet while outdoors or in a well-ventilated area to avoid breathing airborne dust. Pets may be bathed and groomed 4 hours after treatment to remove dead-fleas, ticks and lice.

- 1. Hold can upside down and sprinkle powder over pet's back, from head to tail. Keep out of pet's eyes and face.
- 2. Rub in until powder penetrates to skin covering around the neck and ears, the stomach, legs and the base of the tail.
- 3... Repeat once a week (if necessary).

It is not advisable to use this or similar pesticides on (puppies) (or) (kittens) under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing or medicated animals. Sepsitivity may occur after using ANY pesticide product for pets. It 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.

## FOR PET LIVING QUARTERS

(Rid Flea Carpet Powder kills fleas, ticks and lice on contact.) Treat pet bedding and sleeping quarters liberally using 15 to 20 "sprinkles" (approximately 1 ounce) over a 50 sq. ft. area. Allow dust to remain for 3 to 4 hours and then, vacuum or sweep-up and discard as instructed under Storage and Disposal. To prevent a second generation from flea eggs repeat treatment in 5 to 7 days or as needed.

- 1. Treat\* pet bedding and sleeping area by liberally using 15-20 "sprinkles" (approximately I ounce) over a 50 sq. ft. area.
- 2. Let sit for 4 hours.
- 3. Vacuum or sweep-up and discard immediately:
- 4. Repeat once a week (if necessary).

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MASTER LABEL

### STORAGE AND DISPOSAL

Storage: Do not contaminate water, food, or feed by storage or disposal. Store in a cool dry place out of reach of children.

Disposal: Do not reuse this container. Securely wrap in several layers of newspaper before discarding in trash.

Do not contaminate water, food or feed by storage or disposal. Pesticide Storage: Store 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.

## **OPTIONAL/ALTERNATE TEXT**

Kills (fleas) (ticks) (lice) (and) (ants) that live and breed in carpets.

- May also be used on cats and dogs for rapid control of fleas and ticks.

Kills fleas, ticks, lice and ants

Kills (fleas) (ticks) (lice)

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

Kills (and repels) (fleas) (and) (ticks)

(Starts) Killing (through) contact

Kills (through) contact

# NON-PESTICIDAL RELATED CLAIMS AND OTHER OPTIONAL TEXT

Sprinkle & Vacuum

For use in (homes) (basements) (pet sleeping quarters) (and) (storage areas)

Easy to use

Sprinkle, (brush), (wait 60 minutes) (and) vacuum

400 sq. ft. coverage

Fresh Scent

For use in homes and pet sleeping quarters

Made in U.S.A.

The Hartz Mountain Corporation

Secaucus, NJ 07094 and St. Thomas

Ontario N5P 3W7 Canada

HOME TREATMENT

Carpet Insecticide & Freshener

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

MASTER LABEL

Filled by weight, not by volume. Some settling may occur

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

For more information, call our experts at xxx-xxxx

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

Hartz (brand name) products are designed to compliment 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 flea life cycle)

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