

2596-93

0710712009

1/7



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 7, 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® 2 in 1® Flea & Tick Killer for Cats – Fine Mist Spray, EPA Reg. No. 2596-93
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 Statements:

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

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

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

Ingredient Statement comment(s):

4. Revise the numerical figures in the footnote for Piperonyl Butoxide, Technical* as follows:
"*Equivalent to 0.096% (butylcarbityl)(6-propylpiperonyl) ether and 0.024% related compounds."
5. 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 section, Hazards to Humans and Domestic Animals subsection comment(s):

6. To facilitate inclusion of language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist, replace this section with: "Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Apply this product only as specified on this label. Do not apply to (use on) kittens less than twelve (12) weeks old."

First Aid Statement section, Hotline Number subsection comment(s):

- 7. Replace 2nd sentence in this subsection with: "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414." It is important to 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.

Directions for Use section comment(s):

- 8. To facilitate inclusion of language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist, add the following new subsection in its own text box immediately following the statement "It is a violation of Federal law ..." as follows:

<p>GENERAL PRECAUTIONS & USE RESTRICTIONS</p> <ul style="list-style-type: none"> • Apply this product only as specified on this label. • Do not contaminate of food or feedstuffs. • 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. • Do not allow adults, children or pets to enter the treated area until sprays have dried. • Remove birds and cover fish aquariums before application.

Storage and Disposal section comment(s):

- 9. Revise the subsection header "**Pesticide Disposal:**" to read "**Container Disposal:**"

Optional Language section comment(s):

- 10. Delete all repellency claims throughout this section of the label.

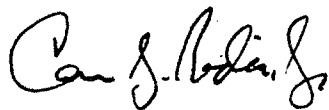
The Hartz Mountain Corporation should note that a notice of availability of EPA's RED for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). In addition, EPA's RED for products containing piperonyl butoxide was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42385-42386). Further, EPA's RED for products containing MGK® 264 insecticide synergist was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42381-42383). As a result, additional data and/or labeling changes may be required for products containing pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist.

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 Rodia.Carmen@epa.gov.

Sincerely Yours,

 *Richard J. Gebken*

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

Enclosure: Label stamped "Accepted with Comments"

002596-00093 D409319

4/7

FRONT PANEL

Hartz® 2 in 1® Flea & Tick Killer for Cats – Fine Mist Spray

Alternate Brand Names

~~Hartz® UltraGuard® Flea & Tick Cat Spray~~

ACCEPTED
With COMMENTS
In EPA Letter Dated:
July 7, 2009
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
2596-93

ACTIVE INGREDIENTS:

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:	99.620%
TOTAL	100.00%

*Equivalent to 0.080% (butylcarbityl)(6-propylpiperonyl) ether and 0.020% related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements

~~See (back) (side) panel(s) for (ingredients) (and) additional precautionary statements.
[Ingredient statement on back of 8 fl. oz. package only.]~~

NET CONTENTS _____ fl. oz. (_____ ml)

EPA Reg. No. 2596-93
EPA Est. 2596-NJ-1

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

5/7

BACK PANEL

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON CATS

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 cat. It is not advisable to use this or similar pesticides on kittens under 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 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 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. •Call a poison control center or doctor for treatment advice.

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 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 1-800-274-1414 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 toward 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).

6/7

EPA Reg. No.: 2596-93

MASTER LABEL

- ~~2. Apply lightly and rub into animal's coat. Ruffle hair for spray to reach skin.~~
- ~~3. After 10 minutes, dry cat with towel.~~
- ~~4. Comb and brush coat.~~
- ~~5. Repeat once a week if necessary. Use on bedding and other areas as needed.~~
- ~~6. Kills fleas in 5 to 10 minutes. Ticks are tough—Spray directly.~~

- 1. Hold bottle upright about 6 inches from pet.
- 2. Spray lightly until tips of the pet's hair are moist. Keep spray out of pet's eyes.
- 3. Rub spray into animal's coat. For longhaired cats, ruffle fur to allow the spray to reach skin.
- 4. After 10 minutes, dry cat with towel.
- 5. Comb and brush coat.
- 6. Repeat once a week (if necessary).
- 7. If you see a tick, spray it directly.
- 8. Use on pet bedding as needed.

STORAGE AND DISPOSAL

Do not reuse empty container. Wrap container and put it in trash collection.

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store 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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

OPTIONAL LANGUAGE

Repellent

~~REPELS FLIES GNATS AND MOSQUITOES~~

KILLS FLEAS LICE AND TICKS INCLUDING THE DEER TICK, CARRIER OF LYME DISEASE

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

Kills (fleas) (lice) (and) (ticks) including the deer tick, carrier of lyme disease

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

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

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

(Starts) Killing (through) contact

Kills (through) contact

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Made in U.S.A.

The Hartz Mountain Corporation
Secaucus, NJ 07094 and St. Thomas
Ontario N5P 3W7 Canada

Fine Mist Spray

Deodorant

Fresh Scent

For more information or in emergency call 1-800-XXX-XXXX

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

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

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

Hartz (brand name) products are designed to complement each other in an integrated program for flea & tick management. To assure proper treatment, we recommend use of only Hartz (brand name) products.

As with all flea & tick products, they are most effective when used as part of a total program aimed at reducing fleas and ticks in the (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 product registered for these uses, such as Hartz (brand name) line (products).