

2596-153

09-03-2009

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 3, 2009

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

Subject: Amended Labeling, Response to EPA Letter Dated November 11, 2008, Response to PR Notices 2001-1 & 2007-4 and Addition of Optional Marketing Statements Hartz® Reference 122, EPA Reg. No. 2596-153 Your Submission Dated June 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):

Environmental Hazards section comment(s):

1. To facilitate inclusion of language from the RED for phenothrin, replace this section with:

"ENVIRONMENTAL HAZARDS: This product is highly toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment wash-waters or rinsate. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. See Directions for Use for additional precautions and restrictions."

First Aid section comment(s):

2. Replace the last paragraph in this section with: **"HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center, doctor or veterinarian, or going for treatment. **For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414."**¹

Directions for Use section comment(s):

3. Add the statements **"READ ENTIRE LABEL BEFORE EACH USE"** and **"USE ONLY ON DOGS"** immediately following the statement "It is a violation of..." These statements must be bolded and capitalized.

¹ 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.

Storage and Disposal section comment(s):

- 4. To facilitate inclusion of language from PR Notice 2007-4, replace the existing "Pesticide Disposal:" subsection with:

"PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill container. **If empty:** 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."

Non-Pesticide Related Claims and Other Optional Text section comment(s):

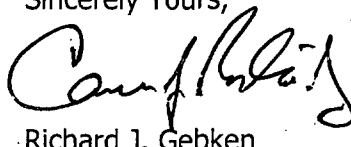
- 5. Delete the text marked with "strikethrough" in the 5th non-pesticide related claim since it implies that oatmeal has efficacious properties.

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,

FOR
= 

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

Enclosure: Label stamped "Accepted with Comments"
002596-00153 D416123

Hartz® Ref. 122

Alternate Names:

- Hartz® UltraGuard™ Rid Flea & Tick™ Shampoo for Dogs with Oatmeal
- Hartz® Advanced Care™ 2 in 1® Flea & Tick Shampoo with Oatmeal
- Hartz® Advanced Care™ 2 in 1® Rid Flea™ Dog Shampoo with Oatmeal
- Hartz® 2 in 1® Rid Flea™ Dog Shampoo with Oatmeal
- Hartz® InControl™ Flea & Tick Oatmeal Shampoo for Dogs (&) (Puppies)

ACTIVE INGREDIENT:

Phenothrin.....	0.27%
OTHER INGREDIENTS	99.73%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

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

NET CONTENT _____ fl. oz. (_____ ml)

EPA Reg. No. 2596-153
EPA Est. 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:
September 3, 2009
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
2596-153

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: CAUTION: Causes moderate eye irritation. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS: Consult a veterinarian before using this product on debilitated, aged, medicated, 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.

ENVIRONMENTAL HAZARDS: This product is toxic to fish.

FIRST AID

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.

DIRECTIONS FOR USE

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

Do not use on puppies under 6 months of age.

Do not use on cats or kittens.



[To be used on package]

1. Wet pet's coat thoroughly with water and rub shampoo into coat starting with head
2. Keep out of pet's eyes

3. Work backward from head to tail until coat is completely covered with foamy lather
4. Let stand or continue to massage in for 5 minutes
5. Rinse and towel dry
6. Repeat weekly (if necessary).

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 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 LABEL TEXT

Kills fleas
Kills ticks
Kills fleas and ticks
Kills 99% of fleas within (5) (24) hours
Kills 93% of ticks within 48 hours
Fast acting
Kills (Fleas) (&) (and) (Ticks) (through contact)
Kills (fleas) (ticks)
(Starts) Killing (through) contact
Kills (through) contact

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

With encapsulated oatmeal beads

Deodorizing (fresh scent)

(Soothes) (Calms) (Relieves) (Comforts) irritated skin with (encapsulated) oatmeal

Contains Oat Extract

⑤ Hartz® In Control™ Flea & Tick Oatmeal Shampoo was developed to ~~not only~~ kill fleas and ticks ~~but contains Oat extract.~~

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

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

(www.hartzincontrol.com)

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

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]

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