

2596-153

11/04/2008

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

NOV - 4 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Robert Rosenwasser
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Dear Mr. Rosenwasser:

Subject: Hartz Ref # 122
EPA Reg. No. 2596-153
Submission dated 7/2/08

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

Delete the following claims as you have not submitted data to support these claims:

Immediately starts to kill fleas & ticks through contact
...repels...
Flea and tick control
Breaking the life cycle

Delete the following drug claims:

Soothes irritated skin
To help soothe and relieve dry or irritated skin
Fleas and ticks may not only harm your pet with the numerous diseases they may carry,
but their bites can cause itchy or irritated skin
To help provide soothing relief.

Delete the following enhanced efficacy claims:

Complete your preventative program with products that kill both adult and pre-adult fleas
Complete your defense against fleas

The following statements are required to be on the front panel. They may not be displaced by marketing claims.

Product name
Ingredient Statement



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Keep out of Reach of Children
Signal Word
First Aid Statement
Net Contents

The alternate brand names must be followed by the word "insecticide".

Revise the Hazards to Humans and Domestic Animals as follows:

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.

Delete "for best results" from the directions for use, as this language makes following the directions for use optional.

Delete from the Directions for use the following, as it is in the Hazards to Domestic Animals statements:

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

Restore the Storage Statement as follows:

Do not contaminate water, food or feed by storage and disposal. Store in a cool dry place.

The label must display batch codes, in accordance with PR Notice 2007.


In accordance with PR Notice 2007-4, the disposal instructions must be modified to include "Nonrefillable container".

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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 FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list 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 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 the EPA's Office of Enforcement and Compliance Assurance. As an alternative, you may refer consumers to the company's phone number or e:mail address.

Please note that a notice of availability of EPA's reregistration eligibility document (RED) for products containing phenothrin (sumithrin) was published in the Federal Register on 10/22/08. Additional data and/or labeling changes may be required for products containing phenothrin. For more information, see the following website:
<http://www.epa.gov/pesticides/reregistration/status.htm>.

If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

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

Hartz® Ref. 122

7/1/08

4/7

EPA Reg. No.: 2596-153

MASTER LABEL BASED ON 1/28/05 EPA STAMPED APPROVED LABEL

Hartz® Ref. 122

ACCEPTED
with COMMENTS
In EPA Letter Dated:

NOV - 4 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2596-153

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)

- ~~Hartz® Flea and Tick Skin and Coat Shampoo for Dogs~~
- ~~Hartz® Advanced Care™ Flea and Tick Skin and Coat Shampoo for Dogs~~
- ~~Hartz® Advanced Care™ 2 in 1® Skin and Coat Shampoo~~
- ~~Hartz® Advanced Care™ 2 in 1® Rid Flea™ Plus Dog Shampoo~~
- ~~Pet Principles by Hartz® Flea & Tick Shampoo with Oatmeal for Dogs and Puppies~~
- ~~InControl by Hartz Flea & Tick Shampoo with Oatmeal for Dogs and Puppies~~

ACTIVE INGREDIENT:	— (BY WEIGHT) (NOM.)
Phenothrin.....	0.27%
OTHER INGREDIENTS	<u>99.73%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for (ingredient statement,) additional precautionary and first aid statements.

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

READ ENTIRE LABEL BEFORE EACH USE**USE ONLY ON DOGS****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. 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. For best results, let stand or continue to massage in for 5 minutes
5. Rinse and towel dry

6. Repeat weekly (if necessary).

~~Wet dog's coat thoroughly with water. Rub shampoo into coat, starting with head, at the rate of approximately 1 teaspoon (5 mL) for every 5 lbs of body weight. Work backward until coat is completely covered with foamy lather. Let lather stay on for 5 minutes, then rinse and towel dry. Keep away from dog's eyes. Repeat weekly (if necessary).~~

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

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 99% of fleas within (5) (24) hours

Kills 93% of ticks within 48 hours

Fast acting

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

With encapsulated oatmeal beads

Deodorizing (fresh scent)

Soothes irritated skin with (encapsulated) oatmeal

Contains Oat Extract (to help soothe and relieve dry or irritated skin)

Fleas and ticks may not only harm your pet with the numerous diseases they may carry, but their bites can cause itchy or irritated skin. Hartz® In Control™ Flea & Tick Oatmeal

Shampoo was developed to not only kill fleas and ticks but contains *Oat extract* to help provide soothing relief.

Hartz® *Every Pet's Best Friend™*

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

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

(www.hartzincontrol.com)

Money back guarantee by Hartz®

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]

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)