

2596-149

11/13/2008

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

NOV 13 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

Dear Mr. Rosenwasser:

Subject: Hartz Ref 111
EPA Reg. No. 2596-149
Submission dated 7/2/08
Rescission of Agency letter dated 9/11/08 regarding notification dated 8/5/08

The 9/11/08 Agency letter reviewing the notification dated 8/5/08 is hereby rescinded, as the notification contained numerous drug claims, implied safety claims and unsupported efficacy claims.

The amendment 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.

The following alternate brand names are not acceptable as they are drug claims:
Sensitive Skin Therapy
Conditioning Moisturizing Coat Therapy
Skin Relief Therapy

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

Delete the following drug claims:
Sensitive Skin Therapy
Skin Relief Therapy
Therapy
Soothing irritation caused by flea and tick bites
For Extra Sensitive Skin
Soothing comfort for sensitive skin
Helps heal skin

Invigorates skin
 Formulated for use on extra sensitive skin
 For dry sensitive skin
 Soothing
 Sensitive skin relief therapy with aloe to sooth and calm
 Coat therapy to nourish and moisturize
 Coat therapy to refresh
 Rich Conditioning Therapy
 Deep Cleansing Therapy
 Skin therapy with soothing aloe
 Coat therapy with moisturizing coconut
 Coat therapy with nourishing moisturizers
 Coat therapy with refreshing eucalyptus
 Coat therapy with refreshing cleansers
 Skin treatment to nourish and moisturize
 Coat treatment to refresh
 Soothing formula
 To sooth and calm
 Sensitive skin formula

Delete the following implied safety claims:

Deep Cleansing cleaning treatment to eliminate pet odors
 Nourishes skin
 Easily removes eliminates oil dirt and other residue
 To deep clean
 To refresh skin and coat
 To nourish moisturize coat
 Fragrance free
 Fragrance & dye free
 Free of fragrance & dyes
 Fragrance free
 Dye free
 To nourish and moisturize
 To refresh
 Cleans and beautifies all in one
 Cleans
 Freshens

Add to the first sentence in the Directions for Use the following:

To kill fleas and ticks on dogs and cats

Delete the following claims which detract from the Precautionary Statements and Directions for Use:

To remove dirt
 Removes deep dirt
 Conditioning formula

Improves Manageability
Detangles
Beautifies

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

- Product name
- Ingredient Statement
- Keep out of Reach of Children
- Signal Word
- First Aid Statements
- Net Contents

All references to "ova" "ovum" "egg" "hatching" must be qualified by "flea".

Delete "new" as this product has been registered since 1999.

Life cycle claims must be limited to fleas.

Delete the following efficacy claims for which you must submit data:

- Kills fleas that may transmit tapeworm.
- Tick control
- Controls tick infestation
- Kills ticks before they grow into biting adults
- Claims to repel
- Controls ticks round the clock for up to one month 28 days 4 weeks

Delete the following claims which imply 100% efficacy:

- Claims using the terms "protect" "protects" and "protection".
- Claims using the terms "prevent," "prevents", "prevention."
- Claims using the terms "treat" "treats"
- Claims using the term "stops"
- One step to treat and prevent
- Flea egg and flea larvae treatment
- One step to treat existing problem and prevent future infestations
- Controls flea population growth infestation
- Active ingredient specifically targeting flea eggs and flea larvae – stopping their ability to mature and infest your home
- X day protection
- Complete your preventative program
- Complete your defense
- Focused on breaking the flea life cycle
- Controls flea infestation where it starts
- Prevents reinfestation
- To prevent future infestations

Delete the following enhanced efficacy claims:

Dual action

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

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

Revise the Hazards to Humans and Domestic Animals as follows:

Hazards to Humans: Caution.

Hazards to Domestic Animals: Do not use on puppies kittens puppies or kittens less than 12 weeks of age. 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.

In accordance with PR Notice 2007-4, the disposal instructions must be modified to include the following:

Nonrefillable container. Do not refill or reuse this container.

In accordance with the label review manual, if you list one inert ingredient, such as coconut, eucalyptus, aloe, mint you must list them all, in descending order by weight.

Revise the Environmental Hazards statements in accordance with the Allethrins RED as follows:

This product is toxic to fish and shrimp. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.

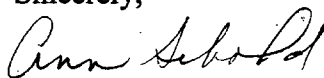
Acceptance of this label does not constitute approval of claims appearing on this label that are made for other Hartz products. Label claims for other Hartz products must be qualified by a statement referring the user to the labels for those products.

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 allethrans was published in the Federal Register on 9/26/07. Additional data and/or labeling changes may be required for products containing allethrans. 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)

cc: Joyce Edwards
Linda Arrington

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Hartz® Ref. 111

7/1/08

EPA Reg. No.: 2596-149

MASTER LABEL BASED ON 12/10/99 EPA STAMPED APPROVED LABEL

Hartz® Ref. 111

Alternate Brand Names

Hartz® UltraGuard Plus™ Foaming Flea & Tick Shampoo for Dogs

Hartz® UltraGuard Plus™ Foaming Flea & Tick Shampoo for Cats

Hartz® UltraGuard Plus™ Flea & Tick (Shampoo for Cats) (Cat Shampoo)

Hartz® UltraGuard Plus™ Flea & Tick (Shampoo for Dogs) (Dog Shampoo)

Hartz® InControl™ Sensitive Skin Therapy Flea & Tick (Dog Shampoo) (Dog & Puppy Shampoo)

Hartz® InControl™ Sensitive Skin Therapy Flea & Tick Shampoo for Dogs (& Puppies)

Hartz® InControl™ (Conditioning) (Moisturizing) Coat Therapy Flea & Tick (Dog Shampoo) (Dog & Puppy Shampoo)

Hartz® InControl™ (Conditioning) (Moisturizing) Coat Therapy Flea & Tick Shampoo for Dogs (& Puppies)

Hartz® InControl™ Skin (Relief) Therapy (with Aloe) Flea & Tick (Dog Shampoo) (Dog & Puppy Shampoo)

Hartz® InControl™ Skin (Relief) Therapy (with Aloe) Flea & Tick Shampoo for Dogs (& Puppies)

Hartz® Advanced Care® 3 in 1 Shampoo for Dogs and Puppies

Hartz® Advanced Care® 3 in 1 Shampoo for Cats and Kittens

Hartz® Advanced Care® 3 in 1 Foaming Shampoo for Dogs and Puppies

Hartz® Advanced Care® 3 in 1 Foaming Shampoo for Cats and Kittens

~~Hartz® Advanced Care® 4 in 1 Shampoo for Dogs and Puppies~~

~~Hartz® Advanced Care® 4 in 1 Shampoo for Cats and Kittens~~

~~Hartz® Advanced Care® 4 in 1 Foaming Shampoo for Dogs and Puppies~~

~~Hartz® Advanced Care® 4 in 1 Foaming Shampoo for Cats and Kittens~~

~~Hartz® 3 in 1 Foaming Shampoo for Dogs~~

~~Hartz® 3 in 1 Foaming Shampoo for Cats~~

~~Hartz® 3 in 1 Foaming Shampoo for Dogs and Puppies~~

~~Hartz® 3 in 1 Foaming Shampoo for Cats and Kittens~~

~~Pet Principles by Hartz® Foaming Flea & Tick Shampoo for Dogs & Puppies~~

~~Pet Principles by Hartz® Foaming Flea & Tick Shampoo for Cats and Kittens~~

~~InControl by Hartz® Foaming Flea & Tick Shampoo for Dogs & Puppies~~

~~InControl by Hartz® Foaming Flea & Tick Shampoo for Cats and Kittens~~

ACCEPTED
with COMMENTS
In EPA Letter Dated:

NOV 13 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2596-149

ACTIVE INGREDIENTS:

(By Weight)

d-trans Allethrin (CAS# 584-79-2).....0.109%

N-octyl bicycloheptene dicarboximide (CAS# 113-48-4).....0.154%

(S)-Methoprene (CAS #65733-16-6).....0.101%

OTHER INGREDIENTS99.636%

TOTAL 100.00%

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.

[Ingredient statement on the back of 5.5 fl oz package only]

NET CONTENT ____ fl. oz. (____ ml) *[ranges from 6 fl. oz. to 64 fl. oz.]*

EPA Reg. No. 2596-149

EPA Est. No. 2596-NJ-1

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Do not let children or pets play with this product. Do not use on (puppies) (kittens) (puppies or kittens) less than 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.

ENVIRONMENTAL HAZARDS

Do not contaminate lakes or streams by disposal of waste water.

DIRECTIONS FOR USE

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

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON (DOGS) (CATS) (DOGS and CATS)

~~To kill fleas, lice and ticks (including the Deer tick which may carry Lyme disease) wet (dog's) (cat's) (pet's) coat thoroughly with water and rub shampoo into coat starting with head. Work backward until coat is completely covered with foamy lather. Let lather stay on 5 minutes, then rinse and towel dry. Repeat as required, but not more often than once a week. [It is recommended that the pet's bedding or sleeping quarters be treated for flea and tick control with a product registered for the use, such as (Control Pet Care System~~

MASTER LABEL BASED ON 12/10/99 EPA STAMPED APPROVED LABEL

Home Flea and Tick Killer (alternate name)}

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)

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.

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) (and) (ticks) (and) (lice)
- Prevents reinfestation (and flea build-up) for (1 month) (28 days) (4 weeks)
- With (vIGRen) (insect growth regulator)
- Prevents (flea) eggs (ova) (ovum) from hatching for (over 1 month) (28 days) (4 weeks)
- Kills flea eggs (and prevents their hatching) for (over 1 month) (28 days) (4 weeks)
- Kills flea eggs (and larvae)
- Kills hatching (flea) eggs (ova) (ovum)
- Plus kills (flea eggs) (larvae) to prevent future infestations (up to) 1 month
- Egg stop (formula)
- Contains an insect growth regulator
- Stops the flea and tick life cycle
- Kills all stages of the flea (life cycle)
- Kill flea eggs before they hatch
- Kills adult fleas and ticks

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Kills the Deer tick, which may carry Lyme disease

Kills Deer ticks

Kills fleas and ticks, including the Deer tick, which may carry Lyme disease

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)

(Plus) kills (keeps killing) pre-adult flea stages (too)

Breaks the flea life cycle

(Plus) Kills (fleas) (and) (ticks) and pre-adult fleas (before they grow into biting adults)

(Plus) Kills fleas and ticks and (continues to protect against) (prevents) pre-adult fleas from (changing) (growing) (developing) into biting adults

(Plus) Prevents infestation by halting the flea reproductive cycle

(Plus) halts the flea life cycle by killing flea eggs (and flea larvae)

One step to treat and prevent

One step to treat existing problem and prevent future infestations

(Plus) Provides protection against future infestations

Treats & (and) Prevents in one step

(Plus) Prevents Fleas Eggs (and flea larvae) from hatching for (1 month) (28 days) (4 weeks)

(Plus) Kills flea eggs (and flea larvae) helping to prevent re-infestations

(Plus) Kills (flea eggs) (and flea larvae) before they hatch

Helps prevent flea re-infestation for (1 month) (28 days) (4 weeks)

(Plus) Stops fleas from multiplying

(Plus) Protects against pre-adult fleas

Kills (3 stages) of (tick) (the tick) life cycle

(Plus) kills (adult ticks) (larvae) (and) (&) (nymphs)

Kills (pre-adult) ticks

Kills (and Prevents) (Flea Eggs) (and) (Flea Larvae) for (one month) (4 weeks) (28 days)

Kills and repels (fleas) (ticks) (flea eggs) (flea larvae) for (1 month) (28 days) (4 weeks)

Kills (fleas) (ticks) (flea eggs) (flea larvae) for (1 month) (28 days) (4 weeks)

(Starts) killing (through) contact

Kills (through) contact

Controls flea and tick infestations on dogs

Flea and tick control

(one product) kills (fleas) (ticks) plus flea eggs (flea larvae)

Flea egg and flea larvae treatment

Kills all stages of the flea life cycle

Controls (kills) fleas, ticks round -the clock for up to (1 month) (28 days) (4 weeks)

Controls flea (population growth) (infestation)

Focused on breaking the flea life cycle

Controls flea infestation where it starts

Active ingredient (specifically) targeting flea eggs and flea larvae - stopping their ability to mature and infest your home

Help prevent flea re-infestation for (1 month) (28 days) (4 weeks)

X Day Protection

~~(This product) (alternate brand name) contains [(both) (an adulticide to kill adult fleas and ticks) and an insect growth regulator (IGR) to kill flea eggs before they hatch] [an insecticide which kills adult fleas and ticks and an insect growth regulator which prevents flea eggs and flea larvae from maturing into adults] (Adult fleas spend virtually all of their time on your pet, but they produce eggs which drop off the pet and develop in the environment) [once fleas are apparent on your pet, there can already be an infestation of their pre-adult stages in your home. (this product) (alternative brand name) is designed to kill both the adult flea and flea eggs and flea larvae, thereby breaking the flea life cycle]~~

~~{(Hartz Ref. 111) (this product) (alternate name) contains both [an insecticide to kill adult fleas and ticks and an insect growth regulator (IGR) to kill flea eggs before they hatch] (an effective insecticide which kills adult fleas and ticks, and a long-lasting insect growth regulator which prevents flea eggs from hatching and larvae from maturing into adults).} Adult fleas spend virtually all of their time on your pet, but they produce vast numbers of eggs which drop off the pet and develop in the environment. [(Hartz Ref. 111) (this product) (alternate name) kills flea eggs before they drop off your pet.] Once fleas are apparent on your pet, there is already an infestation of their pre-adult stages in your home. Normal insecticides will not kill the flea eggs. But (Hartz Ref. 111) (this product) (alternate name) is designed to kill both the adult flea and its eggs and larvae, thereby breaking the flea life cycle. The shampoo will also break the tick life cycle by killing adult ticks, including the Deer tick, which may carry Lyme disease.~~

Important Information:

The ABCs of Flea & Tick Management

~~(Control Pet Care System) (alternate name) products are designed to work together in a complete insecticidal system. For elimination of fleas and ticks, it is necessary to treat not only the pet but also its surrounding environment. Use (Control Pet Care System) (alternate name) products and follow these simple ABCs to get rid of fleas and ticks on your pet and around your home.~~

~~Step A—Treat Your Pet with one of the (Control Pet Care System) (alternate name) on-animal products such as Conditioning Shampoo, Dip or Spray to kill fleas and ticks living on your pet.~~

~~Step B—Protect Your Pet with a (Control Pet Care System) (alternate name) Repellent or Flea Collar to keep fleas and ticks from re-infesting your pet. The (Control Pet Care System) (alternate name) Ultimate Flea Collar with vIGRen will also prevent flea eggs from hatching.~~

~~Step C—Treat Your Home both indoors and outdoors with (Control Pet Care System) (alternate name) Home Spray Killer or Fogger with vIGRen and (Control Pet Care~~

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~~System) (alternate name) Yard and Kennel Spray to protect your entire home and guard against reinfestation.~~

~~Be sure to read the full directions and precautions on the label of each product you use. For more information about flea and tick problems and how to solve them, call 1-800-275-1414 weekdays, 9 am to 5 pm (Eastern time) (E.S.T.) vIGRen is a registered trademark of Wellmark Intl.~~

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NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

- For dogs
- For cats
- For puppies
- For kittens
- Dual action
- Contains protein conditioners
- Cleans
- Freshens
- Beautifies
- Deodorizes

~~vIGRen is a registered trademark of Wellmark Intl.~~

~~Hartz® Every Pet's Best Friend™~~

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

~~(Money back guarantee) (by Hartz®)~~

~~Made in (the) U.S.A. (by) ©The Hartz Mountain Corporation, Secaucus, NJ 07094 (U.S.A.)~~

~~[For more information (about flea and tick problems and how to solve them) (or in an emergency) call (our flea and tick experts at) 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~~

~~New (Note: for new introductions to market; to be maintained only for six months)~~

~~Soothes irritation caused by flea & tick bites~~

~~(For) (Extra) (Sensitive Skin)~~

~~(Soothing comfort) for sensitive skin~~

~~Helps heal skin with Chamomile (Extract)~~

~~Deep Cleansing (Cleaning) (Treatment) (to eliminate (pet) odors)~~

~~Invigorates skin with Eucalyptus (Extract)~~

~~Conditions & Restores Shine~~

~~(Rich)(Deep) Conditioning~~

~~Nourishes skin with Coconut (Extract)~~

~~Refreshing Mint Fragrance~~

~~Improves Manageability~~

~~(Easily) removes (eliminates) oil (dirt) (and other residue)~~

~~(Now)(with)(Added)(Contains)Eucalyptus (Extract) to (deep)(clean) (and) (&)~~

~~(deodorize)~~

~~(Now) (with) (Added) (Contains) Eucalyptus (Extract) to refresh (skin) (and) (&) (coat)~~

~~(Now) (with) (Added) (Contains) Coconut (Extract) to (nourish) (moisturize) coat~~

~~Detangles~~

~~(Now)(with) (Contains)(eucalyptus) (to remove) dirt and odors~~

~~Removes (deep) dirt and odors~~

~~Formulated for use on (extra) sensitive skin~~

~~Soothing Milk & Coconut Fragrance~~

~~Fragrance Free~~

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For Dry Sensitive Skin

Fragrance & Dye Free

Free of (fragrance) (&) (and) dyes

Fragrance Free

Dye Free

Dye Free

(Sensitive) Skin (Relief) Therapy with Aloe to soothe and calm

Coat therapy to nourish and moisturize

Coat therapy to refresh and deodorize

Sensitive Skin Therapy

With Aloe

Rich Conditioning Therapy

Deep Cleansing Therapy

Skin therapy with soothing aloe

Coat therapy with moisturizing coconut

Coat therapy with nourishing moisturizers

Coat therapy with refreshing eucalyptus

Coat therapy with refreshing cleansers

Skin treatment to nourish and moisturize

Coat treatment to refresh and deodorize

Soothing formula with aloe

Conditioning formula

Deodorizing formula

(With) Aloe to soothe and calm

(With) coconut to nourish and moisturize

With eucalyptus to refresh and deodorize

Sensitive skin formula

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)