

2596-137

02/20/2007

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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

FEB 20 2007

Margaret W. Dickson  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, New Jersey 07094-3688

Subject: Response to Agency Letter Requiring Update of Label as per PR Notices 2001-1 and 2001-6

EPA Reg. No. 2596-137  
Hartz ® One Spot Repellent for Dogs

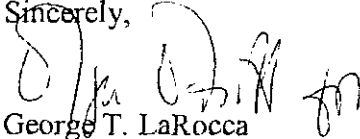
Your submission dated February 8, 2006

Dear Ms. Dickson:

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. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. Your use directions are only for dogs and puppies under or over 30 lbs. Therefore, delete all other statements that refer to weights other than "under 30 lbs" or "over 30 lbs." Refer to comment 3 in our letter of June 22, 1999.
2. Delete the alternate brand names listed on the front panel. These names have not been approved by the Agency. Alternate brand names must be approved by the Agency as per 40CFR 152.10(b) (2)9(ii).
3. Add the following statement to the precautionary statements related to cats: "*May be toxic and potentially fatal if applied to or ingested by cats*".
4. Add "and *other aquatic organisms*" at the end of the sentence under Environmental Hazards.
5. On page 6 replace "*Eliminating*" with "*Controlling*".

If you have any questions regarding this action, please contact Olga Odiott of my team at (703) 308-9369.

Sincerely,  
  
George T. LaRocca  
Product Manager (13)  
Insecticide Branch  
Registration Division (7505P)

Enclosure

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Hartz® One Spot Repellent for Dogs

2/7/06

EPA Reg. No.: 2596-137

PROPOSED MASTER LABEL (based on label submitted by Hartz 2/26/01 in response to EPA 12/7/00 letter)

# Hartz® One Spot Repellent for Dogs

## Alternate Brand Names

Hartz® Control Pet Care System® One Spot Repellent for Dogs

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies Under 30 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies Over 30 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies Over 60 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies Under 15 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies 16 - 30 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies 31 - 45 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies 46 - 60 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies 61 - 90 lbs.

Hartz® Control Pet Care System® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies Over 90 lbs.

Releve Pet Protection System® Once-a-Month™ Flea and Tick Treatment for Dogs and Puppies 30 lbs. and Under

Releve Pet Protection System® Once-a-Month™ Flea and Tick Treatment for Dogs and Puppies Over 30 lbs.

Hartz® Advanced Care® Once-a-Month™ Flea & Tick Treatment for Dogs and Puppies

**IMPORTANT: Intended for Use on Dogs**

**DO NOT USE ON CATS**

[Icon of cat in circle with slash through it]

**ACTIVE INGREDIENT:**

(By Weight) (Nom.)

Permethrin (CAS #52645-53-1).....45.0%

**OTHER INGREDIENTS** .....55.0%

**(TOTAL** .....100.0%)

*Note: CAS numbers may or may not appear on product label*

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See back panel for (ingredients and) additional precautionary statements.

NET CONTENTS: X tubes, XX fl. oz. (X cc) each[, XX fl. oz. (X cc) total]

EPA Reg. No. 2596-137

EPA Est. No. 2596-NJ-1

[Made in (the) U.S.A. (by)]

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
**FEB 20 2007**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
2596-137

©The Hartz Mountain Corporation

Secaucus, NJ 07094 (U.S.A.)

(and St. Thomas, Ontario N5P 3W7 Canada)

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**READ ENTIRE LABEL BEFORE (EACH) USE**

**USE ONLY ON DOGS AND PUPPIES OVER 6 MONTHS OF AGE**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

**CAUTION:** Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

**HAZARDS TO DOMESTIC ANIMALS**

**CAUTION: DO NOT USE ON CATS.** Do not use on puppies less than 6 months old. Cats which actively groom or come in close physical contact with treated dogs may be at risk of serious harmful effect. Do not use this product in households with both dogs and cats. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity, such as slight transient irritation or hair loss at the site of application, 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.
- Have the product container or label with you when calling for advice or going for treatment.

**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 CATS. May be toxic or potentially fatal if applied to or ingested by cats.**

**Directions Option 1 (for use on any size package):**

*(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)*

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). (Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully.) (Hold bottom of tube with one hand. With the other hand, snap cap off.)

Position the tip of the tube on the dog's back between the shoulder blades. Use the tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail. (Repeat every month.) [Repeat (reapply) every 30 days if necessary.]

**Directions Option 2 (for use on packages intended for dogs 15 lbs. and under, 16-30 lbs., and up to 30 lbs.):**

*(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)*

(This product is packaged in single dosage ampules. One ampule (1 cc) is the correct dosage for a small dog.) (This product contains an ampule inside a vial.) Point tip (of ampule) up and away from your face. Squeeze the middle of the tube to break the ampule. Position (Press) the tip of the tube on the dog's back between the shoulder blades and squeeze tube (to apply entire contents of the ampule (1 cc) to the animal) (to push the entire contents of the ampule (1 cc) through tip of the tube onto the animal). (Repeat every month.) [Repeat (reapply) every 30 days if necessary.]

**Directions Option 3 (for use on packages intended for dogs over 30 lbs., 31-45 lbs., 46-60 lbs., over 60 lbs., 61-90 lbs., and over 90 lbs.):**

*(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)*

(This product is packaged in single dosage ampules. One ampule is the correct dosage for a large dog.) (This product contains an ampule inside a vial.) Point the tip (of the entire vial) up and away from your face. Squeeze the middle of the tube to break the ampule. Position (Press) the tip of the tube on the dog's back between the shoulder blades and squeeze the tube to apply the contents from the ampule to the dog until the

contents level reaches the ½ mark indicated on the tube. Invert the vial upright (tip pointing up) and go to the dog's tail. Position the tip of the tube at the base of the tail and apply the remaining contents of the tube to the base of the dog's tail. (Repeat every month.) [Repeat (reapply) every 30 days if necessary.]

**Directions Option 4 (for use in warehouse club packaging. This product contains 6 monthly dosages, each 1 cc):**

*(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)*

**For Dogs Over 30 lbs.** Remove one applicator tube from the package and hold in an upright position. Pull off cap. Turn the cap around and place on top of tube. [Simply press (twist) cap (down) to break the seal of tube.] (Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.) (Hold bottom of tube with one hand. With other hand, snap cap off.) Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades and squeeze out the contents (of the tube) (from the tube to the dog). Remove second applicator tube from package and hold in an upright position. Pull off cap. Turn the cap around and place on top of tube. [Simply press (twist) cap (down) to break the seal of tube.] (Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.) (Hold bottom of tube with one hand. With other hand, snap cap off.) Remove cap carefully. Invert the applicator tube upright and to to the dog's tail.. Position the tip of the tube at the base of the tail and apply the contents of the tube to the base of the dog's tail. (Repeat every month.) (Repeat every 30 days if necessary.)

**STORAGE AND DISPOSAL:**

Do not contaminate water, food, or feed by storage and disposal. Store in a cool, dry place. **If empty:** Do not reuse the container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information (and help at any step) call our flea and tick experts at (phone #) (time).

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Hartz® One Spot Repellent for Dogs

2/7/06

EPA Reg. No.: 2596-137

PROPOSED MASTER LABEL (based on label submitted by Hartz: 2/26/01 in response to EPA 12/7/00 letter)

**OPTIONAL/ALTERNATE LABEL TEXT**

Kills and repels the Deer tick, (which may carry Lyme disease) (a vector of Lyme disease)

Apply to one spot for (head to tail) (total body) flea and tick protection (control)

Kills fleas before they lay eggs

Controls (Kills) (and) (Repels) fleas and ticks for up to 30 days (1 month) (4 weeks)

Kills and repels ticks (the American dog tick) (Brown dog tick)

(Lasts)(Works)(Protects) for 30 days (1 month)(4 weeks)

90% control of fleas and ticks in 48 hours (2 days)

Repels 95% of ticks within 3 days (72 hours)

Repels 90% of fleas within 3 days (72 hours)

Prevents re-infestation for 1 month (30 days)(4 weeks)

Hartz® (Control Pet Care System) products are designed to complement each other in an integrated program for flea and tick management. We recommend use of Hartz® (Control Pet Care System) products.

[As with all flea and tick products, they are] [(One Spot) (this product) (alternate brand name) (is)] most effective when used as part of a total program aimed at reducing fleas and ticks in the dog's environment.

Be sure to treat the animal's bedding and surroundings with product registered for these uses, such as [example: the Hartz® (Control Pet Care System) line.]

**Important Information: The ABC's of Flea and Tick Management**

**B—Protect Your Pet**

A—Treat Your Pet to kill fleas and ticks living on your pet

B—Protect Your Pet to keep fleas and ticks from re-infesting your pet

C—Treat Your Home both indoors and outdoors, to protect your entire home and guard against re-infestation.

**Step A—Treat Your Pet** with one of the Hartz® (Control Pet Care System) on-animal products, such as conditioning shampoo, dip, powder or spray, to kill fleas and ticks living on your pet. Use a Hartz® (Control Pet Care System) product containing (PRECOR®) (vIGRen®), an insect growth regulator (IGR) to also stop hatching flea eggs from developing into biting adults.

**Step B—Protect Your Pet** with a Hartz® (Control Pet Care System) repellent or flea and tick collar to keep fleas and ticks from re-infesting your pet. The (Hartz® Control Pet Care System Ultimate Flea Collar with vIGRen® and Rabon®) (alternate brand name) will also prevent flea eggs from hatching.

**Step C—Treat Your Home** both indoors and outdoors, with (Control Pet Care System Home Flea and Tick Killer or Fogger with vIGRen®) (alternate brand names) and (Control Pet Care System Yard and Kennel Spray) (alternate brand name) to protect your entire home and guard against re-infestation. [The (Control Pet Care System) (alternate brand name) Flea Trap will also serve to help break the flea life cycle (by killing fleas) in hard to reach areas of your home.]

Be sure to read the full directions and precautions on the label of each product you use.

Rabon® is a registered trademark for tetrachlorvinphos

vIGRen® is a registered trademark of Wellmark International

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## The Stress-Free System for Eliminating Fleas & Ticks

### On Animal Protection

#### *Relief for your pet*

Use Releve pet Protection System Conditioning Shampoo, Dip, Spray or Powder to kill fleas and ticks living on your pet.

### Repellent

#### *Keep fleas and ticks off your pet*

Prevent any more fleas and ticks from coming onto your pet by spraying your pet with Releve Pet Protection System Repellent for Dogs or Repellent for Cats.

### Continuous Protection

#### *Long-term protection for your pet*

Keep fleas and ticks from reinfesting your pet with Releve Pet Protection System 7 Month Flea & Flea Egg Collar with vIGRen, which will prevent flea eggs from hatching and Rabon to kill adult fleas and ticks.

### Home & Yard

#### *Protect your home and yard*

Kill fleas and ticks around your home with Releve Pet Protection System Carpet Powder, Yard and Kennel Spray, Home Flea & Tick Kill and Home Fogger.

**Remember to always read each product label and follow the directions carefully.**

Rabon is a registered trademark for tetrachlorvinphos  
vIGRen is a registered trademark of Wellmark International

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Hartz<sup>®</sup> One Spot Repellent for Dogs

2/7/06

EPA Reg. No.: 2596-137

PROPOSED MASTER LABEL *(based on label submitted by Hartz 2/26/01 in response to EPA 12/7/00 letter)*

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**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

Value Pack

3 (6) (11) (12) month supply

First (Second) (Third) Month

This product contains three monthly dosages, each (X fl. oz) (0.65) (1) (2) (3) (cc)(ml)

For Dogs and Puppies Over 90 lbs.

For Dogs and Puppies 61-90 lbs.

For Dogs and Puppies Over 60 lbs.

For Dogs and Puppies 31 to 60 lbs.

For Dogs and Puppies Over 30 lbs.

For Dogs and Puppies Up to 30 lbs.

For Dogs and Puppies 46 to 60 lbs.

For Dogs and Puppies 31 to 45 lbs.

For Dogs and Puppies 16 to 30 lbs.

For Dogs and Puppies 15 lbs. and Under

Convenient(.) (Easy) to use applicator

Easy (Simple) to use (handle) (apply)

Easy and convenient to use

No mess

Disposable applicator

Spreads naturally with dog's movement (skin and hair oils)

Apply to one spot—spreads over the dog's complete body (from head to tail) through the natural motion of the animal

Satisfaction guaranteed

Money back guarantee

Guaranteed to work\*

If not completely satisfied return unused portion for a full refund

Hartz<sup>®</sup> Every Pet's Best Friend™

VISIT OUR WEBSITE

[www.hartz.com](http://www.hartz.com)

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