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Systems Integration Group, Inc.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 22, 1999

Ms. Pat Bieler
Hartz Mountain Corp.
400 Plaza Drive
Secaucus, New Jersey 07094

Subject: Label Revisions, Additional Container Sizes and Marketing Copy
Hartz One Spot Repellent for Dogs
EPA Reg. No. 2596-137
Your Application Dated March 22, 1999

Dear Ms. Bieler:

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) We do not have in your file any efficacy data to support your mosquito control claims. Please remove all references to mosquitoes from your label. If you wish to retain these claims, please submit or cite (with MRID numbers) the appropriate efficacy data. If you are citing data other than your own, please remember to submit an offer to pay statement and new data matrix.
- 2) Please revise the Disposal statement to read as follows:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Store in a cool, dry place. Do not re-use empty tube. Wrap and discard in trash.

- 3) Please remove the statements "for Dogs and Puppies 31 to 60 lbs", "for Dogs and Puppies 16 to 30 lbs", and "for Dogs and Puppies 15 lbs and Under". Your use directions are simply for "dogs under 30 lbs" and "dogs over 30 lbs" - the dosages are not broken down more finely than that.
- 4) Please remove the phrase "For all Dogs" since the product is not for use on dogs under 6 months old. We recommend you place the statement "**USE ONLY ON DOGS OVER 6 MONTHS OF AGE**" on the front panel to alert the purchasing consumer of this limitation.
- 5) You can recommend use of other pet products including your own product line but cannot state "To assure proper treatment, we recommend use of only Hartz Control Pet Care System products". Thus delete the phrase "To assure proper treatment" and the word "only".
- 6) Under Directions for Use complete the instructions for applying the product to the dogs tail.
- 7) In your "HAZARDS TO DOMESTIC ANIMALS" category, after your "DO NOT USE ON CATS" statement, please add "Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of toxic exposure".
- 8) We note that some of your alternate back panels do not contain all of the requested PR Notice 96-6 information. Please make sure that your product has all the information requested in PR Notice 96-6 (regardless of which panel is used) as well as your company's complete address (including the street) and telephone number.

If you have any questions regarding this action, please feel free to contact me at (703) 305-6100 or Tracy Keigwin at (703) 305-6605.

Sincerely,

Tracy Keigwin
Tracy George T. LaRocca
 Product Manager (13)
 Insecticide Branch
 Registration Division (7505C)

FRONT PANEL

Hartz® Control Pet Care System One Spot Repellent for Dogs

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUN 22 1999

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

2596-137

() = Alternate Copy

**IMPORTANT Intended for use on Dogs
DO NOT USE ON CATS**

(for Dogs and Puppies Over 60 lbs.)

(for Dogs and Puppies 31 to 60 lbs.)

(for Dogs and Puppies Over 30 lbs.)

(For All Dogs)

(for Dogs and Puppies 16 to 30 lbs.)

(for Dogs and Puppies 15 lbs and Under)

Value Pack (3 month supply) (6 month supply) (1 month supply) (12 month supply)

first month, second month, third month

ACTIVE INGREDIENT:

By Weight (Nom.)

Permethrin (CAS# 52645-53-1) 45%

OTHER INGREDIENTS: 55%

KEEP OUT OF REACH OF CHILDREN

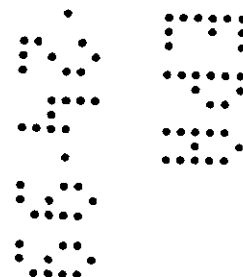
CAUTION: SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents:- (3 tubes, 0.65 cc, 0.02 fl oz each; 1.95 cc, 0.06 fl oz total)

(3 tubes, 1 cc, 0.03 fl oz each; 3 cc, 0.09 fl oz total)

(3 tubes, 2 cc, 0.06 fl oz each; 6 cc, 0.18 fl oz total)

(3 tubes, 3 cc, 0.10 fl oz each; 9 cc, 0.30 fl oz total)



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BACK PANEL

Hartz® Control Pet Care System One Spot Repellent for Dogs

(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 16 to 30 lbs.)

(for Dogs and Puppies 15 lbs and Under)

(For All Dogs)

Kills and Repels the Deer Tick, which may carry Lyme Disease (a vector of Lyme Disease)

Kills fleas (and mosquitos) before they lay eggs

● Controls (Kills) (Repels) fleas & ticks (and mosquitos) for 30 days (1 month) (4 weeks)

Kills and repels ticks (The American Dog Tick) (Brown Dog Tick)

Kills and repels mosquitos (a major carrier of canine heartworms)

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

Convenient, Easy to use applicator

Easy (Simple) to use (Handle) (Apply)

Spreads Naturally with Dog's Movement (Skin and Hair Oils)

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)

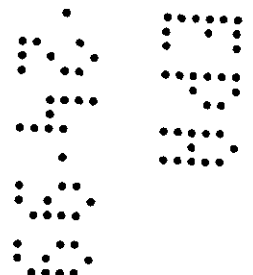
Prevents re-infestation for 1 month (30 days) (4 weeks)

No Mess

Disposable Applicator

Apply to One Spot for (Head to Tail) (Total Body) Flea and Tick (and mosquito) Protection (Control)

Apply to One Spot - spreads over the dog's complete body (from head to tail) through the natural motion of the animal.



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ALTERNATE COPY

Hartz Control Pet Care System 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 Control Pet Care System products.

BACK PANEL

**READ ENTIRE LABEL BEFORE USE.
USE ONLY ON DOGS OVER 6 MONTHS OF AGE.**

For use on dogs and puppies only

Use **ONLY** on dogs or puppies over 6 months of age. **DO NOT USE ON CATS OR OTHER ANIMALS.**

DIRECTIONS FOR USE:

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

(Note: this statement to be used on 1 cc package)

FOR SMALL DOGS (less than 30 pounds) (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 the tip of the tube (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 (1cc) to the animal (.....to push the entire contents of the ampule (1 cc) through tip of the tube onto the animal).

(Note: this statement to be used on 2 cc package)

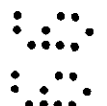
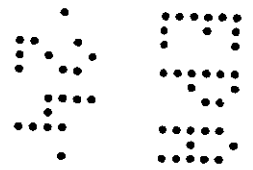
FOR LARGE DOGS (30 lbs and larger): (This product is packaged in single dosage ampules. One ampule (2 cc) is the correct dosage for a large dog.) (This product contains an ampule (2 cc inside a vial.) Point (the tip of the entire vial up) tip up and away from your face. Squeeze the middle of the tube to break the ampule. Position the tip of the tube (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 1/2 mark indicated on the tube. Invert the vial upright. (Tip pointing up) and go to the dog's tail. Position the tip

ALTERNATE PACKAGING DIRECTIONS

This product contains three monthly dosages, each (3 cc) (2 cc) (1 cc) (0.65 cc)

FOR SMALL DOGS (less than 30 pounds)

1. Use **ONLY** on dogs or puppies over 6 months of age. **DO NOT USE ON CATS.**
2. Remove one applicator tube from package and hold in an upright position.
3. Pull off cap. Turn the cap around and place on top of tube.
[3. Simply press cap down to break the seal of tube.]
[3. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.]
[3. Hold bottom of tube with one hand. With other hand, snap cap off.]



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4. (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.
5. Repeat every month. (Repeat (reapply) every 30 days if necessary).

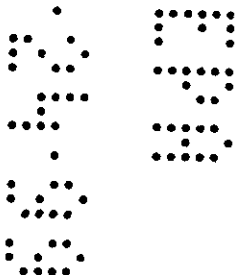
FOR LARGE DOGS (30 pounds and larger)

1. Use ONLY on dogs or puppies over 6 months of age. DO NOT USE ON CATS.
2. Remove one applicator tube from package and hold in an upright position.
3. Pull off cap. Turn the cap around and place on top of tube.
 [3. Simply press cap down to break the seal of tube.]
 [3. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip (snap cap off)]
4. (Remove cap carefully.) Position the tip of the tube on the dog's back between the shoulder blades and squeeze (out half) (tube to apply one-half) the contents (of the tube) (from the tube to the dog).
5. Invert the applicator tube upright 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.
6. Repeat every month. (Repeat (reapply) every 30 days if necessary).

ALTERNATE PACKAGING DIRECTIONS - for use in warehouse club packaging
 This product contains 6 monthly dosages, each (1 cc)

For Dogs Over 30 Lbs.

1. Use ONLY on dogs or puppies over 6 months of age. DO NOT USE ON CATS OR OTHER ANIMALS.
2. Remove one applicator tube from package and hold in an upright position.
3. Pull off cap. Turn the cap around and place on top of tube
 [3. Simply press (twist) cap down to break the seal of tube.]
 [3. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.]
 [3. Hold bottom of tube with one hand. With other hand, snap cap off.]
4. 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).
5. Remove second applicator tube from package and hold in an upright position.
6. Pull off cap. Turn the cap around and place on top of tube
 [6. Simply press (twist) cap down to break the seal of tube.]
 [6. Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.]
 [6. Hold bottom of tube with one hand. With other hand, snap cap off.]
7. Remove cap carefully. Invert the applicator tube upright and go 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.
8. Repeat every month. (Repeat every 30 days if necessary).



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[(As with all flea and tick products, they are) One Spot is most effective when used as part of a total program aimed at reducing fleas and ticks (and mosquitos) in the dog's environment.] Be sure to treat the animal's bedding and surroundings with products registered for these uses, such as (example: the Hartz Control Pet Care System line).

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage and disposal. Store in a cool, dry place. Do not re-use empty tube. Wrap and discard in trash.

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 six month old. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing 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: This product is toxic to fish.

FIRST AID: If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

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

EPA Reg. No. 2596-137

EPA Est. No. 2596-NJ-1

If not completely satisfied, return unused portion for a full refund.

OPTIONAL COPY #1

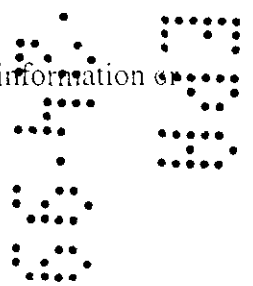
B - Protect Your Pet

Step A - TREAT YOUR PET with one of the Control on-animal products such as Conditioning Shampoo , Dip, Powder or Spray to kill fleas and ticks living on your pet. Use a Control product containing vIGRen®, an Insect Growth Regulator (I.G.R.), to also stop hatching flea eggs from developing into biting adults.

Step B - PROTECT YOUR PET with a Control repellent or flea and tick collar to keep fleas and ticks from reinfesting your pet. The Control Pet Care System Ultimate Flea Collar™ will also prevent flea eggs from hatching.

Step C - TREAT YOUR HOME, both indoors and outdoors, with Control Pet Care System Home Flea & Tick Killer or Fogger with vIGRen and Control Pet Care System Yard and Kennel Spray to protect your entire home and guard against reinfestation. The Control Pet Care System Flea Trap will also serve to help break the flea life cycle by killing fleas in hard-to-reach areas in your home.

Be sure to read full directions and precautions on the label of each product you use. For more information or help at any step, call our flea and tick experts at 1-800-275-1414, weekdays 9am-5pm EST.



Rabon® is a registered trademark for Tetrachlorvinphos
vIGRen® is a registered trademark of Wellmark Intl.

OPTIONAL COPY #2

The Stress-Free System for Eliminating Fleas & Ticks

On Animal Protection

Relief for your

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 Killer and Home Fogger.

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

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vIGRen® is a registered trademark of Wellmark Intl.

