

2596-146

9-24-2001

110



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 24 2001

Ms. Pat Bieler
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094-3688

Dear Ms. Bieler:

Subject: Label Amendment - Response to Agency Letter, 12/00
Hartz Ref. 101
EPA Reg. No. 2596-146
Your Submission Dated February 26, 2001

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.

1. Remove statements on page 3 of revised label beginning, "Cats which come in close physical contact....". These statements are directly at odds with the amended language requested in the Agency's letter dated 12/00. Replace these statements with, "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".
2. Provide a copy of the labeling present on the individual vials demonstrating the statement "Do not use on cats".
3. Amend the section under FIRST AID to include the following language: IF IN EYES is: "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".
4. Submit three copies of the complete labeling revised in accordance with the above comments.

Stamped labeling is enclosed for your records. If you have any questions regarding this letter, please contact Linda Werrell Gerber of my team at (703) 308-8033.

Sincerely,

A handwritten signature in black ink, appearing to read "George T. LaRocca".

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

2/10

MANDATORY COPY

FRONT PANEL

Product Name (Note: One of the following alternate brand names may be used.)

- Hartz® Ref. 101
- Hartz® Control Pet Care System® One Spot Repellent for Dogs
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies Under 30 lbs.
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies Over 30 lbs..
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies Over 60 lbs..
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies Under 15 lbs.
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies 16-30 lbs.
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies 31-45 lbs.
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies 46-60 lbs.
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies 61-90 lbs.
- Hartz® Control Pet Care System® One Spot™ for Dogs and Puppies Over 90 lbs
- Releve Pet Protection System® One Spot™ Flea & Tick Treatment for Dogs and Puppies 30 lbs and Under
- Releve Pet Protection System® One Spot™ Flea & Tick Treatment for Dogs and Puppies Over 30 lbs

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

Icon of cat in circle with a slash through it.

ACTIVE INGREDIENT:	By Weight (Nom.)
Permethrin (CAS# 52645-53-1).....	45.0%
(S)-Methoprene (CAS # 40596-69-8).....	2.9%
OTHER INGREDIENTS:.....	52.1%

(Note to EPA - Placement of Ingredient Statement previously approved as optional for front or back panel depending on box design.)

KEEP OUT OF REACH OF CHILDREN

CAUTION: SEE BACK PANEL FOR (INGREDIENT STATEMENT AND) ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: ~~X tubes, Net~~ XX fl oz each, X cc XX fl oz total

**with COMMENTS
In EPA Letter Dated:**

SEP 24 2001

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

2596-146

3/10

BACK PANEL

READ ENTIRE LABEL BEFORE USE.

Use **ONLY** on dogs or puppies over 6 months of age.

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. (Note: One of the direction statements listed in the optional copy will be inserted here.)

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 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 a 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: 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

EPA Reg. No. 2596-146

4/10

OPTIONAL COPY

Value Pack (1 month supply) (3 month supply) (6 month supply) (11 month supply) (12 month supply) (3 Months Protection)

First month, second month, third month

1st Dose, 2nd Dose, 3rd Dose

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

- (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)

Cats which come in close physical contact with recently treated dogs may be at risk of an adverse reaction. To minimize the chance of an adverse reaction, cats should be kept separated from the recently treated dog for a minimum of 6 hours.

For Use on Dogs and Puppies Only

Advanced Care

Advanced Flea and Tick [and Mosquito] Topical Treatment

Continuous Protection Against Fleas & Ticks

Kills and Prevents Fleas, Ticks and Flea Eggs

prevents (flea) (and mosquito) eggs from hatching (for 30 days) (1 month) (4 weeks)

kills (flea) (and mosquito) eggs before they hatch

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

kills flea eggs (and mosquito)(and larvae)

kills hatching eggs

contains an insect growth regulator

contains an adulticide

stops the flea and tick (and mosquito) life cycle

5/10

kills all stages of (the) (adult) flea(s) (and mosquito) (life cycle)
kills the Rocky Mountain Wood Tick, which may carry Rocky Mountain Spotted Fever
Kills and Repels the Deer Tick, which may carry Lyme Disease (a vector of Lyme Disease)
(The major carrier of human and canine Lyme Disease)

Continuous Protection Veterinarian Approved

Kills fleas (and mosquitoes) before they lay eggs

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

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

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

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

Convenient, Easy to use applicator That's Easy and Convenient to Use

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

Apply to One Spot - s 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 (two spots) for (Head to Tail) (Total Body) Flea and Tick (and mosquito)

Protection (Control) preads over the dog's complete body (from head to tail) through the natural motion of the animal.

One tube gives 30 days protection

Flea control for dogs with (PRECOR®) (vIGRen®) Insect Growth Regulator (IGR)

(PRECOR®) (and) (vIGRen®) (is a) (are) registered trademark(s) of Wellmark International

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.

6/10

OPTIONAL DIRECTION STATEMENTS (Please note: All direction statements reflect the same formula and dosage rate.)

1. (Note: This statement may be used on any size package.)

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 the tube. Simply press cap down to break the seal of the tube. Remove cap carefully.) (Hold bottom of tube with one hand. With other hand, snap cap off.) (Hold bottom of tube with one hand. With 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.)

2. (Note: This statement may be used on the following packages. For dogs 15 lbs and under, for dogs 16-30 lbs., for dogs under 30 lbs.)

(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 (1cc) through tip of the tube onto the animal). (Repeat every month.) (Repeat [reapply] every 30 days if necessary.)

3. (Note: This statement may be used on the following packages. For dogs over 30 lbs, for dogs 31-45lbs, for dogs 46-60 lbs, for dogsover 60 lbs, for dogs 61-90 lbs, for dogs over 90 lbs.)

(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) 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 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.)

7/10

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

For Dogs Over 30 lbs. Remove one 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. 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 go 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).

[(As with all flea and tick products, the are) One Spot is most effective when used as part of a total program aimed at reducing fleas and ticks (and mosquitoes 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).

Satisfaction Guaranteed

Money Back Guarantee

Guaranteed to Work*

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

If not completely satisfied with this product, return it to place of purchase with your receipt for a full refund.

For more information about [Brand Name] products call 1-800-XXX-XXXX weekdays from 8 am to 8 pm EST.

For more information, or (in case of emergency) help at any step), call our Flea and tick experts at (telephone number), (time)

Guaranteed to Work or Your Money Back

8/10

[The Hartz Ref. 101 contains both (an insecticide to kill adult fleas and ticks (and mosquitoes) and an insect growth regulator (IGR) to kill flea (and mosquito) eggs before they hatch.) (a powerful, effective insecticide which kills adult fleas and ticks (and mosquitoes), and a long lasting insect growth regulator which prevents flea (and mosquito) eggs 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.) (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 the Hartz Ref. 101 is designed to kill both the adult flea (and mosquito) eggs and larvae, thereby breaking the flea (and mosquito) life cycle.) (The repellent will also break the tick life cycle by killing adult ticks, including the Deer Tick, which may carry Lyme Disease, and the Rocky Mountain Wood Tick, which may carry Rocky Mountain Spotted Fever.)

(One Spot® provides relief from flea infestations for one month by controlling and preventing fleas on your dog and puppy. Adult fleas can live on your pet while also producing vast numbers of eggs which drop off your pet and develop in the surrounding environment. One Spot® kills the adult flea, its eggs and larvae, thereby breaking the flea life cycle. One Spot® breaks the tick life cycle by killing ticks, including the Rocky Mountain Wood Tick and the Deer Tick (the major carrier of human and canine Lyme Disease). One Spot® also kills and repels mosquitoes, a major carrier of canine heartworms).

After application, through its natural movement, your pet's skin and hair oils carry One Spot® over the pet's body for protection against fleas, ticks, (mosquitoes), flea eggs and larvae. Initially, to kill existing adult flea populations, you may need to treat the home, pet's bed and yard with traditional flea products such as home sprays, foggers and/or yard & kennel spray. One Spot® can be used in conjunction with the entire Control Pet Care System® product line.

To help remind you when you last applied treatment, simply write in the date when each dose is applied.

First Dose _____
Second Dose _____
Third Dose _____

Visit our Website
www.hartz.com
Hartz. Every Pet's Best Friend

9/10

Important Information: The A B C's of Flea and Tick Management

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 CollarJ 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.

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.

10/110

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.

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