

2596-151

09/06/2007

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

SEP - 6 2007

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 119
EPA Reg. No. 2596-151
Submission dated 4/17/07

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.

Confirm the fluid ounce net contents for dogs over 60 lbs. and correct if necessary.

To avoid misuse, all product names, including the outer package as well as the individual tubes, must include the size dog/puppy for which the product is intended.

The weight class 4-30 lbs is not approved. The label provides two size tubes (in terms of net contents) for this weight class.

The net contents on the individual tubes must be the net contents for each weight class. A range is not acceptable.

On the individual tube label, revise the reference to the complete label to read:
Read accompanying label before use.

Delete the following claim, which is not supported by the data submitted:
Starts working on contact.

Delete the following comparative claim:
Powerful results when you need it.

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Delete the following claims, which are false and misleading:

When your dog has fleas and ticks, your family and pet may be exposed to: (fleas that may cause) flea allergy dermatitis, flea bite anemia, tapeworm infestation, deer ticks which may carry lyme disease, lyme disease.

Delete references to a website, as this reference makes the website collateral labeling, and the collateral labeling has not been reviewed.

Delete the following claims which imply 100% efficacy:

Claims using the terms "protect" and "protection".

Claims using the term "eliminates."

Claims to "provides relief from flea infestations."

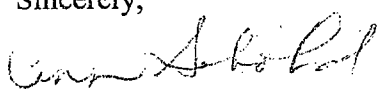
Acceptance of this label does not constitute approval of claims appearing on this label that are made for other Hartz products. Label claims for other Hartz products must be qualified by a statement referring the user to the labels for those products.

As noted in the Agency's letter of Dec. 14, 2006, the due data for data supporting mosquito claims is due Dec. 14, 2007. Copies of the efficacy and companion animal safety reviews are enclosed.

Changes in package size must be submitted as an amendment and not as a notification as they may affect both efficacy and margins of exposure for the treated dog.

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

Sincerely,



for

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

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under EPA Reg. No.
2596-151

Hartz® Reference 119

Alternate Brand Names

- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 4 to 15 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 4 to 30lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 16 to 30 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 31 to 45 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 46 to 60 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 61 to 90 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing Over 90 lbs.
- Hartz® 3 in 1® Flea & Tick Drops for Dogs and Puppies

Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing 4 to 15 lbs
 Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing 16 to 30 lbs
 Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing 31 to 60 lbs
 Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing > 60 lbs

ACTIVE INGREDIENT:

Phenothrin (CAS # 26002-80-2).....85.7%

OTHER INGREDIENTS.....14.3%

(TOTAL).....100.0%)

(Notes—CAS numbers may or may not appear on label; Ingredient Statement – optional front or back panel)

KEEP OUT OF REACH OF CHILDREN

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

See (side) (back) panel for ingredients and additional precautions

Net Contents: Contains [number] tubes; depending upon size of dog, range from 0.04 fl. oz. (1.1 mL) to 0.19 fl. oz. (5.6 mL) applicators. (Note – multiple packages containing from 1 tube to 150 tubes)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
4 to 15 lbs.	0.04 fl. oz., 1.1 mL
16 to 30 lbs.	0.04 fl. oz., 1.3 mL
31 to 60 lbs.	0.14 fl. oz., 4.1 mL
> 60 lbs.	0.19 fl. oz., 5.9 mL

EPA Reg. No. 2596-151
 EPA Est. No. 2596-NJ-1

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

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READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS (AND) (OR) (PUPPIES) OVER 12 WEEKS OF AGE.
DO NOT USE ON DOGS OR PUPPIES WEIGHING 4 LBS. OR LESS

[SEE PACKAGE LABELING FOR FIRST AID, STORAGE AND DISPOSAL AND OTHER PRECAUTIONARY STATEMENTS]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

HAZARDS TO DOMESTIC ANIMALS

DO NOT USE ON CATS OR KITTENS. Do not use on puppies less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity such as slight transitory redness of the skin 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. • **You may also contact 1-800-275-1414 for emergency medical treatment information.** • 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.

[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.

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 this 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.

INDIVIDUAL TUBE TEXT

- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 4 to 15 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 4 to 30 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 16 to 30 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 31 to 45 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 46 to 60 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing 61 to 90 lbs.
- Hartz® Advanced Care™ 3 in 1® Flea and Tick Drops for Dogs and Puppies Weighing Over 90 lbs.
- Hartz® 3 in 1® Flea & Tick Drops for Dogs and Puppies

- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing 4 to 15 lbs.
- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing 16 to 30 lbs.
- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing 31 to 60 lbs.
- Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs [(&) (and) Puppies] Weighing > 60 lbs.

[Product name will be followed by weight of dog for which tube is intended]

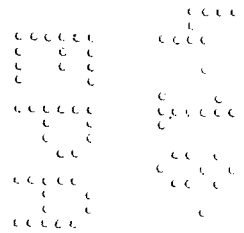
Keep Out of Reach of Children
Caution

Read entire label before use

[Active Ingredient:]
Phenothrin.....85.7%

Range of volumes from 0.04 fl. oz. (1.1 mL) to 0.19 fl. oz (5.9 mL) depending upon size of dog

EPA Reg. No. 2596-151
EPA Est. No. 2596-NJ-1
The Hartz Mountain Corp.



OPTIONAL/ALTERNATE LABEL TEXT

Actively Kills and Repels Fleas and Ticks for up to 30 days.
Actively Kills Fleas and Ticks for up to 30 days.
Kills and Repels Fleas and Ticks on contact for up to 30 days.
Kills Fleas and Ticks on contact for up to 30 days.
Starts working on contact.
Powerful results when you need it.
Clean fresh scent.

[All bolded text below represents one label statement with each selected line bulleted.]

When your dog has fleas and ticks, your family and pet may be exposed to:

(Fleas that may cause)

Flea allergy dermatitis

Flea bite anemia

Tapeworm infestation

(Deer ticks which may carry Lyme disease)

Lyme disease

To learn more about treating current infestations and preventing future outbreaks please visit our website www.hartz.com

To learn more visit www.hartz.com

Hartz recommends that you visit your veterinarian twice a year.

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

3 month supply

For Dogs (and) Puppies

For Dogs (and) Puppies (weighing) (4-15 lbs) (4-30 lbs) (16 - 30 lbs.) (31 - 45 lbs.) (31-60 lbs.) (46-60 lbs.) (> 60 lbs.) (61 - 90 lbs.) (over 90 lbs.)

X month supply

1st dose, 2nd dose, 3rd dose, Xth dose

X months' protection

first month, second month, third month, Xth month

X monthly treatments

Triple pack

Value pack

Advanced Care™

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

Kills and repels mosquitoes

3-in-1

This product (alternate name brand) kills (controls) fleas, ticks, and mosquitoes

Kills (repels) fleas, ticks & mosquitoes

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

Contains an adulticide

Stops the flea and tick (and mosquito) life cycle by killing the adult form of these pests

Kills (adult) fleas (and mosquitoes)

OPTIONAL/ALTERNATE LABEL TEXT, continued

~~Kills the Rocky Mountain wood tick which may carry Rocky Mountain spotted fever~~
Kills and repels the Deer tick which may carry Lyme disease
Controls (kills) (repels) up to (30 days) (1 month) (4 weeks)

Hartz Ref. 119 (alternate brand name) is the monthly treatment that effectively controls flea & tick infestations. This formula kills and prevents adult fleas, (ticks), (and mosquitoes). (It also repels and kills mosquitoes.)

(Baby) Fresh (scent) (fragrance)
(Baby) Powder (scent) (fragrance)
Pleasant (scent) (fragrance)
Clean, (baby) fresh (scent) (fragrance)
(Baby) Clean (scent) (fragrance)
Convenient (easy to use) applicator
Easy (simple) to use (handle) (apply)
Spreads naturally with (dog's) movement (skin and hair oils)
Controls (kills) 95% of fleas and 81% of ticks in 24 hours (1 day)

Repels 96% of ticks within 1 day (24 hours)
Repels 95% of fleas within 1 day (24 hours)
Special formula for (dogs) (and) (or) (puppies)
Specially formulated for (dogs) (and) (or) (puppies)
For (dogs) (and) (or) (puppies) over 12 weeks of age
For (dogs) (and) (or) (puppies) over 4 lbs.

For dogs and puppies
Topical treatment that's easy and convenient to use
3 month supply

Fast acting
Long lasting
(Effective) flea & tick control
Controls flea and tick infestations
Controls (kills) (repels) (eliminates) ~~(lasts)~~ ~~(works)~~ up to 30 days (1 month) (4 weeks)
Flea tick (and mosquito) control for (dogs) (and) (or) (puppies)
Hartz Ref. 119 (alternate brand name) provides relief from flea and tick infestation (from flea and tick populations) on (dogs) (and) (or) (puppies) by controlling and preventing adult flea and ticks

Disposable applicator
No mess
Apply as a stripe for head to tail (total body) flea and tick (and mosquito) ~~protection~~ (control)
Apply as a stripe - spreads over the dog's complete body from head to tail through the natural motion of the animal
Kills fleas before they lay eggs

OPTIONAL/ALTERNATE LABEL TEXT, continued

(Control (kills) (repels) (~~lasts~~) (~~works~~) adult fleas and ticks (mosquitoes) round-the-clock for up to (30 days)(1 month) (4 weeks)

This product (package) contains X monthly doses, each ___ fl. oz (___ mL)

One tube gives (provides) 30 days protection

Flea control for dogs

Satisfaction guaranteed

Money back guarantee

Guaranteed to work*

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

Hartz (brand name) 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 (Brand name) products

After application, the treated area may appear wet or oily for up to 24 hours.

(As with all flea and tick products, they are)[Hartz Ref. 119 (alternate name brand) is] most effective when used as a part of a total program aimed at reducing fleas and ticks (and mosquitoes) in the (dog's) (and) (or) (puppy's) environment.

Be sure to treat the animal's bedding and surroundings with products registered for these uses, such as the Hartz Control Pet Care System (alternate name brand) Line.

Hartz Ref. 119 (alternate name brand) contains (an insecticide to kill adult fleas and ticks) (and mosquitoes) [a powerful, effective insecticide that kills adult fleas and ticks (and mosquitoes)].

Adult fleas spend virtually all of their time on your pet. They produce vast numbers of eggs that 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.

Hartz Ref. 119 (alternate brand name) provides relief from flea infestations for one month by controlling (killing) and preventing adult fleas on your (dog) (and) (puppy).

Adult fleas can live on your pet while also producing vast numbers of eggs that drop off your pet and develop in the surrounding environment. Hartz Ref. 119 (alternate name brand) kills the adult flea, thereby breaking the flea life cycle. Hartz Ref. 119 (alternate name brand) breaks the tick life cycle by killing adult ticks, including the ~~Rock Mountain Wood Tick and Deer Tick~~ (which may carry Lyme disease). Hartz Ref. 119 (alternate name brand) also kills and repels mosquitoes, (which may carry canine heartworms).

OPTIONAL/ALTERNATE LABEL TEXT, continued

After application, through its natural movement, your pet's skin and hair oils carry Hartz Ref. 119 (alternate name brand) over the pet's body for protection against fleas (and) ticks, (and)(mosquitoes).

Immediately the (dog's) (and) (or) (puppy's) skin and hair oils will begin to carry this solution over the (dog's) (and) (or) (puppy's) entire body, killing fleas (and) ticks, (and)(mosquitoes).

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 sprays. Hartz Ref. 119 (alternate name brand) can be used in conjunction with the entire (brand name) 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 _____

To see a (visual) demonstration of application (ask our online experts) (visit our web site at www.hartz.com)

Hartz—Every Pet's Best Friend.

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

(For more information about (brand name) products call 1-800-275-1414 weekdays from 9 a.m. to 5 p.m. EST.

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

Protect Your Pet

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

- 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.

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

Step A - Treat Your Pet with one of the Control Pet Care System (alternate brand name) on-animal products, such as Conditioning Shampoo, Dip, Powder, Spray or Spot -On to kill fleas and ticks living on your pet. Use a Hartz Control Pet Care System (alternate brand name) product containing vIGRen®, an insect Growth Regulator (IGR), to also stop hatching flea eggs from developing into biting adults.

OPTIONAL/ALTERNATE LABEL TEXT, continued

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

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

Rabon® is a registered trademark for tetrachlorvinphos

vIGRen® is a registered trademark of Wellmark Intl.

