



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

DEC 14 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Joseph Conti
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Dear Mr. Conti:
Subject: Hartz Ref 119
EPA Reg. No. 2596-151
Submission dated 8/24/06

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 package for dogs 31 to 60 lbs with a dose of 0.09 fl. oz. is not approved. The dose for dogs 31 to 45 pounds must be packaged in 0.09 fl. oz. size tubes and the dose for dogs 46 to 60 pounds must be packaged in 0.14 fl. oz. size tubes. The label must reflect these package size changes.

Revise the packaging for the smallest weight classes as follows:
For dogs and puppies weighing 4 to 15 lbs (0.04 fl. oz)
For dogs and puppies weighing 4 to 30 lbs. (0.04 fl. oz.)

Add to the label the following:
Do not use on dogs or puppies weighing 4 lbs or less.

Within one year you must submit data (with the appropriate PRIA fee) to support mosquito claims or remove mosquito claims from the label.

Within one year you must submit data (with the appropriate PRIA fee) to support claims against the Rocky Mountain wood tick or remove these claims from the label.

Revise the Precautionary Statements to read as follows:

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.

In accordance with the efficacy review, remove the following enhanced efficacy claims:

- Fast Acting
- Long Lasting

As set forth in the label review manual, the individual tubes must bear the following labeling: Product name, including the weight of dog for which the product is intended, ingredient statement, signal word, child hazard warning, EPA registration number, EPA establishment number, net contents, and a statement referring the user to the accompanying label. The product name must match the name on the exterior package.

The product names "Omni Force" and "Ultra Force," unless trademarked, are enhanced efficacy claims and must be deleted.

The "3 in 1" claim when not appearing as a trademarked product name must be qualified by an explanation. Otherwise it is an enhanced efficacy claims and must be deleted.

The claim "3 month protection" must be qualified to explain what pests it refers to and how you get this length of protection.

Add at the end of the First Aid statements the following:

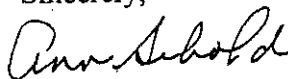
You may also contact 1-800 xxx-xxxx for emergency medical treatment information.

Delete claims that the product lasts works protects adult fleas and ticks.

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

All future changes in package size must be submitted as an amendment and not as a notification. A copy of the efficacy and companion animal safety reviews are enclosed. If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,



for

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

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 15 lbs. and Under
- 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 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[®] 3 in 1[®] Flea & Tick Drops for Dogs and Puppies Weighing 30 lbs. and Under
- Hartz[®] 3 in 1[®] Flea & Tick Drops for Dogs and Puppies Weighing 31 to 60 lbs
- Hartz[®] 3 in 1[®] Flea & Tick Drops for Dogs and Puppies Weighing 61 to 90 lbs.
- Hartz[®] 3 in 1[®] Flea & Tick Drops for Dogs and Puppies Weighing Over 90 lbs

- Hartz[®] Omni Force Drops for Dogs & Puppies
- Hartz[®] Omni Force Drops for Dogs & Puppies Weighing 30 lbs. and Under
- Hartz[®] Omni Force Drops for Dogs & Puppies Weighing 31 to 60 lbs.
- Hartz[®] Omni Force Drops for Dogs & Puppies Weighing 61 to 90 lbs.
- Hartz[®] Omni Force Drops for Dogs & Puppies Weighing Over 90 lbs.

- Hartz[®] Ultra Force Drops for Dogs & Puppies
- Hartz[®] Ultra Force Drops for Dogs & Puppies Weighing 30 lbs. and Under
- Hartz[®] Ultra Force Drops for Dogs & Puppies Weighing 31 to 60 lbs.
- Hartz[®] Ultra Force Drops for Dogs & Puppies Weighing 61 to 90 lbs.
- Hartz[®] Ultra Force Drops for Dogs & Puppies Weighing Over 90 lbs.

ACCEPTED
FOR COMMENTS
Label Dated:
8/14/2006
Insecticide,
Fungicide Act,
the pesticide
EPA Reg. No.
2596-151

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

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)

Hartz[®] Reference 119
EPA Reg. No.: 2596-151
MASTER LABEL

4 8 11
8/22/06

For Dogs and Puppies Weighing:	Net Contents (Each tube)
15 lbs. and under	0.04 fl. oz, 1.1 mL
16 to 30 lbs.	0.04 fl. oz, 1.3 mL
30 lbs. and under	0.04 fl. oz, 1.3 mL
31 to 60 lbs.	0.09 fl. oz, 2.6 mL
61 to 90 lbs.	0.16 fl. oz, 4.6 mL
Over 90 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.)
(and St. Thomas, Ontario N5P 3W7 Canada)

READ ENTIRE LABEL BEFORE EACH USE

[USE ONLY ON DOGS (AND) (OR) (PUPPIES) OVER 12 WEEKS OF AGE.]

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

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

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 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.

(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 15 lbs. and Under
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 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® 3 in 1® Flea & Tick Drops for Dogs and Puppies Weighing 30 lbs. and Under
Hartz® 3 in 1® Flea & Tick Drops for Dogs and Puppies Weighing 31 to 60 lbs
Hartz® 3 in 1® Flea & Tick Drops for Dogs and Puppies Weighing 61 to 90 lbs.
Hartz® 3 in 1® Flea & Tick Drops for Dogs and Puppies Weighing Over 90 lbs

Hartz® Omni Force Drops for Dogs & Puppies
Hartz® Omni Force Drops for Dogs & Puppies Weighing 15 lbs. and Under
Hartz® Omni Force Drops for Dogs & Puppies Weighing 16 to 30 lbs.
Hartz® Omni Force Drops for Dogs & Puppies Weighing 31 to 60 lbs.
Hartz® Omni Force Drops for Dogs & Puppies Weighing 61 to 90 lbs.
Hartz® Ultra Force Drops for Dogs & Puppies
Hartz® Ultra Force Drops for Dogs & Puppies Weighing 15 lbs. and Under
Hartz® Ultra Force Drops for Dogs & Puppies Weighing 16 to 30 lbs.
Hartz® Ultra Force Drops for Dogs & Puppies Weighing 31 to 60 lbs.
Hartz® Ultra Force Drops for Dogs & Puppies Weighing 61 to 90 lbs.
Hartz® Ultra Force Drops for Dogs & Puppies Weighing Over 90 lbs

Keep Out of Reach of Children
Caution

Read entire label before use

Phenothrin.....85.7%

Range of volumes from 0.04 fl. oz. (1.1 mL) to 0.19 fl. oz (5.6 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

For Dogs (and) Puppies
For Dogs (and) Puppies (15 lbs. & under) (16 - 30 lbs.) (30 lbs. and Under) (31 - 60 lbs.) (61 - 90 lbs.) (over 90 lbs.)
3 month supply
1st dose, 2nd dose, 3rd dose
3 months' protection
first month, second month, third month
3 monthly treatments
Triple pack
1 month supply
6 month supply
12 month supply
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 (protection)
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)
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) (lasts) (works) (protects) 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)

OPTIONAL/ALTERNATE LABEL TEXT, continued

Special formula for (dogs) (and) (or) (puppies)
Specially formulated for (dogs) (and) (or) (puppies)
For ~~all~~ (dogs) (and) (or) puppies over 12 weeks of age
For dogs and puppies
topical treatment that's easy and convenient to use
Fast acting
Long lasting
(Effective) flea & tick control
Controls flea and tick infestations
Controls (kills) (repels) (lasts) (works) (protects) (eliminates) 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
(Control (kills) (repels) (lasts) (works) (protects) adult fleas and ticks (mosquitoes) round-the-
clock for up to (30 days) (1 month) (4 weeks)
This product (package) contains three monthly doses (one monthly dose), each ___ fl. oz
(___ mL)
One tube gives (provides) 30 days protection
Flea control for dogs (~~eats~~)
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.

OPTIONAL/ALTERNATE LABEL TEXT, continued

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).

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.

OPTIONAL/ALTERNATE LABEL TEXT, continued

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).

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.

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

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.