

2596-151

05-19-2004

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

MAY 19 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Masuo Robinson  
Agent for Hartz Mountain Corporation  
Robinson Associates  
102 Greenfield Pl  
Los Gatos, CA 95032

Dear Mr. Robinson:

Subject: Hartz Ref No. 119  
EPA Reg. No. 2596-151  
Submission dated 5/17/04

This letter is in response to the referenced label amendment request submitted in connection with your registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. The label is acceptable subject to the comments listed below. It is important to note that this label amendment approval only relates to condition 2 of the amended notice of conditional registration dated November 19, 2002. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

Delete "By Wt. (Nom)" from the ingredient statement.

On page one, the net contents for dog products must be displayed as fluid ounces, and the metric measures (cc) are optional. On page 3, the marketing claim "This product contains three monthly doses (one monthly dose), each (\_\_\_ cc)." must be displayed in fluid ounces, with the metric measure optional.

The marketing claim on page 4 about the tick life cycle must be revised to read as follows:

Hartz Ref. 119 breaks the tick life cycle by killing adult ticks...

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

Sincerely,

*for Ann Sibold*  
Richard Gebken  
Acting Product Manager 10  
Insecticide Branch  
Registration Division (7505C)

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
MAY 19 2004

Required Copy

**FRONT PANEL**

Hartz® REF. NO.119

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

**Alternate Brand Names:**

Hartz® ADVANCED CARE™ 3 in 1™ Flea & Tick Drops for Cats Weighing More Than 10 lbs.

Hartz® ADVANCED CARE™ 3 in 1™ Flea & Tick Drops for Cats and Kittens Weighing 10 lbs. Or Less

†Hartz® ADVANCED CARE™ 3 in 1™ Flea & Tick Drops for Dogs and Puppies

Hartz® Advanced Care® Once-A-Month® Flea and Tick Drops for Cats and Kittens Weighing 10 Lbs. or Less

Hartz® Advanced Care® Once-A-Month® Flea and Tick Drops for Cats Weighing More Than 10 Lbs.

Advanced Care for Cats ≤ 10 Lbs.

Advanced Care for Cats > 10 Lbs.

Advanced Care 3 in 1 Drops for Cats ≤ 10 lbs.

Advanced Care 3 in 1 Drops for Cats > 10 lbs.

Advanced Care 3 in 1 Drops for Dogs

†Hartz® Advanced Care® Once-A-Month® Flea and Tick Drops for Dogs and Puppies

†This product will be marketed to dogs in the following weight classes: 15 lbs. and under, 16 to 30 Lbs., 31 to 60 Lbs., 61 to 90 Lbs., over 90 Lbs.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See Back Panel For (Ingredient, And, Additional Precautionary Statements

(Note: Optional language in parentheses or brackets)

For use on cats and kittens weighing 10 Lbs. or less. Net Contents: Contains [add in the number of tubes] 0.03 fl. oz. (1cc) applicators.

OR

For use on cats weighing more than 10 Lbs. - Net Contents: Contains [add in the number of tubes] 0.04 fl. oz. (1.3 cc) applicators

OR

[Note for dogs - Net Contents of Individual tube: -ranges from 1.1 cc to 5.9 cc (0.04 if oz to 0.19 fl oz each) depending on the size of dog or puppy to be treated]

[Note- multiple packages containing from 1 tube to 150 tubes.]

**BACK PANEL**

(Note to EPA -Active ingredient statement has previously been approved for back panel placement on this type of product due to package design.)

**ACTIVE INGREDIENT:** By Wgt. (Nom.)  
Phenothrin (CAS # 26002-80-2)..... 85.7%

**OTHER INGREDIENTS**.....14.3%

**READ ENTIRE LABEL BEFORE EACH USE**

USE ONLY ON (DOGS AND PUPPIES) (CATS AND KITTENS) OVER 12 WEEKS OF AGE.

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS**

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

**For Dogs: HAZARDS TO DOMESTIC ANIMALS**

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.

**For Cats: HAZARDS TO DOMESTIC ANIMALS**

Do not use on kittens less than 12 weeks old. Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or on animals known to be sensitive to pesticide products without first consulting a veterinarian. Signs of individual animal sensitivity that may occur after the use of this product include skin irritation or hair loss at the application site; salivation, tremors (twitching of muscles), and in some circumstances, severe full body tremors. Animals should be observed after application for any sign of sensitivity. If signs of sensitivity occur, bathe your pet with mild soap, rinse with large amounts of water and consult a veterinarian immediately.

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**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

Use only on (dogs or puppies) (cats or kittens) over 12 weeks of age.

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.)

**FOR DOGS:**

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.

**FOR CATS:**

Position the tip of the tube at the base of the cat's head. Use the tip of the tube to part the cat's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a spot at the base of the cat's head. Application to the base of the cat's head will reduce the opportunity for the cat to lick the product. Avoid contact with the cat's eyes and mouth.

Repeat every month.

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.

**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.

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

EPA Reg. No.2596-151

EPA Est. No. \_\_\_\_\_

**Additional labeling that is not mandatory but may be use for advertising or private label products. Alternate phrasing is designated by parentheses and/or brackets**

(For Dogs and Puppies) (15 lbs. & under) (16- 30 lbs.) (31- 60 Lbs.) (61 -90 lbs.) (over 90 Lbs.)

(For Cats and Kittens (weighing) 10 Lbs. & under) (For Cats (weighing) over 10 Lbs.)

(3 months supply) (1st dose, 2nd dose, 3rd dose) ((1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>) treatment(s))

(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)

[Advanced Flea and Tick (and Mosquito) Topical Treatment]

[(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) 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)]

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Hartz Ref. 119 is the monthly treatment that effectively controls flea & tick infestations. This gentle formula kills and prevents adult fleas, (ticks), (and mosquitoes) (Note: This phrase, "gentle formula", will appear only on the rear label of the package). 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], (Convenient)

[Easy (simple) to use (handle) (apply)]

[Spreads naturally with (dog's) (cat'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) (cats)]

[(Specially formulated for (dogs) (cats)]

[(For all (dogs and puppies) (cats and kittens) over 12 weeks of age] [For (dogs and puppies) (cats and kittens)

(Advanced topical treatment that's easy and convenient to use)

[Fast acting]

[Long lasting]

[(Gentle) formula] (Note: This phrase will appear only on the rear label of the package.)

[(Effective) flea & tick control], (Effective)

(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) (cats)]

[Hartz Ref. 119 provides relief from flea and tick infestation (from flea and tick populations) on (dogs and puppies) (cats and kittens) by controlling and preventing adult flea and ticks]

(Disposable applicator)

(No mess)

[For Cats: Apply to one spot for full body (total body) flea and tick (and mosquito) protection (control)] [Apply to one spot- spreads over the cat's complete body through the natural motion of the animal]

For Dogs: 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 contains three monthly doses (one monthly dose), each (\_\_\_ cc)]

[One tube gives 30 days protection]

[Flea control for dogs (cats)]

(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 is) most effective when used as a part of a total program aimed at reducing fleas and ticks (and mosquitoes) in the (dog's) (puppy's) (cat's) (kitten's) environment] (Be sure to treat the animal's bedding and surroundings with products registered for these uses, such as the Hartz (Brand or sub-brand) line.

[Hartz Ref. 119 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).

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(Hartz Ref. 119 is designed to kill the adult flea (and adult mosquito) thereby breaking the (pest) (insect) (flea) (and mosquito) life cycle) (adult Deer Tick which may carry Lyme Disease and the adult Rocky Mountain Wood Tick which may carry Rocky Mountain Spotted Fever)

Hartz Ref. 119 provides relief from flea infestations for one month by controlling (killing) and preventing adult fleas on your (dog and puppy) (cat and kitten). 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 kills the adult flea, thereby breaking the flea life cycle. Hartz Ref. 119 breaks the adult tick life cycle by killing ticks, including the Rock Mountain Wood Tick and Deer Tick (which may carry Lyme Disease). Hartz Ref. 119 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 over the pet's body for protection against fleas and ticks, (mosquitoes). [Immediately the dog's (cat's) skin and hair oils will begin to carry this solution over the (dog's) (cat's) entire body killing fleas and ticks.] 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. Hartz Ref. 119 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 (treatment) is applied.

First (Dose, Treatment) \_\_\_\_\_

Second (Dose, Treatment) \_\_\_\_\_

Third (Dose, Treatment) \_\_\_\_\_

(To see a visual demonstration of application) (ask our online experts) visit our web site [www.hartz.com](http://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):

.....  
.....  
.....

**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.

**INDIVIDUAL TUBE language**

[Advanced Care for Cats (10 lbs.)]  
[Advanced Care for Cats > 10 lbs.]

[Advanced Care 3 in 1 Drops for Cats ≤10 lbs.]  
[Advanced Care 3 in 1 Drops for Cats > 10 lbs.]  
[Advanced Care 3 in 1 Drops for Dogs]

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

Read entire label before use

Phenothrin 85.7%

0.03 fl. oz. (1cc) or 0.04 fl. oz. (1.3cc)

EPA Reg. No.2596-151

EPA Est. No. \_\_\_\_\_

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

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