

2596-148

05-19-2004

1/6



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. 117  
EPA Reg. No. 2596-148  
Submission dated 5/10/04

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.

In the first complete paragraph on page 4, clarify that Hart Ref 117 breaks the tick life cycle by killing adult ticks.

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

FRONT PANEL  
HARTZ® Ref. No. 117

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
2596-148

**Alternate Brand Names:**

Hartz® ADVANCED CARE™ 4 in 1 Flea & Tick Drops Plus+ for Cats and Kittens Weighing 10 lbs. Or Less

Hartz® ADVANCED CARE™ 4 in 1 Flea & Tick Drops Plus + for Cats Weighing More Than 10 lbs.

Hartz® ADVANCED CARE™ 4 in 1 Flea and Tick Drops Plus + for Cats and Kittens Weighing 10 lbs. Or Less

Hartz® ADVANCED CARE™ 4 in 1 Flea and Tick Drops Plus + for Cats Weighing More Than 10 lbs.

Hartz® Advanced Care® Brand® Flea and Tick Drops Plus+ for Cats and Kittens Weighing 10 lbs. or less

Hartz® Advanced Care® Brand® Flea and Tick Drops Plus+ for Cats Weighing more than 10 lbs.

Advanced Care + for Cats ≤ 10 lbs.

Advanced Care + for Cats > 10 lbs.

Advanced Care 4 in 1 Drops for Cats ≤ 10 lbs.

Advanced Care 4 in 1 Drops for Cats > 10 lbs.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See Back Panel For (Ingredients 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

[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 INGREDIENTS:**

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

S-methoprene (CAS #65733-16-6).....2.9%

**OTHER INGREDIENTS**.....11.4%

**READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON 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.

**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 which may occur after the use of this product include skin irritation, hair loss at the applications 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.

**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.

o/c

#### DIRECTIONS FOR USE

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

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 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.

**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 2596-148  
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.**

[3 Monthly Treatments]  
[3 Months Supply] [1<sup>st</sup> Dose, 2<sup>nd</sup> Dose, 3<sup>rd</sup> Dose][3 Months Protection]  
[First Month, Second Month, Third Month] [Triple Pack]  
[1 Month Supply] [6 Month Supply] [12 Month Supply [Value Pack]  
[Advanced Care]  
[Advanced Flea and Tick [and Mosquito] Topical Treatment]  
[4 in 1 [protection: [this product] kills [controls] fleas, ticks, and mosquitoes plus flea eggs.]  
[Kills (repels) fleas, ticks & mosquitoes plus flea eggs]  
[prevents flea eggs from hatching [1 month] [30 days] [4 weeks]  
[Kills flea eggs [and larvae] [kills hatching eggs]  
[Contains an insect growth regulatory] [contains an adulticide]  
[Contains a ovicide effective against flea eggs]  
[Stops the tick and mosquito life cycle by killing the adult form of these pests]  
[Stops the flea life cycle by killing adult fleas and flea eggs and larvae]  
[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]  
[Controls] [ Kills] [Repels] [Lasts] [Works] [Protects] [Fleas, Ticks],  
[and Mosquitoes] Round-the-Clock for up to 30 days [1 month]  
[For use on cats and kittens only]  
[Convenient, Easy to use Applicator]  
Easy [simple] to use [Handle] (Apply)]  
[Spreads Naturally with Cat's Movement (Skin and Hair Oils)]  
[Control [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 Cats] [Specially formulated for cats]  
[For all cats and kittens over 12 weeks of age] [For cats and kittens]  
[Flea Egg and Larvae Treatment]  
[Kills and prevents Flea Eggs and Larvae]

2/16

[Advanced Flea Egg and Larvae Topical Treatment That's Easy and Convenient to Use]

[Fast Acting]

[Long Lasting]

[Convenient]

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

[Effective Flea & Tick Control]

[Controls flea and tick infestations]

[Controls [Kills] [Repeals] [Lasts] [Works] [Protects] up to 30 days

[1 month] [4 weeks]

[Flea Control for Cats with [PRECOR®] [vIGRen®] Insect Growth Regulator [IGR]

[Hartz Ref. No 117 provides relief from the flea and tick infestation [from flea and tick populations] on cats and kittens by controlling and preventing adult ticks and fleas and flea eggs and larvae]

[No mess]

[Disposable Applicator]

[Apply to one spot for full body [Total Body] Flea and Tick [and Mosquito] Protections [Control]

[Apply to one spot – spreads over the cat's complete body through the natural motion of the animal.]

[This product contains three monthly doses [one monthly dose], each 0.03 fl. oz [1 cc] 0.04 fl. oz [1.3 cc]

[One tube gives 30 days protection]

[Flea Control for Cats with [PRECOR®] [vIGRen®] Insect Growth Regulator [IGR]

[Satisfaction Guaranteed] [Money-Back Guarantee]

[Guaranteed to Work\* \*If not completely satisfied, return unused portion for a full refund]

[PRECOR®] [and] [vIGRen®] [is a] [are] registered trademark[s] of Wellmark Intl.]

Why use Hartz Ref. No. 117? Hartz Ref. No. 117 contains two [2] special [active] ingredients. The first [active] ingredient, phenothrin, is specifically designed to kill adult fleas, ticks, and [repel] mosquitoes. The second [active] ingredient, [S]-methoprene, is designed to kill flea eggs and larvae. This combination provides our pet with complete

protection. Why is it important to kill flea eggs and larvae? Fleas spend virtually all their life on your pet and they produce a vast number of eggs, which drop off the pet and develop in the environment. Once you see fleas on your pet there is already an infestation of pre-adult flea stages in your home. Hartz Ref. No. 117 is specifically designed to kill adult fleas, flea eggs, and larvae, thereby breaking the flea lifecycle and making your pet flea free.

[brand or sub-brand] products are designed to complement each other in an integrated program for flea & tick management. To assure proper treatment, we recommend use only Hartz [brand or sub-brand] products.]

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

[Hartz Ref. No 117 with vIGRen® - Insect Growth Regulator, is the monthly treatment that effectively controls flea & tick infestations. This gentle formula kills and prevents adult fleas and ticks plus flea eggs and larvae [Note: This phrase will appear only on the rear label of the package]. [It also repeals and kills mosquitoes].

[As with all flea and tick products, they are] [Hartz Ref. 117 is] most effective when used as part of a total program aimed at reducing fleas and ticks [and mosquitoes] in the cat'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. 117 contains] [an insecticide to kill adult fleas and ticks] [and mosquitoes] and an insect growth regulator [IGR] to kill flea 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 eggs and larvae from maturing into adults.] [Adult fleas spend virtually all of their time on your pet but they produce vast number 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] [Hartz Ref. 117 is designed to kill the adult flea [and adult mosquito] and flea eggs and larvae, thereby breaking the [pest] [insect] [flea] [and mosquito] life cycle]. [The repellent will also

4/6

break the tick life cycle by killing adult ticks, including the Deer Ticks which may carry Lyme Disease and the Rocky Mountain Wood Tick which may carry Rocky Mountain Spotted Fever]

Hartz Ref. 117 provides relief from flea infestations for one month by controlling and preventing adult fleas on your cat and kitten. 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. Hartz Ref. 117 kills the adult flea, its eggs and larvae, thereby breaking the flea life cycle. Hartz Ref. 117 breaks the tick life cycle by killing ticks, including the Rocky Mountain Wood Tick and Deer Tick [which may carry Lyme Disease]. Hartz Ref. 117 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. 117 over the pet's body for protection against fleas and 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. Hartz Ref. 117 can be used in conjunction with the entire Hartz [brand or sub-brand] product line.

To help remind you when you last applied treatment, simply write in the date when each dose [treatment] is applied. [3 (Three) monthly treatments]

First dose [treatment] \_\_\_\_\_

Second dose [treatment] \_\_\_\_\_

Third dose [treatment] \_\_\_\_\_

[To see a visual demonstration of application] [ask our online experts] visit our website [www.hartz.com](http://www.hartz.com) Hartz Every Pet's 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 tick 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 Hartz [brand or sub-brand] 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 [brand or sub-brand] 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 [brand or sub-brand] repellent or flea and tick collar to keep fleas and ticks from re-infesting your pet. The Hartz [brand or sub-brand] 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 [brand or sub-brand] Home Flea and Tick Killer or Fogger with vIGRen and Hartz [brand or sub-brand] Yard and Kennel Spray to protect your entire home and guard against reinfestation. The Hartz [brand or sub-brand] Flea Trap will also serve to help break the flea life cycle killing in hard- to- reach areas of your home.

5/10

Rabon® is a registered trademark of Tetrachlorvinphos  
viGRen® is a registered trademark of Wellmark

**INDIVIDUAL TUBE language**

[Advanced Care + for Cats ≤ 10 lbs.]  
[Advanced Care + for Cats > 10 lbs.]

[Advanced Care 4 in 1 Drops for Cats ≤ 10 lbs.]  
[Advanced Care 4 in 1 Drops for Cats > 10 lbs.]

**Keep Out of Reach of Children**

**CAUTION**

**Read entire label before use**

Phenothrin.....85.7%  
[S]-methoprene.....2.9%

0.03 fl. oz. [1 cc] or 0.04 fl. oz. [1.3 cc]

EPA Reg. No. 2596-148

EPA Est. No. 2596-\_\_\_\_\_

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

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