



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505C)
 Ariel Rios Building
 1200 Pennsylvania Ave., NW
 Washington, D.C. 20460

EPA Reg. Number:

2596-148

Date of Issuance:

NOV 19 2002

Term of Issuance:

Conditional

Name of Pesticide Product:

Hartz Ref. No. 117

Amended NOTICE OF PESTICIDE:

 x Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

John J. Wrubel
 The Hartz Mountain Corporation
 400 Plaza Drive
 Secaucus, NJ 07094

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to any change in labeling. Any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above pesticide is hereby registered/re-registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

Registration in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that:

1. You submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Claims that the product is waterproof are supported by submitting scientific justification within 12 months of the approval of this amended registration. If the information and/or data submitted show that the product is not waterproof, Hartz will request an amendment to remove this claim from its labeling. If such an amendment is necessary, Hartz will request the amendment no later than 14 days from receipt of notification from EPA that the submitted information and/or data does not support the claim that the product is waterproof.

Signature of Approving Official:

Joseph M. Tavano
 Joseph Tavano
 Acting Product Manager 10
 Insecticide Branch
 Registration Division (7505C)

Date:

November 19, 2002

3. **Additional Companion Animal Safety Study.** Hartz must submit an additional companion animal safety study on this product no later than 12 months after the effective date of this amendment. The study will be conducted using the protocol set forth in EPA Guidelines 870.7200, using dose levels of 1X, 3X and 5X, with a vehicle control at 5X the recommended dose. The Guideline protocol will be modified as follows: (1) Study personnel will observe the study animals hourly for 12 hours following administration of the final dose; (2) each such observation will last a minimum of one minute; and (3) in addition to the clinical observations called for by the Guidelines, researchers will watch for and record any fine or coarse muscle tremors.

An independent testing laboratory will conduct the companion animal safety study and will deliver copies of the final study report simultaneously both to Hartz and directly to EPA upon completion of the study. Hartz will notify EPA when the in-life stage of the study has begun. In the event of unforeseen circumstances that will result in Hartz' inability to submit the study within 12 months from the effective date of the amended registrations, and absent any force majeure preventing notification, Hartz will notify EPA of this situation within 3 business days of Hartz' receipt of notification of the unforeseen circumstance. Hartz will provide to EPA the name and address of the independent laboratory no later than the date it notifies EPA of the in-life stage notification.

The fulfillment of this condition is not dependent on obtaining any particular study result; rather, the condition will be met by timely submission of a study run using the agreed-upon protocol if EPA finds the study to be acceptable. Acceptability does not pertain to the results of the study, only as to whether the study is acceptable for review. If, in EPA's judgment, the study was not submitted by the agreed-upon date, or was not conducted according to the agreed-upon protocol, or if the study is found to be unacceptable for review, EPA may commence cancellation action under FIFRA section 6(e). Hartz retains all its rights, under FIFRA section 6(e). If EPA determines that the study is not acceptable for review, EPA will, before initiating cancellation, allow Hartz to correct any deficiencies no later than 14 days after the date EPA notifies Hartz of those deficiencies.

EPA will review the results of the study and other information available to the Agency and may determine that further regulatory action is warranted. Hartz retains all its rights under FIFRA, including without limitation rights under sections 6(b), 6(c) and 6(d), to contest such an action.

4. **Enhanced 6(a)(2) Reporting.** Using the procedures set forth in 40 C.F.R. Part 159 and PR Notices 98-3 and 98-4, for this product Hartz will submit quarterly

reports of allegations of toxic or adverse incidents and will submit separate quarterly reports of allegations of incidents involving cats. In addition, for calendar years 2003 and 2004 in each such quarterly report for this product, Hartz will submit for each alleged incident that is reported in the DA, DB or DC categories, a list of the clinical signs alleged, and, for each incident reported to Hartz through the ASPCA system, the certainty category (corresponding to the clinical signs) assigned to each incident by the ASPCA/National Animal Poison Control Center.

5. **Orderly Product Exchange.** Upon the effective date of this amendment, Hartz will cease sale and distribution of this product as currently labeled in domestic markets. As soon as new product bearing the approved amended labeling is available, but in no case later than 60 days after the effective date of this amendment, Hartz will commence an orderly product exchange. Hartz will provide to customers a replacement kit which will include packaging that can be used to return any existing stocks to Hartz, with courier costs prepaid by Hartz, and a credit to the customer for each package of the product that is returned. Each kit will contain a reminder to the customer that Hartz is committed to replacing or refunding the purchase price to any consumer who wishes to return the product for any reason and that the retailer can return such product to Hartz for credit. For Hartz customers making new orders, the replacement kit also will include: (1) the product with amended labeling; and (2) a brochure to be made available to consumers at the point of sale. For some customers Hartz may arrange for retrieval of existing stocks and delivery of the replacement product, brochure, and reminder letter by Hartz personnel or someone contracted by Hartz. Within 10 business days of the effective date of this amendment, Hartz will provide EPA with a sample of the replacement kit. No later than 3 business days after the date of the first shipment of replacement product, Hartz will notify EPA that the shipment has been released. In this notification, Hartz will provide to EPA the date the shipment was released and the customer who will be receiving the shipment. Beginning 30 days from the date of the first shipment, Hartz will provide monthly reports that contain the following information: (1) the amount of product that has been returned to Hartz; and (2) the amount of new product shipped in its replacement. The reports will include returns by customers under this orderly product exchange as well as by consumers under the unconditional product guarantee and will state such.

Among other language, the point of sale brochure will include the following statements: "As is provided on our product label, our products are guaranteed to work or your money back. If you are not completely satisfied, return unused product for a full refund or replacement product by calling 1-800-275-1414."

Hartz will not sell or distribute for use in the United States any stocks of the product returned to Hartz under this program unless such stocks have been

repackaged and relabeled in new blister packs and individual folding cartons with labeling in accordance with the amended registrations. Such relabeling and repackaging must occur within a registered establishment. Hartz will maintain records so that the formulation in the repackaged products can be tracked. Hartz will track the formulation using their variant codes (indicating repackaged product) on the individual folding cartons or blister packs.

6. **Consumer Education Program.** No later than 30 days from the effective date of the amended registrations, Hartz will provide the Agency with a plan for Hartz' consumer education campaign relating to and encouraging the proper use of this product (the "Plan"). As expeditiously as possible, the Agency will review the proposals and provide Hartz with comments or suggestions. The target audiences of the education campaign shall include at least veterinarians, pet product stores, large retail stores, pet magazines, and users of Hartz products in Hartz' database. With the Plan, Hartz will provide EPA a list of the audiences that the campaign will target. Additionally, the Plan must include:

(A) Hartz posting consumer education materials on Hartz' website within 10 business days from the first shipment of replacement kits in connection with the orderly product exchange. The 1-800-275-1414 number will appear on the website for product questions as well as flea and tick questions.

(B) Hartz providing to customers, with each order shipped in 2003, point of sale brochures that are identical to those in the replacement kit.

(C) By March 31, 2003 a Hartz direct mail campaign of consumer educational material to pet owners, pet stores and veterinarians. The 1-800-275-1414 number will appear in the direct mailers.

7. **Individual Applicator Tube Labeling.**

(A) No later than 14 days from the effective date of this amendment, Hartz will provide to the Agency, a plan to effectuate amended tube labeling which will include:

(1) A time frame for the new tubes to be available for sale and distribution.

(2) The modifications Hartz will make to the existing tubes to meet the conditions of registration. Hartz will provide to EPA a complete description of the new tube design that must comply with FIFRA and its implementing regulations including but not limited to: tube size, tube color and contrasting label language color, how tube labeling is affixed to tubes, etc. Hartz will provide EPA with timely notice of any necessary changes to the design prior to the delivery of the mock-up in (A)(4) below.

(3) A draft label for the tubes which will contain the following language as appropriate for the formulation:

(a) "Advanced Care ■ for Cats ≤10 lbs." or "Advanced Care ■ for Cats > 10 lbs."

(b) "Read entire label before use"

- (c) Fluid Ounces alone or in addition to "cc"
 - (d) Registrant's Name
 - (e) EPA Reg. No.
 - (f) Active ingredient statement
 - (g) "Keep Out of Reach of Children"
 - (h) Signal Word
- (4) A date by which Hartz will provide EPA with a mock-up of the new tube design/labeling. The mock-up must contain the language in (A)(3) above and must comply with FIFRA and its implementing regulations.

(B) Beginning on January 15, 2003, Hartz will provide to EPA monthly status reports on their progress towards new tubes and tube labeling.

(C) No later than 12 months from the effective date of this amendment, Hartz will cease sale and distribution of the old tubes and old tube labeling and will begin sale and distribution of the new tubes with the amended labeling.

Submit two copies of the revised final printed label and tube language, for the record before you release the product for shipment.

If the conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

DRAFT November 11, 2002 Amendment (replacement page submitted on November 14, 2002)

Mandatory Copy

FRONT PANEL

Hartz Ref. No. 117

Alternate Brand Names:

Hartz® Advanced Care® Brand® Flea & Tick Drops Plus+ for Cats and Kittens Weighing 10 lbs and Under
Hartz® Advanced Care® Brand® Flea & Tick Drops Plus+ for Cats and Kittens Weighing Over 10 lbs

New Alternate Brand Names: Advanced Care + for Cats ≤ 10 lbs.
 Advanced Care + 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: [add in the number of tubes] 0.03 fl.oz. (1cc) applicators

OR

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

[Note – multiple packages containing 1 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:	By Weight (Nom.)
phenothrin (CAS# 26002-80-2).....	85.7%
(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

HAZARD 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.

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

NOV 19 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2596-148

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 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.

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.

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.

Remove 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 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 re-use the 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. _____

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

[3 month(ly) Supply (Treatment(s))] (1st Dose, 2nd Dose, 3rd 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 (for 30 days) (1 month) (4 weeks)]

[kills flea eggs before they hatch]

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

[kills flea eggs (and larvae)] (kills hatching eggs)

(contains an insect growth regulator) (contains and adulticide)

(contains an 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]

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[Easy (simple) to (Handle) (Apply)]

[Spreads Naturally with 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 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)

(Advanced Flea Egg and Larvae 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)

(It is also waterproof)

[Effective Flea & Tick Control]

[Controls flea and tick infestations]

[Controls (Kills) (Repels) (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 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) Protection (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 (1cc)]

[One tube give 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 your 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.

(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.)

(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 repels and kills mosquitoes.)]

[As with all flea and tick products, they are) (Hartz Ref. No. 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 Control Pet Care System line.)

[The Hartz Ref. No. 117 contains both (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 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.) Hartz Ref. No. 117 is designed to kill both 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 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.)

Hartz Ref. No. 117 provides relief from flea infestations for one month by controlling and preventing fleas on you 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. No. 17 kills the adult flea, its eggs and larvae, thereby breaking the flea life cycle. Hartz Ref. No. 117 breaks the tick life cycle by killing ticks, including the Rocky Mountain Wood Tick and the Deer Tick (which may carry Lyme Disease). Hartz Ref. No. 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. No. 117 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. Hartz Ref. No. 117 can be used in conjunction with the entire Hartz Control Pet Care System product line.

To 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.

[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-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)

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 the full directions and precautions on the label of each product you use.

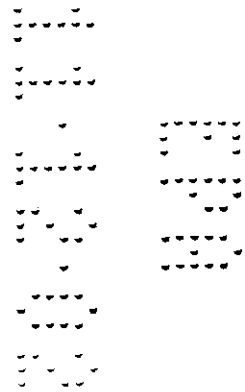
Step A – Treat Your Pet with one of the Hartz Control Pet Care System on-animal products, such as Conditioning Shampoo, Dip, Powder or Spray to kill fleas and ticks living on your pet. Use a Hartz Control Pet Care System product containing vIGRen[®], and Insect Growth Regulator (IGR), to also stop hatching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

Step B – Protect Your Pet with a Hartz Control Pet Care System repellent or flea and tick collar to keep fleas and ticks from re-infesting your pet. The Hartz Control Pet Care System 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 Home Flea and Tick Killer or Fogger with vIGRen and Hartz Control Pet Care System Yard and Kennel Spray to protect your entire home and guard against re-infestation. The Hartz Control Pet Care System Flea Trap will also serve to help break the flea life cycle by killing in hard-to-reach areas of your home.

[®]Rabon is a registered trademark of tetrachlorvinphos

[®]vIGRen is a registered trademark of Wellmark International.



DRAFT November 11, 2002 Amendment (replacement page submitted on November 14, 2002)

Individual dosing TUBE language to be sold or distributed by Hartz no later than 12 months from the effective date of this amendment.

Advanced Care + for Cats \leq 10 lbs.

OR

Advanced Care + 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. (1cc) or 0.04 fl.oz. (1.3cc)

EPA Reg. No. 2596-148

The Hartz Mountain Corp.