



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:

2596-151

Date of Issuance:

NOV 19 2002

Term of Issuance:

Conditional

Name of Pesticide Product:

Hartz Ref. No. 119

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 use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

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

Registration is 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.** Refer to EPA Reg. No. 2596-148 for the explicit requirements of this condition. Compliance with all requirements as set forth in this section under EPA Reg. No. 2596-148 will fulfill the condition of registration for this product. Failure to comply with EPA Reg. No. 2596-148 may result in **cancellation** under FIFRA section 6(e).

EPA will review the results of the study conducted under EPA Reg. No. 2596-148 and other information available to the Agency and may determine that further regulatory action is warranted. Hartz retains all its rights under FIFRA, including 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 all 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 the 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 delivery of the mock-up (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 \leq 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.

Required Copy

FRONT PANEL

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

Hartz® Ref. No. 119

NOV 19 2002
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® Brand® Once-A-Month® Flea and Tick Drops for Cats and Kittens

This product will be marketed to cats in the following weight classes: 10 lbs. & under, over 10 lbs.

New Alternate Brand Names: **Advanced Care for Cats ≤ 10 lbs.**
 Advanced Care for Cats > 10 lbs.

Hartz® Advanced Care® Brand® 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. & 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 (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. (1 cc) applicators.

OR

For use on cats (and kittens) 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 fl 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 which 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.

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 label of each product you use.

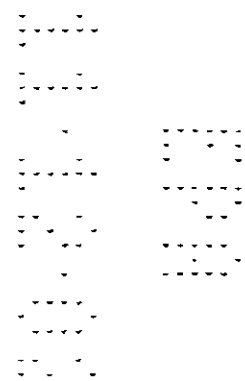
STORAGE AND DISPOSAL

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) (10 lbs. & under) (over 10 lbs.)

(3 months 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)

[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)]

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 will

appear only on the rear label of the package). It also repels and kills mosquitoes. It is also waterproof.

(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) (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)

(Waterproof)

(Waterfast)

(Works even when wet)

[Keeps working even after your (pet) (dog) (puppy) (cat) (kitten) has (gone swimming or has) been out in the rain]

[Fast acting]

[Long lasting]

[(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) (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 fleas 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]

[(Controls (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 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 Control Pet Care System line)

[Hartz Ref. 119 contains (an insecticide to kill adult fleas and ticks) (and mosquitoes) (a powerful, effective insecticide which kills adult fleas and ticks (and mosquitoes))] (Adult fleas spend virtually all of their time on your pet. 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. 119 is designed to kill the adult flea (and adult mosquito) thereby breaking the (pest) (insect) (flea) (and mosquito) life cycle) (Hartz Ref. 119 will also 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. 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 which 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 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, you 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 waterfast (waterproof) 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 is applied.

First dose _____
Second dose _____
Third dose _____

(To see a visual demonstration of application) (ask our online experts) 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 XX A.M. to XX P.M. EST.

