

2596-155

08/19/2005

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg.  
Number:  
2596-155

Date of Issuance:  
AUG 19 2005

Term of Issuance: Conditional

Name of Pesticide Product:  
Hartz Reference 123

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration  
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, New Jersey 07094-4501

**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 you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 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. Make the following label changes before you release the product for shipment:

- a. Add the phrase "EPA Registration Number 2596-155".
- b. On page 1, above product name, add the heading "Master Label" and a statement underneath it to indicate that this master label includes label text for different size packages and application rates specific to the pet's age and body weight.

(continued on page 2)

Signature of Approving Official:

*Rita Kumar*

Date: AUG 19 2005

- c. Please add a subheading of appropriate container size to each set of alternate brand names on page 1.
  - d. The label format is not clear as presented. Indicate what constitutes the front and back panels of each container size, and where rest of the statements will appear on each label.
  - e. On page 2, change the second statement as follows: "Use only on kittens over 12 weeks of age, and cats weighing 9 pounds or less."
  - f. On page 2, Hazards to Domestic Animals, change the first statement as follows: "For external use only on cats...kittens." Change the third statement under this heading as follows: "Do not use on kittens less than 12 weeks old or cats weighing over 9 pounds."
  - g. On page 4, Directions for Use, change the sixth statement as follows: "Use only on kittens over 12 weeks of age and cats weighing less than 9 pounds."
  - h. The alternate brand names given on the Tube Labeling for both sizes (pages 5 and 9) are not the same as the alternate brand names given on the front page. Alternate brand names on the outer package and the tube must match.
  - i. On page 6, change the second statement as follows: "Use only on cats over 6 months of age and weighing 9 pounds or over."
  - j. On page 6, Hazards to Domestic Animals, change the first statement as follows: "For external use only on cats." Change the third statement under this heading as follows: "Do not use on cats less than 6 months of age or weighing less than 9 pounds."
  - k. On page 8, Directions for Use, change the sixth statement as follows: "Use only on cats over 6 months of age and weighing 9 pounds or over."
  - l. On page 10, change this statement: "Kills 100% of the fleas on cats cats within 24 hours (and continues to prevent infestation for four weeks)" to the following: "Kills fleas on cats within 24 hours (and continues to prevent infestation for four weeks)". The claim of 100% control within 24 hours is not acceptable.
  - m. On pages 4 and 8, provide all optional pictures and graphics that you intend to use for demonstrating tube opening and application.
3. Within 24 months from the date of this letter, submit a transferrable residue study on cats. Prior to initiating this study, a protocol should be submitted to the Agency for review.
  4. Within 12 months from the date of this letter, submit results of the one year storage stability (830.6317), and corrosion characteristics (830.6320) studies that are being conducted for this product.

5. Submit production information for this product for the fiscal year in which this use is conditionally registered, in accordance with FIFRA section 29. The fiscal year begins October 1, and ends September 30. The production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year. This information should be submitted to:

Registration Support Branch  
Registration Division (7505C)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Washington D.C. 20460-0001

6. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(a). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,



Rita Kumar  
Senior Regulatory Specialist  
Insecticide Rodenticide Branch  
Registration Division (7505C)

Enclosure

# Hartz® Reference 123

Alternate Brand Name(s)

Hartz® Advanced Care™ Rapidfire Flea Drops for Cats  
Hartz® Advanced Care™ Express Flea Drops for Cats  
Hartz® Advanced Care™ Full-Speed Flea Drops for Cats

Hartz® Advanced Care™ Rapidfire Flea Drops for Cats and Kittens  
Hartz® Advanced Care™ Express Flea Drops for Cats and Kittens  
Hartz® Advanced Care™ Full-Speed Flea Drops for Cats and Kittens

**ACTIVE INGREDIENTS:**

|   |                |
|---|----------------|
| Dinotefuran*  | 14.85%         |
| N-methyl-N'-nitro-N''-[(tetrahydro-3-furanyl)methyl]guanidine |                |
| <b>OTHER INGREDIENTS</b>                                      | <u>85.15%</u>  |
| <b>TOTAL</b>  | <b>100.00%</b> |

\*(CAS #165252-70-0)

- Notes: 1. CAS numbers may or may not appear on product label  
2. Ingredient Statement – optional front or back panel

## KEEP OUT OF REACH OF CHILDREN

**CAUTION:** See back panel for (ingredient statement,) first aid, additional precautionary statements and directions for use.

NET CONTENTS: \_\_\_\_\_ fl. oz. (\_\_\_\_\_ mL)

Note: Unit packaging will contain either 0.04 fl. oz. (1.2mL) for single applications to cats or kittens weighing less than 9 lbs. or 0.06fl. oz. (2.0mL) for single applications to cats weighing 9 lbs. or more.. Outer packaging may contain up to 150 units.

EPA Reg. No. 2596-RLL  
EPA Est. No. 2596-NJ-1

[Made in the USA]  
[Company Name and Address]

ACCEPTED  
with COMMENTS  
in EPA Initial Review  
AUG 19 2005  
Under the Federal Insecticide  
Fungicide, and Rodenticide Act  
as amended, this product  
is registered under the  
2596-155

**LABEL TEXT FOR 1.2ml PACKAGING ONLY**

**READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON CATS [OR] [AND] KITTENS OVER 12 WEEKS OF AGE AND UNDER 9 LBS**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes. Harmful if swallowed. Harmful if absorbed through skin. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

**For external use on cats (and)(or) kittens**

**Do not use on animals other than cats (and)(or) kittens**

**Do not use on cats (and) (or) kittens less than 12 weeks old and over 9 lbs.**

Do not use this product, without first consulting a veterinarian, on debilitated, aged, medicated, pregnant or nursing animals or animals known to be sensitive to pesticide products. Do not use if your pet has an existing condition without first consulting a veterinarian. Individual sensitivities, while rare, 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 persist, or become more severe, contact your veterinarian immediately and notify Hartz at 1-800-275-1414. Do not apply more than once every 30 days.

**LABEL TEXT FOR 1.2ml PACKAGING ONLY**

**PHYSICAL OR CHEMICAL HAZARDS**

Combustible. Do not use or store near heat or open flame.

| <b>FIRST AID</b>  |  |
|---|--|
| <b>If in eyes:</b>  | 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.<br>Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice                         |
| <b>If swallowed:</b>  | Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.<br>Do not induce vomiting unless told to do so by a poison control center or doctor.<br>Do not give any liquid to the person.<br>Do not give anything by mouth to an unconscious person. |
| <b>If on skin:</b>  | Take off contaminated clothing.<br>Rinse skin immediately with plenty of water for 15 – 20 minutes.<br>Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice  |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. |  |

**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 tube. 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.

For more information (or in case of emergency) (or for help during any step) call (our flea and tick experts at) [1-800-275-1414] [weekdays, 9am-5pm E.S.T.]

**LABEL TEXT FOR 1.2ml PACKAGING ONLY**

**DIRECTIONS FOR USE**

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

Do not get this product in (your) pet's eyes or mouth.

Apply one applicator tube only.

Do not reapply for 30 days.

{This product (package) contains three (four)(one) monthly (30-day) application(s), [each 0.04fl. oz (1.2mL)]}

Use **only** on cats [and][or] kittens [over] **12** weeks of age and under 9 lbs.

**DO NOT USE ON ANY OTHER ANIMAL[S].**

- (1.) Remove one applicator tube from the package and hold in an upright position.
- (2.) Unscrew the tube cap. Remove the cap from the tube.
- (3.) The cap contains a point that can pierce the safety seal on the tube. Carefully hold the tube upright. Pointed away from the face and body. Puncture the safety seal of the tube.

{Alternate tube language:

- (1.) Remove one applicator tube from the package and hold in an upright position.
- (2.) Do not squeeze the bulb holding the product while opening the package.
- (3.) Holding the applicator upright and with the end of the applicator tube pointing away from the face and body, tear the opening tab of the applicator. Keep the tube in an upright position until you are ready to apply the product to your pet.}

OPTIONAL – Picture(s)/Graphic(s) demonstrating tube opening

- (4.) Using the tip of the applicator to part the cat's (kitten's) hair at skin level, apply to one spot at the base of the cat's (kitten's) head. Contact with the cat's (kitten's) eyes and mouth should be avoided. Once the material has been applied, hold the cat (kitten) in an upright position for a period of 2 minutes, to prevent any potential loss of applied material.

OPTIONAL – Picture(s)/Graphic(s) demonstrating application

- (5.) Repeat every month
- (6.) It is recommended that you (your pet) visit(s) your (a) veterinarian (at least) twice a year.
- (7.) Be sure to read full directions and precautions on label of each product you use.

LABEL TEXT FOR 1.2ml PACKAGING ONLY

TUBE LABELING

Hartz® Reference 123

Alternate Brand Name(s)

Hartz® Rapidfire Drops for Cats < 9lbs  
Hartz® Express Drops for Cats < 9lbs  
Hartz® Full-Speed Drops for Cats < 9lbs

KEEP OUT OF REACH OF CHILDREN

CAUTION  
READ ENTIRE LABEL BEFORE USE

Dinotefuran (CAS #165252-70-0).....14.85%

[0.04 fl. oz. (1.2 mL)]

EPA Reg. No. 2596-RLL

EPA Est. No. 2596-NJ-1



**LABEL TEXT FOR 2.0ml PACKAGING ONLY**

**READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON CATS OVER 6 MONTHS OF AGE AND 9 LBS AND OVER**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes. Harmful if swallowed. Harmful if absorbed through skin. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**HAZARDS TO DOMESTIC ANIMALS**

**For external use on cats.**

**Do not use on animals other than cats**

**Do not use on cats less than 6 months of age and under 9 lbs.**

Do not use this product, without first consulting a veterinarian, on debilitated, aged, medicated, pregnant or nursing animals or animals known to be sensitive to pesticide products. Do not use if your pet has an existing condition without first consulting a veterinarian. Individual sensitivities, while rare, 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 persists or become more severe contact your veterinarian immediately and notify Hartz at 1-800-275-1414. Do not apply more than once every 30 days.

**LABEL TEXT FOR 2.0 ml PACKAGING ONLY**

**PHYSICAL OR CHEMICAL HAZARDS**

Combustible. Do not use or store near heat or open flame.

| <b>FIRST AID</b>  |  |
|---|--|
| <b>If in eyes:</b>  | 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.<br>Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice                         |
| <b>If swallowed:</b>  | Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice.<br>Do not induce vomiting unless told to do so by a poison control center or doctor.<br>Do not give any liquid to the person.<br>Do not give anything by mouth to an unconscious person. |
| <b>If on skin:</b>  | Take off contaminated clothing.<br>Rinse skin immediately with plenty of water for 15 – 20 minutes.<br>Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice  |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. |  |

**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 tube. 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.

For more information (or in case of emergency) (or for help during any step) call (our flea and tick experts at) [1-800-275-1414] [weekdays, 9am-5pm E.S.T.]

**LABEL TEXT FOR 2.0 mL PACKAGING ONLY**

**DIRECTIONS FOR USE**

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

Do not get this product in (your) pet's eyes or mouth.

Apply one applicator tube only.

Do not reapply for 30 days.

{This product (package) contains three (four)(one) monthly (30-day) application(s), [each 0.06fl. oz (2.0 mL)]}

Use **only** on cats over 6 months of age and 9 lbs. and over  
DO NOT USE ON ANY OTHER ANIMAL[S].

- (1.) Remove one applicator tube from the package and hold in an upright position.
- (2.) Unscrew the tube cap. Remove the cap from the tube.
- (3.) The cap contains a point that can pierce the safety seal on the tube. Carefully hold the tube upright. Pointed away from the face and body. Puncture the safety seal of the tube.

{Alternate tube language:

- (1.) Remove one applicator tube from the package and hold in an upright position.
- (2.) Do not squeeze the bulb holding the product while opening the package.
- (3.) Holding the applicator upright and with the end of the applicator tube pointing away from the face and body, tear the opening tab of the applicator. Keep the tube in an upright position until you are ready to apply the product to your pet.}

OPTIONAL – Picture(s)/Graphic(s) demonstrating tube opening

- (4.) Using the tip of the applicator to part the cat's (kitten's) hair at skin level, apply to one spot at the base of the cat's (kitten's) head. Contact with the cat's (kitten's) eyes and mouth should be avoided. Once the material has been applied, hold the cat (kitten) in an upright position for a period of 2 minutes, to prevent any potential loss of applied material.

OPTIONAL – Picture(s)/Graphic(s) demonstrating application

- (5.) Repeat every month
- (6.) It is recommended that you (your pet) visit(s) your (a) veterinarian (at least) twice a year.
- (7.) Be sure to read full directions and precautions on label of each product you use.

**LABEL TEXT FOR 2.0mL PACKAGING ONLY**

**TUBE LABELING**

**Hartz® Reference 123**

Alternate Brand Name(s)

Hartz® Rapidfire Drops for Cats ≥9lbs  
Hartz® Express Drops for Cats ≥9lbs  
Hartz® Full-Speed Drops for Cats ≥9lbs

KEEP OUT OF REACH OF CHILDREN

CAUTION  
READ ENTIRE LABEL BEFORE USE

Dinotefuran (CAS #165252-70-0).....14.85%

[0.06 fl. oz. (2.0 mL)]

EPA Reg. No. 2596-RLL

EPA Est. No. 2596-NJ-1

**OPTIONAL LABEL TEXT FOR BOTH THE 1.2ml and 2.0 ml PACKAGES**

For cat and kittens weighing less than 9 lbs. (FOR THE 1.2 ML PACKAGE only)  
For cats weighing 9 lbs or more (FOR THE 2.0 ML PACKAGE only)

3 (4) month supply  
1<sup>st</sup> dose (application) (treatment), 2<sup>nd</sup> dose (application) (treatment), 3<sup>rd</sup> dose (application) (treatment), 4<sup>th</sup> dose (application) (treatment)  
3-month (30 day), (4-month), (6-month), (12-month) protection

First month, Second month, Third month, Fourth month  
This product (package) contains three (four)monthly doses (applications) (treatments)

1 month (30 day) supply  
This product (package) contains one (monthly) dose (application) (treatment)

4 month supply  
This product (package) contains four (monthly) dose (applications) (treatments)

6 month supply  
This product (package) contains six monthly doses (applications) (treatments)

12 month supply  
This product (package) contains twelve monthly doses (applications) (treatments)

Fast-acting  
Long Lasting (Gentle) (Effective)  
Flea control for cats (and) (kittens)  
Kills fleas (within 24 hours)  
Kills *Ctenocephalides felis* [the cat flea]  
For the Prevention and Treatment of Fleas on Cats  
Kills 100 % of the fleas on cats within 24 hours (and continues to prevent infestation for four weeks)  
One treatment prevents further flea infestation(s) for at least 4 weeks (one month) (30 days)  
One tube gives (provides) 30 day(s) (one month) (4 week) protection  
Kills (Controls) fleas [for up to 30 days (1 month) (4 weeks)]  
Lasts (Works) for up to 30 days (one month) (4 weeks)  
Protects against fleas [for up to 30 days (one month) (4 weeks)]  
Prevents re-infestation for (at least) one month (30 days) (4 weeks)  
One treatment effectively kills fleas through one month (30 days) (4 weeks)  
Fast (quick) drying (formula)  
Hartz® Ref. 123 (alternate brand name) is a monthly treatment that effectively controls flea infestations  
Hartz® Ref. 123 (alternate brand name) provides relief from flea infestation(s) [flea populations] on (cats) (and) (or) (kittens) by controlling (killing) (fleas) and preventing adult fleas

**OPTIONAL LABEL TEXT FOR BOTH THE 1.2ml and 2.0 ml PACKAGES**  
**continued**

This (gentle) formula kills (fleas) and prevents adult fleas  
Spreads naturally with (cat's) movement  
Spreads naturally with cat's skin and hair oils  
Spreads Rapidly (Quickly)  
Fast (Quick) (Rapid) Protecting (Protection)  
Quick (Speedy) Kill

Following label directions, an application to one spot spreads (rapidly) over the cat's (kitten's) complete body (from head to tail) through the natural motion of the animal

Specially formulated for cats (and) (or) kittens)  
Special formula for cats (and) (or) kittens)

Hartz® Ref. 123 (alternate brand name) contains [an insecticide to kill adult fleas] [a powerful, effective insecticide which kills adult fleas]. (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. 123 (alternate brand name) provides relief from flea infestations for one month by controlling (killing) and preventing adult fleas on your cat (and)(or) (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.

After application, through its natural movement, your pet's skin and hair oils carry Hartz® Ref. 123 (alternate brand name) over the pet's body for protection against fleas. Initially, to kill existing adult flea populations, you may need to treat ~~the~~ <sup>in</sup> home, pet's bed (bedding) and yard with traditional flea products such as home sprays, foggers, and/or yard and kennel sprays.

To help remind you when you last applied treatment,  
simply write (sticker) (in) the date when each dose (application) is applied (made).  
First Dose (Application) (Treatment) \_\_\_\_\_  
Second Dose (Application) (Treatment) \_\_\_\_\_  
Third Dose (Application) (Treatment) \_\_\_\_\_  
Fourth Dose (Application) (Treatment) \_\_\_\_\_

**OPTIONAL LABEL TEXT FOR BOTH THE 1.2ml and 2.0 ml PACKAGES**  
**NON-PESTICIDE RELATED CLAIMS**

Value Pack

Easy (and convenient) to use

Convenient, easy-to-use applicator

Easy (simple) (convenient) to use (handle) (apply)

No mess

No Noticeable Odors

No oily residue (on) (pet's) (coat) (fur)

Disposable applicator

(Available Only Through Licensed Practicing Veterinarians)

Satisfaction guaranteed

Guaranteed to work or your money back

If not completely satisfied (with this product), return (unused portion) [unused (unopened) tubes] (with your receipt) for a full refund

If not completely satisfied with this product, return (unused portion) [unused (unopened) tubes] (it) (to place of purchase with your receipt) for a full refund

Money back guarantee

Be sure to carefully read the label directions for use and precautionary statements before each use

(VISIT OUR WEBSITE) [web address]

Ask our online experts

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