

2596-155

07/21/2006

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUL 21 2006

Ms. Margaret Waters Dickson
Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Dear Ms. Dickson:

Subject: Label amendment; additional efficacy claims
Hartz Reference 123
EPA Registration Number 2596-155
Your submission dated 4/6/2006 and 4/18/2006

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7), is acceptable 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.
2. Make the following label changes before you release the product for shipment:
 - (a). Delete the following label claims: "*Kills 96% of fleas in 6 hours (and continues to prevent infestation for four weeks)*" and "*Kills 100% of fleas in 12 hours (and continues to prevent infestation for four weeks)*". These are considered heightened efficacy claims, and are not allowed by the Agency.
 - (b). Alternatively, you may replace these claims with the following: "*Kills fleas within 6 hours (and continues to prevent infestation for four weeks)*" and "*Kills fleas within 12 hours (and continues to prevent infestation for four weeks)*".
3. Submit two copies of the revised final printed label 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

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of these conditions.

A stamped copy the label is enclosed for your records. A copy of the efficacy review is also enclosed for your perusal. If you have any questions, please do not hesitate to contact me at (703) 308-8291, or send an e-mail.

Yours Sincerely,



Rita Kumar
Senior Regulatory Specialist
Insecticide-Rodenticide Branch
Registration Division (7505C)
e-mail: kumar.rita@epa.gov

Enclosures (2)

Hartz® Ref. 123
EPA Reg. No.: 2596-155 (Conditional Registration)
MASTER LABEL

MASTER LABEL
INCLUDES LABEL TEXT SPECIFIC TO DIFFERENT PACKAGE SIZES AND APPLICATION RATES
BASED ON PET'S AGE AND BODY WEIGHT

FRONT PANEL – BOTH PACKAGE SIZES

4002-11
with COMMENTS
in EPA Letter Dated
JUL 21 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
EPA Reg. No. 2596-155

Hartz® Reference 123

Alternate Brand Name(s)

FOR CATS:

- 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
- Net Contents: 0.06 fl. oz. (2.0 mL) (for cats 6 months of age or older, and weighing 9 lbs. or over)*

FOR CATS AND KITTENS:

- 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
- Net Contents: 0.04 fl. oz. (1.2 mL)*
(for cats or kittens weighing over 12 weeks of age, and weighing less than 9 lbs.)

ACTIVE INGREDIENTS:

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

*(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.

BACK PANEL LABEL TEXT FOR 1.2 mL PACKAGING ONLY

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON KITTENS OVER 12 WEEKS OF AGE AND CATS WEIGHING 9 POUNDS (LBS.) OR LESS**

**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 only on cats (and) (or) kittens

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

Do not use on kittens less than 12 weeks old or cats weighing over 9 pounds (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.

PHYSICAL OR CHEMICAL HAZARDS

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

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. Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice
If swallowed:	Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. 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.	

BACK PANEL LABEL TEXT FOR 1.2 mL PACKAGING ONLY--CONTINUED

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.]

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 0.04 fl. oz (1.2mL)]}

Use **only** on kittens over 12 weeks of age and cats weighing less than 9 pounds (lbs.).

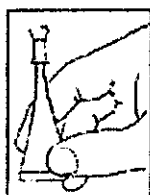
DO NOT USE ON ANY OTHER ANIMAL[S].

- (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.}

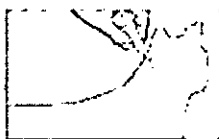
OPTIONAL – Picture(s)/Graphic(s) demonstrating tube opening:



BACK PANEL LABEL TEXT FOR 1.2 mL PACKAGING ONLY--CONTINUED

(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.

TUBE LABELING TEXT FOR 1.2 mL PACKAGING ONLY

Hartz® Reference 123

Alternate Brand Name(s)

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
(For cats and kittens over 12 weeks of age, and weighing less than 9 lbs.)

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. 2596-155

EPA Est. No. 2596-NJ-1

BACK PANEL LABEL TEXT FOR 2.0 mL PACKAGING ONLY

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS OVER 6 MONTHS OF AGE AND WEIGHING 9 POUNDS (LBS.) OR 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 only on cats

Do not use on animals other than cats

Do not use on cats less than 6 months of age or weighing less than 9 pounds (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.

PHYSICAL OR CHEMICAL HAZARDS

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

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. Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice
If swallowed:	Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If on skin:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. 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.	

BACK PANEL LABEL TEXT FOR 2.0 mL PACKAGING ONLY--CONTINUED

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.]

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)]}

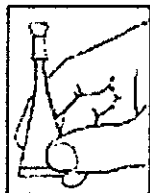
Use **only** on cats over 6 months of age and weighing 9 pounds (lbs.) or over
DO NOT USE ON ANY OTHER ANIMAL[S].

- (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:



BACK PANEL LABEL TEXT FOR 2.0 mL PACKAGING ONLY--CONTINUED

(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.

TUBE LABELING TEXT FOR 2.0 mL PACKAGING ONLY

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
(For cats over 6 months of age, and weighing 9 lbs. or over)

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. 2596-155

EPA Est. No. 2596-NJ-1

OPTIONAL LABEL TEXT FOR BOTH THE 1.2 mL AND 2.0 mL PACKAGES
MAY APPEAR ON FRONT OR BACK PANEL

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

1st dose (application) (treatment), 2nd dose (application) (treatment), 3rd dose (application)
(treatment), 4th 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) doses (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 96% of fleas in 6 hours (and continues to prevent infestation for four weeks)

Kills 100% of fleas in 12 hours (and continues to prevent infestation for four weeks)

Kills 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 1.2 mL AND 2.0 mL PACKAGES--CONTINUED
MAY APPEAR ON FRONT OR BACK PANEL**

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 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 1.2 mL AND 2.0 mL PACKAGES --CONTINUED
MAY APPEAR ON FRONT OR BACK PANEL
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

(Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation)