

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 6, 2017

Anna McGrath The Hartz Mountain Corporation 400 Plaza Drive Secaucus, New Jersey 07094-3688

Subject: Notification per PRN 98-10 – Minor change in label

Product Name: HARTZ REFERENCE #141

EPA Registration Number: 2596-174

Application Date: 12/22/2016 Decision Number: 524749

Dear Ms. McGrath:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

[Label reader's notes or Optional/alternate text is shown in italics, parenthesis or brackets]

FRONT PANEL

Hartz® Reference #141

or Alternate brand names(see last pages)

[All market place labels to have picture of cat and to include the following information on the front panel] Use Only on Cats and Kittens [over 3 lbs. but less than 5 lbs.] [And weighting][5 lbs. and over] & 12 Weeks of Age and Older

ACTIVE INGREDIENTS	
Etofenprox	40.0%
(S)-Methoprene	
OTHER INGREDIENTS	
TOTAL	
KEEP OUT OF REACH OF CHILDREN CAUTION See back (side <i>or</i> other) panel for ingredients and additional preca	utionary statements
Net Contents : fl oz. (ml)	
Contains (number) tubes, each fl oz. (ml)	NOTIFICATION
BACK PANEL EPA Reg. No. 2596-174 EPA Est. No.	2596-174 The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: CAUTION: Causes moderate eye irritation. Avoid contact with 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 Only. Do not use on kittens less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Sensitivities 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.

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 or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information."

01/06/2017

[Label reader's notes or Optional/alternate text is shown in italics, parenthesis or brackets]

BACK PANEL (CON'T.)

RESTRICTIONS

USE ONLY ON CATS OR KITTENS 12 WEEKS OF AGE AND OLDER DO NOT USE ON OTHER ANIMALS

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR CATS

DO NOT APPLY MORE THAN ONE (1) TUBE PER TREATMENT ON ANY CAT DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY.

DO NOT APPLY TO CATS WEIGHING LESS THAN 3-LBS. (insert lowest weight of weight class)

DO NOT ALLOW YOUR CATS TO INGEST THIS PRODUCT HOUSEHOLDS WITH MORE THAN ONE CAT: PREVENT CATS FROM GROOMING EACH OTHER UNTIL SOLUTION HAS DRIED.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL BEFORE USE

This product contains xx monthly dosages [one monthly dose], each (1 and 1.8 ml [cc]]. Do not apply more than once every month.

Do not get this product in your cat's eyes or mouth.

(PACKAGING DIRECTIONS)

- 1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
- 2. Twist dispensing tip clockwise about 1/2 turn while pushing down to break the applicator's [tube's] seal. Do not remove the dispensing tip.
- 3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing tip of the applicator [tube] on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] (product) has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
- 4. Repeat application [once every month] [once monthly].

(ALTERNATE PACKAGING DIRECTIONS 2)

- 1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
- 2. Twist dispensing tip clockwise about 1/2 turn until you feel it click into place. Do not remove the dispensing tip.
- 3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing tip of the applicator [tube] on the cat's exposed skin and squeeze out the [entire] contents of the [applicator] tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] (product) has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
- 4. Repeat application [once every month] [once monthly].

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(ALTERNATE PACKAGING DIRECTIONS 3)

- 1. Remove one applicator tube from the package and hold in an upright position pointed away from your face.
- 2. Pull off cap. Turn the cap around and place on top of tube.
- 3. Simply press cap down to break the seal of tube. Remove cap carefully.
- 4. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the tip of the tube on the cat's exposed skin and squeeze out the entire contents of the tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] (product) has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
- 5. Repeat application [once every month] [once monthly].

1 ml [cc] for cats [kittens] under 5 lbs.; 1.8 ml [cc] for cats 5 lbs. and over

For use on cats under 5 lbs.[or 5 lbs. and over] For cats weighing 5 lbs and over [or < 5 lbs] [or Under 5 lbs]

[Include on back panel]

SIDE EFFECTS

Side Effects – Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not refill or reuse this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

(INTRODUCTION)

(Product Name) is a topically applied long-lasting product specifically formulated for cats and kittens containing (or with) an insect growth regulator (IGR) S-Methoprene to prevent and control flea infestations to kill fleas before they hatch. This product also contains the highly effective flea, deer tick, and mosquito killing agent Etofenprox (Brand Name), which kills biting adult fleas, deer ticks, and mosquitoes your cat may acquire from its surroundings. A single application of (Product Name) will provide egg hatch inhibition for up to 1 month. Each package contains enough products for [xx] monthly applications. Adult fleas can live on your cat while producing vast numbers of eggs, which drop off your cat and develop in the surrounding environment.

After application, your cat's skin oils disperse and carry (Product Name) over your cat's body for protection against biting adult fleas and the development of flea eggs. (Product Name) may stain leather and suede fabrics for 24 to 48 hours after application. Once adult fleas are evident on your cat, there is likely an infestation of flea eggs and flea larvae in your home. To completely kill the existing flea population, you may need to treat your home and your cat's bedding, as well as your yard with traditional flea products approved for use on cats, around the home, or in your yard. (Product Name) can be used in conjunction with other HARTZ® premise products. As with all flea products, (Product Name) is most effective when

[Label reader's notes or Optional/alternate text is shown in italics, parenthesis or brackets]

used as part of a total program aimed at reducing all stages of fleas in the cat's environment. HARTZ products are designed to complement each other in an integrated program for flea, deer tick, and mosquito management. To assure proper treatment, we recommend use of HARTZ products as directed to treat all cats in the household, as well as the indoor and outdoor home environments.

(Claims)

Flea & Deer Tick [Protective] for cats [& kittens]

[Flea & deer tick] treatment for cats [& kittens]

[Special formula for cats/kittens][Superior flea prevention and treatment specially formulated for use on [all] cats and kittens [12 weeks of age and older]

Spot On [Topical] [Non-systemic] treatment for cats

Flea, Deer Tick, and Mosquito (Treatment) [Control] [Prevention] (for Cats & Kittens)

[1 month] [monthly] [flea, deer tick, & flea egg](protection)

Monthly treatment for [fleas, flea eggs, & deer ticks]

Flea [and deer tick] [and mosquito] control for your cats

Keeps fleas, deer ticks, and mosquitoes under control

Controls flea, deer tick, and mosquito problems

Provide your cat with flea, deer tick, and mosquito protection, right from the start

On-animal protection from fleas, deer ticks, and mosquitoes

Provides [protection] from fleas, deer ticks, and mosquitoes

Once-a-month [topical] [Spot On] protection from fleas and deer ticks

Long lasting, flea, deer tick, and mosquito protection

Starts killing fleas (in) (within) 15 minutes

Starts killing fleas (in) (within) 15 minutes and lasts (up to) (30 days) (1 Month) (4 weeks)

[Actively] Kills [Controls] [adult] fleas, deer ticks, [larvae], and flea eggs (for) [up to] [4 weeks] [1 month] [per application]

[Actively] Kills [fleas] [deer ticks] [flea eggs] [larvae] [&] [and] [mosquitoes] [by contact Kills (and) (Repels) mosquitoes [for up to 18 days] [by contact]

Controls fleas, deer ticks, and mosquitoes & prevents flea reinfestations

[Kills deer ticks] (for up to 1 month [4 weeks]) [per application]

Protects your [cat] [kitten] from fleas, deer ticks, and mosquitoes (which may transmit heartworm disease)

Effectively controls fleas, deer ticks, and mosquitoes

Kills [Controls] deer ticks [that may transmit Lyme disease] for up to [1 month] [4 weeks]

 $Protect(s)\ your\ cat\ [and\ kittens]\ from\ [against]\ deer\ ticks\ that\ may\ transmit\ Lyme\ disease$

Kills [and repels] mosquitoes that may transmit heartworm disease

Prevents mosquitoes from feeding on cats

Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and may transmit tapeworm infestation

Preventative treatment for fleas that may cause flea allergy dermatitis, flea bite anemia and transmit tape worm infestation

Control highly irritating flea, deer tick, and mosquito [insect] bites

[Hartz] protecting cats for over 85 years

Kills [Controls] flea eggs for up to [30 days] [1 month] [4 weeks] [per application]

Kills flea eggs, the source of home flea infestations and cat re-infestations, for up to [30 days] [1 month] [4 weeks]

[Topical] [flea egg treatment] that's easy and convenient to use

[Kills][Prevents][Keeps] flea eggs from hatching for up to [30 days] [1 month] [4 weeks]

Prevents flea eggs from developing into biting adults for up to [30 days] [1 month] [4 weeks] [per application]

An effective flea topical [A Spot On] product that kills adult fleas and halts the development of flea eggs [immature stages in the flea life cycle]

Kills [flea] eggs before they hatch into biting adults

Prevents re-infestation for up to [1 month] [30 days] [4 weeks]

Kills hatching [developing] flea eggs

Interrupts normal flea development [Stops the flea life cycle]

[Label reader's notes or Optional/alternate text is shown in italics, parenthesis or brackets]

Interrupts the flea life cycle

Breaks the flea life cycle for up to [1 month] [4 weeks] [30 days]

Controls [Kills] [Lasts] [Works] [Protects] flea infestations for up to [1 month] [4 weeks]

One-two punch controls fleas and flea eggs

Controls existing fleas and flea eggs, plus [and] [prevents] future flea infestations

Plus kills flea eggs and larvae to prevent future infestations

(Application claims)

[#] pack [# days'] [#] doses [1/2/3/4/5/6] months supply

One tube gives [1 month] [4 weeks] of protection

[Pre-measured][Convenient][and][&][No mess][easy][simple] to [use] [handle] [apply] disposable applicator [tube]

Convenient [and effective], once-a-month [liquid] [topical] [Spot On] solution

Practical solution

Simple choice [flea & deer tick control]

A [One] simple application provides your cat with protection for up to [1 month]

Apply to one spot for head to tail (total body) flea protection [control]

Apply to 1 spot - spreads over the cat's [entire] body [from head to tail] through skin oils

Spreads with cat's skin oils

[Once][One] Monthly Application

Easy to use [once] monthly application [liquid] prevents [and controls] fleas [& deer ticks]

Reapply [Repeat] [once] monthly

Repeat [treatment] every month

Monthly Control [treatment]

(Applicator claims)

[Free][X] Pro-cision Flo® (Applicators) [tubes] (Included)

[Free][Exclusive][Pinpoint][Applicator] for [pinpoint] [exact] [direct] [easy] [direct to skin] application (included)

Patent pending

For pinpoint accuracy

Direct to your cat's skin

Easily penetrates hair

The [Pro-cision Flo®] [exclusive] [applicator [tube] [easily penetrates hair] [fur] [coat] for [improved]

[direct] application [directly to your cat's skin]

Easy to apply [identify] [use] applicator [tube]

Easy to use applicator [tube] [provides direct on-animal protection]

Longer Applicator [tube] [tip] for easy application [to long-haired cats]

Longer tube [applicator] is ideal for long-haired cats

(Convenient)(easy to use) applicator

(Pro-cision Flo® Applicator) easily gets through cat's fur

(Pro-cision Flo® Applicator) quickly gets through cat's fur, for on-skin application

(Pro-cision Flo® Applicator) easily penetrates cat's fur

(Pro-cision Flo® Applicator) quickly penetrates cat's fur, for on-skin application

(Package configuration statements)

(X) tubes

Value pack (or size)

Club pack

(X) month supply

(X) monthly treatments

[Label reader's notes or Optional/alternate text is shown in italics, parenthesis or brackets]

(Product claims)

Effective Control [Prevention]

Fast [Quick] acting

Starts working by contact

Dual-action for immediate and long-lasting effects

Quick acting, long lasting [treatment]

Long lasting and easy to use [apply]

[Flea prevention] Helps stop itching and scratching [from flea bites]

[Specially formulated for cats [& kittens] For use on cats only Do not use on other animals

(IGR claims)

Contains [Features] an Insect Growth Regulator (IGR) to inhibit the development of flea eggs

Flea control for cats with [PRECOR@][vlGRen®] Insect Growth Regulator (IGR)

[(S)-Methoprene] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle at the egg stage

[(S)-Methoprene] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas [inhibits the development of flea eggs into adult fleas]

Controlling flea reproduction is the first step in controlling flea populations on your cat

[(S)-Methoprene] Insect Growth Regulator (IGR) prevents flea reinfestation on your cat

Flea treatment and preventative with an [insecticide] adulticide and Insect Growth Regulator (IGR)

(Formula claims)

Etofenprox provides a novel [smart] approach to flea, deer tick, and mosquito control

Formula [for cats & kittens]

Features [Contains] an [insecticide] adulticide to kill [and/or] [control] adult fleas [deer ticks, and mosquitoes]

(Prevention claims)

Preventing fleas and deer ticks from infesting your cat is much easier than treating an existing problem

Flea prevention has never been easier

An excellent preventative, offering protection against fleas

Prevents flea, deer tick, and mosquito infestations

Prevents flea recurrence

Control flea infestations by preventing them

Flea prevention is the best flea control strategy

Quick and sure flea, deer tick, and mosquito prevention

A quick and sure way to avert a flea problem is to [prevent it] use a preventative

It is far easier to prevent fleas than to control them

Flea control involves [requires] preventative measures [for your cat] [and] [Year-round] [Flea Treatment] [Preventative] 1 ml [cc] dose for use on cats and kittens under 5 lbs.

1.8 ml [cc] dose for use on cats and kittens 5 lbs. and over (Same size applicators with different fill amounts)]

In case of an emergency or for product use information, call [phone number]

[Adding a Dose Reminder section to appear as follows on the back panel]

To help remind you when you last applied treatment, simply write in the date when each does is applied.

First Dose

Second Dose

Third Dose

[Label reader's notes or Optional/alternate text is shown in italics, parenthesis or brackets]

[TREATMENT SCHEDULE]

Dosage: 1 applicator (or tube) every 30 days per cat

Pet's Name

First Treatment Date

Second Treatment Date (30 Days From 1st) Third Treatment Date (30 Days From 2nd)

NOTES:

[All text below represents one label statement with any selected line]

[Protect your cat from:]

Fleas that may cause:

Flea allergy dermatitis (and/or) Flea bite anemia

Deer ticks which may carry:

Lyme disease

[For more information, call our experts at 1-800-275-1414 (weekdays, 9am - 5 pm EST)]

INDIVIDUAL TUBE TEXT:

Hartz ® Reference #141

or an Alternate Brand Name (see last pages)

Only for use on cats

1 ml [cc] for cats [kittens] under 5 lbs.;

1.8 ml] [cc] for cats 5 lbs and over

Contains Ethofenprox 40%

s-Methoprene 3.6%

KEEP OUT OF REACH OF CHILDREN CAUTION

See full label for additional directions

EPA Reg. No. 2596-174

(Promotional claims)

- (x)% (More) (Free)!
- (x) Month(s) Free!

Bonus Pack

- (x) Tube(s) Free!
- (x) Day(s) (Free)!
- (x) Day(s) of treatment- Free!
- (x) Applicator(s) Free!
- (x) Dose(s) Free!

Value Pack X + Y = Z Monthly Treatments

[Label reader's notes or Optional/alternate text is shown in italics, parenthesis or brackets]

Alternate Brand Names

- Hartz® UltraGuard Plus® Dual Active Flea & Tick Drops for Cats 12 weeks and older
- Hartz® UltraGuard Plus® Dual Active Flea & Tick Drops for Cats & Kittens 12 weeks and older
- Hartz® UltraGuard Plus® Dual Active Flea & Tick Drops for Cats and Kittens 12 weeks and older
- Hartz® UltraGuard Plus® Dual Action Flea & Tick Drops for Cats 12 weeks and older
- Hartz® UltraGuard Plus® Dual Action Flea & Tick Drops for Cats & Kittens 12 weeks and older
- Hartz® UltraGuard Plus® Dual Action Flea & Tick Drops for Cats and Kittens 12 weeks and older
- Hartz® UltraGuard Plus ® Topical Flea & Tick Prevention for Cats 12 weeks and older
- Hartz® UltraGuard Plus ® Topical Flea & Tick Prevention for Cats & Kittens 12 weeks and older
- Hartz® UltraGuard Plus® Topical Flea & Tick Prevention for Cats and Kittens 12 weeks and older
- Hartz® UltraGuard Plus ® Topical Flea & Tick Treatment for Cats 12 weeks and older
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- Hartz® UltraGuard Plus® Topical Flea & Tick Treatment for Cats and Kittens 12 weeks and older
- Hartz® UltraGuard Plus ® Topical Flea & Tick Solution for Cats 12 weeks and older
- Hartz® UltraGuard Plus ® Topical Flea & Tick Solution for Cats & Kittens 12 weeks and older
- Hartz® UltraGuard Plus ® Topical Flea & Tick Solution for Cats and Kittens 12 weeks and older
- Hartz® UltraGuard Pro® Dual Active Flea & Tick Drops for Cats 12 weeks and older
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- Hartz® InControl® Dual Active Flea & Tick Drops for Cats 12 weeks and older
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- Hartz® InControl® Advanced Topical Flea & Tick Solution for Cats & Kittens 12 weeks and older
- Hartz® InControl® Advanced Topical Flea & Tick Solution for Cats and Kittens 12 weeks and older
- Hartz® Pro Force™ Dual Action Topical Drops for Cats 12 weeks and older
- Hartz® Pro ForceTM Dual Action Topical Drops for Cats & Kittens 12 weeks and older
- Hartz® Pro ForceTM Dual Action Topical Drops for Cats and Kittens 12 weeks and older
- Pro ForceTM Dual Action Topical Drops for Cats 12 weeks and older
- Pro Force™ Dual Action Topical Drops for Cats & Kittens 12 weeks and older
- Pro Force™ Dual Action Topical Drops for Cats and Kittens 12 weeks and older
- Hartz® Pro ForceTM Topical Drops for Cats 12 weeks and older
- Hartz® Pro Force™ Topical Drops for Cats & Kittens 12 weeks and older
- Hartz® Pro Force™ Topical Drops for Cats and Kittens 12 weeks and older
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First DefenseTM Dual Action Topical Drops for Cats 12 weeks and older

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First DefenseTM Dual Action Topical Drops for Cats and Kittens 12 weeks and older

Hartz® First Defense™ Topical Drops for Cats 12 weeks and older

Hartz® First Defense™ Topical Drops for Cats & Kittens 12 weeks and older

Hartz® First Defense™ Topical Drops for Cats and Kittens 12 weeks and older

RevoTM Flea and Tick Drops for Cats 12 weeks and older

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Hartz® Revo™ Flea and Tick Drops for Cats 12 weeks and older

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