



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 9, 2018

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

Subject: Notification per PRN 98-10 – addition of alternate brand names and other minor changes
Product Name: HARTZ REFERENCE #152
EPA Registration Number: 2596-184
Application Date: 4/12/2018
Decision Number: 540141

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.

The alternate brand name “*Hartz® 5 lbs. & over UltraGuard® Topical Flea & Tick Prevention for Cats & Kittens*” has been added to 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,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich". The signature is written in a cursive style with a large initial "E".

Elizabeth Fertich
Product Manager 4
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

{FRONT PANEL}

Hartz® Reference #152

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{Alternate Brand Names listed at end of document.}

{Primary Brand Name not to be used on any product labels. The word Cat will be included in all Alternate Brand Names and be at least 75% of the size of the largest letter in the product name}

{Add picture of cat with weight ranges for product.}

Use Only on Cats and Kittens Over 12 Weeks of Age and weighing [3 lbs. but less than 5 lbs.] [5 lbs. and over].

ACTIVE INGREDIENTS

Etofenprox.....40.0%

OTHER INGREDIENTS.....60.0%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back [side] [other] panel for ingredients, First Aid and additional precautionary statements

Net Contents: _____ fl oz (____ mL)

Contains {number} tube[s], each _____ fl oz (____ mL)

{BACK PANEL}

EPA Reg. No. 2596-184

EPA Est. No. 2596-OH-1

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

NOTIFICATION

2596-184

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:

05/09/2018

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 and less than 3 lbs. 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 cats. 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. Due to the bitter taste of the product, oral exposure could result in salivation. Be careful not to get any product in the cat's mouth during application.

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{BACK PANEL} - *continued*

For multiple cat households, prevent the cats from grooming each other until the product has dried. If the salivation continues or other clinical signs are noted, please call 1-800-275-1414.

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 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 1-800-275-1414 for emergency medical treatment information.

RESTRICTIONS

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 OR OTHER PETS TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY

DO NOT APPLY TO CATS WEIGHING LESS THAN {insert lowest weight of weight class} OR LESS THAN 12 WEEKS OF AGE.

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

DO NOT DOUBLE-DOSE OR APPLY MORE THAN ONE APPLICATOR TUBE PER TREATMENT FOR ONE CAT REGARDLESS OF THE CAT'S WEIGHT

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

TO PREVENT HARM TO YOU AND YOUR CAT READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ONLY ON CATS.

This product contains (xx) monthly dosages [one monthly dose], each [0.92 mL] [1.65 mL]. 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] [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 tube'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] [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] [tube] on the cat's exposed skin and squeeze out the [entire] contents of the [applicator tube] [tube] onto the cat's skin. Do not bathe cat within the first 24 hours after [Spot On] [squeeze on] [product] has been applied.
4. Repeat application [once every month] [once monthly].

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{ALTERNATE PACKAGING DIRECTIONS 2}

1. Remove one [applicator tube] [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] [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] [tube] on the cat's exposed skin and squeeze out the [entire] contents of the [applicator tube] [tube] onto the cat's skin. Do not bathe cat within the first 24 hours after [Spot On] [squeeze on] [product] has been applied.
4. Repeat application [once every month] [once monthly].

{ALTERNATE PACKAGING DIRECTIONS 3}

1. Remove one [applicator tube] [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 [applicator tube] [tube].
3. Simply press cap down to break the seal of [applicator tube] [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 [applicator tube] [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].

{Include on back panel}:

SIDE EFFECTS *{Located in lower, right hand corner of back panel}*

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 HANDLING: 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]

[Alternate Brand Name] is a topically applied long-lasting product, up to 30 days [1 month], specifically formulated for cats and kittens. This product contains the highly effective flea, deer tick, and mosquito killing agent Etofenprox. [Alternate Brand Name] kills biting adult fleas, deer ticks, and mosquitoes your cat may acquire from its surroundings. 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.

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After application, your cat's skin oils disperse and carry {Alternate Brand Name} over your cat's body for protection against biting adult fleas. {Alternate Brand 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 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. {Alternate Brand Name} can be used in conjunction with other HARTZ® premise products. As with all flea products, {Alternate Brand Name} is most effective when 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.]

{OPTIONAL/ALTERNATE LABEL TEXT}

{Wherever possible and applicable, Optional/Alternate Label text is listed in bullets for ease of reviewing.}

- Flea & Deer Tick {Protective} for cats [& kittens]
- [Flea & deer tick] treatment for cats [& kittens]
- 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][protection]
- Monthly treatment for [fleas & 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
- On-cat 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 protection, up to {30 days} [1 month] for fleas and deer ticks and 18 days for mosquitoes
- Starts killing fleas [in] [within] 15 minutes
- Starts killing fleas [in] [within] 15 minutes and last [up to] [30 days] [1 Month] [4 weeks]
- [Actively] Kills [Controls] [adult] fleas [and] [&] [deer ticks] [for] [up to] [4 weeks] [1 month] [per application]
- [Actively] Kills [fleas] [Kills] [deer ticks] [for up to [30 days] [1 month]] [&] [and] [mosquitoes] [by contact]
- Kills [and] [Repels] mosquitoes [for up to 18 days] [by contact]
- Controls fleas, deer ticks, and mosquitoes
- {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] [and Cytauxzoonosis] 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 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 90 years
- [Topical] Treatment that's easy and convenient to use
- An effective flea topical [A Spot On] product that kills adult fleas

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- This item is {insert retailer company name} ELECTRONICALLY PROTECTED
- This item is {insert retailer company name} Electronically Protected

{Application claims}

- [#] pack [# days] [#] doses [1/2/3/4/5/6] months supply
- One [applicator tube] [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 tube claims}

- [Free][X] Pro-cision Flo® [Applicator tubes] [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][tube]
- Easy to use applicator [tube] [provides direct on-cat protection]
- Longer [Applicator tube][tube] [tip] for easy application [to long-haired cats]
- Longer [tube] [applicator tube] is ideal for long-haired cats
- [Convenient] [easy to use] [applicator tube] [tube]
- [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} tube[s]
- Value pack {or size}
- Club pack
- {x} month supply
- {x} monthly treatment[s]

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{Product Claims}

- Effective Control [Prevention]
- Fast [Quick] acting
- Starts working by contact
- Quick acting, long lasting treatment for up to 30 days
- Quick acting, long lasting treatment for up to 1 month
- Long lasting treatment for up to 30 days and easy to [use] [apply]
- Long lasting treatment for up to 1 month and easy to [use] [apply]
- [Flea prevention] Helps stop itching and scratching from flea bites

{Formula claims}

- Etofenprox provides a [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]
- 1.65 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}** or visit our Web site:

{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 dose is applied.

First Dose _____
Second Dose _____
Third Dose _____

[TREATMENT SCHEDULE]

Dosage: 1 **{applicator}** **{applicator tube}** **{tube}** **{or tube}** every 30 days per cat

Cat's Name _____

First Treatment Date _____

Second Treatment Date *{30 Days from 1st}*

Third Treatment Date *{30 Days from 2nd}*

{NOTE: 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 #152

{or an Alternate Brand Name -- see last page}

Only for use on cats 12 weeks of age and older weighing *{insert from weight range list below}*:

3 – less than 5 lbs - 0.030 fl oz **{0.92 mL}**

5 lbs and over - 0.056 fl oz **{1.65 mL}**

Contains Etofenprox 40%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read accompanying label before use

EPA Reg. No. 2596-RIU

EPA Est. No. 2596-OH-1

Lot # _____

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{Promotional claims, 6 month duration}

[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

{ALTERNATE BRAND NAMES}

Hartz® 5 lbs. & over UltraGuard® Topical Flea & Tick Prevention for Cats & Kittens
Hartz® 5 lbs. & over UltraGuard® Topical Flea & Tick Prevention for Cats and Kittens
Hartz® UltraGuard® Flea & Tick Drops for Cats
Hartz® UltraGuard® Flea & Tick Drops for Cats & Kittens
Hartz® UltraGuard® Flea & Tick Drops for Cats and Kittens
Hartz® UltraGuard® Topical Flea & Tick Prevention for Cats
Hartz® UltraGuard® Topical Flea & Tick Prevention for Cats & Kittens
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Hartz® UltraGuard® Topical Flea & Tick Control for Cats and Kittens
Hartz® InControl® Flea & Tick Drops for Cats
Hartz® InControl® Flea & Tick Drops for Cats & Kittens
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Hartz® InControl® Topical Flea & Tick Prevention for Cats
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