

2596-164

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 26, 2014

Mr. Sean McNear  
Senior Director, Regulatory Affairs  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

**Subject: Amended Labeling; Submission of Efficacy Data to Support New Speed of Kill Claim  
Hartz® Reference #129, EPA Reg. No. 2596-164  
Your Submission Dated June 12, 2013 & E-Resubmission Dated February 26, 2014**

Dear Mr. McNear:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Should you wish to add/retain a reference to the company's website, smart phone/tablet app and/or a QR code reader on your product label, please be aware that the website, smart phone/tablet app and/or a QR code reader becomes labeling under FIFRA and is subject to review by the Agency. If the website, smart phone/tablet app, and/or a QR code reader is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website, smart phone/tablet app, and/or a QR code reader is referenced on a product's label, claims made on the website, smart phone/tablet app, and/or a QR code reader may not be 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, smart phone/tablet app, and/or a QR code reader contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website, smart phone/tablet app, and/or a QR code reader will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted" as well as copies of the efficacy review and review for minimum treatment weight that were completed for the referenced product amendment are enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

Sincerely yours,

A handwritten signature in black ink that reads "Richard J. Gebken".

Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

Enclosures: Label Stamped "Accepted," dated February 26, 2014  
Efficacy Review, dated December 6, 2013  
Review for Minimum Treatment Weight, dated November 4, 2013

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# Hartz® Reference # 129

Alternate Brand Names

Hartz® UltraGuard® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Topical Treatment for Cats (& Kittens)

Hartz® FieldForce™ Topical Treatment for Cats (& Kittens)

Hartz® First Defense™ Topical Treatment for Cats (& Kittens)

Hartz® UltraGuard® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® InControl® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® Pro Force™ Topical Solution for Cats (& Kittens)

Hartz® FieldForce™ Topical Solution for Cats (& Kittens)

Hartz® First Defense™ Topical Solution for Cats (& Kittens)

FieldForce™ Topical Treatment for Cats (& Kittens)

First Defense™ Topical Treatment for Cats (& Kittens)

FieldForce™ Topical Solution for Cats (& Kittens)

First Defense™ Topical Solution for Cats (& Kittens)

ACCEPTED  
*February 26, 2014*  
Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for the  
pesticide registered under:

EPA. Reg. No: 2596-164

**FRONT PANEL**

**ACTIVE INGREDIENTS:**

Fipronil.....9.70%

**OTHER INGREDIENTS** ..... 90.30%

**TOTAL** .....100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See back panel for additional precautionary statements.

**NET CONTENTS:** 0.051 fl. oz. (1.5 ml), Contains 3 tubes, each 0.017 fl. oz. (0.5 ml)

For use ONLY on CATS and kittens 8 weeks and older weighing 3 lbs. or more

**BACK PANEL**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. CAUTION.**

Harmful if swallowed. Causes eye irritation. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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**HAZARDS TO DOMESTIC ANIMALS.**

For external use only. Do not use on kittens under 8 weeks of age or weighing less than 3 lbs. 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. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Call 1-800-275-1414 for 24-hour assistance.

**PHYSICAL OR CHEMICAL HAZARDS**

**COMBUSTIBLE:** Do not use or store near heat or open flame.

**FIRST AID**

Have product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414 twenty-four (24) hours per day, seven (7) days per week.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**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 eye. Call a poison control center or doctor for treatment advice.

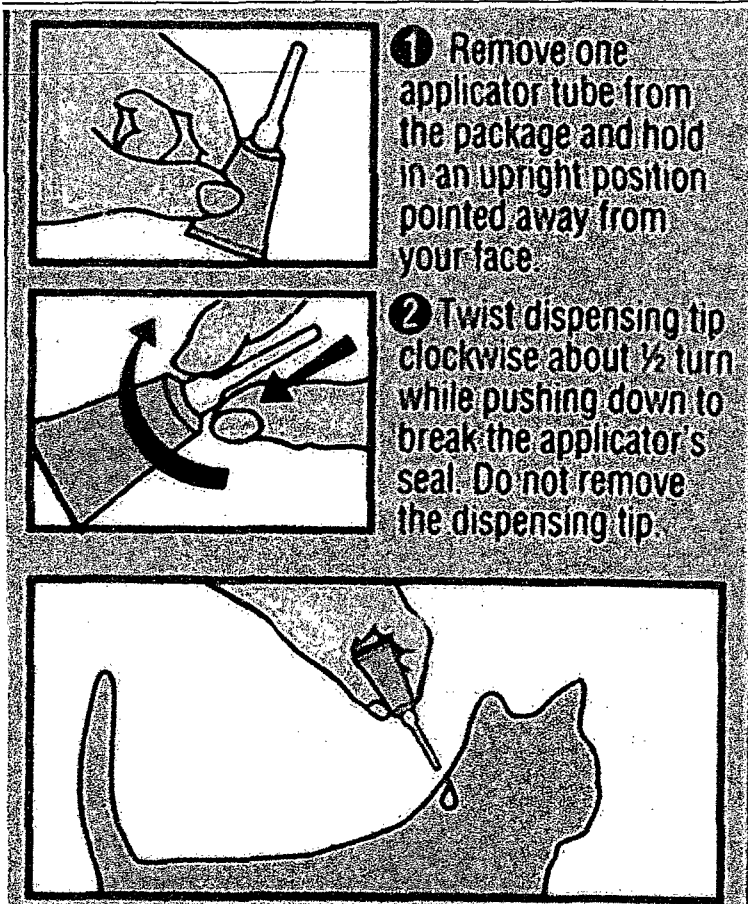
**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS. DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT

To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

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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 ½ turn while pushing down to break the applicator's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Reapply once per month.

**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.

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**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by 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 reuse or refill this container. 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.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-164  
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)  
Made in the U.S.A.

**INDIVIDUAL TUBE TEXT**

[Product Name]  
Only for use on cats 8 weeks and older weighing 3 lbs. or more  
0.017 fl oz (0.5 mL)  
Contains fipronil (9.7%)  
KEEP OUT OF REACH OF CHILDREN  
CAUTION  
See full label for additional directions  
EPA Reg. No. 2596-164

**OPTIONAL/ALTERNATE LABEL TEXT**

**FREQUENCY OF APPLICATION**

[PRODUCT NAME] kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although [PRODUCT NAME] can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of [PRODUCT NAME] kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

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[PRODUCT NAME] remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply [PRODUCT NAME] for 30 days.

[Product Name] can be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

[Product Name] contains Fipronil. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult Fleas

Kills Fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworms) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats 8 weeks or older weighing 3 lbs or more)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months)

Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) on cats 8 weeks or older weighing 3 lbs or more

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

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Stops existing infestations  
Prevents establishment of new infestations

Starts killing new fleas within 30 minutes\*  
\*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)  
Kills all biting stages of ticks  
Kills adult (brown dog) (deer) ticks, nymphs and larvae  
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations  
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Chewing Lice  
Kills Fleas, Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, after contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Ticks, after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills adult Fleas (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)  
Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on cats 8 weeks or older weighing 3 lbs or more) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for cats and kittens 8 weeks or older weighing 3 lbs or more)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on cats)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Stays on and doesn't rub off

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Waterproof

Effective after bathing

Effective after exposure to water

Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.

Avoid contact with treated area until dry.

Can also be used on breeding, pregnant and lactating queens

Convenient to use

Contains Fipronil. (Product name) effectively targets fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.



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Patent(s) Pending Formula

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Contains Fipronil (, the active ingredient used in Frontline Top Spot®).

(Brand name) is not manufactured by or distributed by Merial. Frontline Top Spot® is a registered trademark of Merial Limited.

Only for use on cats and kittens 8 weeks of age or older weighing 3 lbs. or more  
Formulated for cats and kittens 8 weeks of age or older weighing 3 lbs. or more

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose

First month, Second month, Third month Value pack

3 month supply

3 monthly treatment(s)

Apply monthly (every 30 days)

Convenient (easy to use) applicator

Pro-cision Flo® Applicator

3 Pro-cision Flo® Applicator(s)(included)

Made in the U.S.A.

Featuring Pro-cision Flo® Applicator (for easy application)

Direct to your cat's skin

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

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your cat 48 hours after application

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 \_\_\_\_\_