



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 10, 2018

Joseph A. Conti
Sr. Director, Regulatory Affairs and Quality Assurance
Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Label Amendment: Revisions associated with registration extension
Product Name: Hartz Reference #129
EPA Registration Number: 2596-164
Application Date: 25-Jan-18
Decision Number: 537644

Dear Mr. Conti:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Dr. Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

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

Enclosure

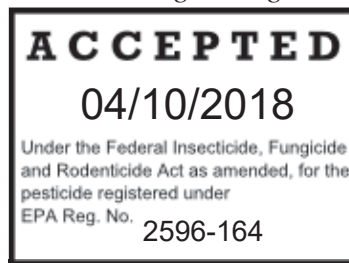
Hartz® Reference # 129

{Note to Reviewer - Brackets used in this label are as follows: { } indicate Notes to Reviewer and/or Text Location/Positioning, [] indicate Optional/Alternate text, () will be included on the label.}

{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 Alternate Brand Name.}

{For each brand as packaged, a large, clear picture of a cat in the weight range will be on the front panel of the label.}

{Alternate Brand Names are listed at end of document}



{FRONT PANEL}

ACTIVE INGREDIENTS:

Fipronil..... 9.70%

OTHER INGREDIENTS 90.30%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for First Aid and additional Precautionary Statements.

NET CONTENTS: 0.051 fl. oz. (1.5 ml), Contains 3 [applicator tubes] [tubes], each 0.017 fl oz [0.5 mL]

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

{BACK PANEL}

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with treated area until dry.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or less than 3 lbs. Sensitivities may occur after using ANY pesticide product for cats. If signs of sensitivity occur bathe your cat with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Cats may experience some temporary irritation at the site of product application. This product is not a substitute for prescribed heartworm preventative. Consult a veterinarian before using this product on medicated, debilitated or aged cats. 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

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.

HOT LINE NUMBER: Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-275-1414 for human and veterinary health concerns, emergency medical treatment information or pesticide incidents.

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. Cat must be dry at time of application and remain dry for 48 hours after application.

TO PREVENT HARM TO YOU AND YOUR CAT READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE.

FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

RESTRICTIONS:

DO NOT REAPPLY MORE THAN ONCE PER MONTH.

DO NOT BATHE FOR 48 HOURS AFTER APPLICATION.

DO NOT APPLY TO CATS UNDER 8 WEEKS OF AGE AND WEIGHING LESS THAN 3 LBS.

DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS.

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR CATS.

DO NOT APPLY MORE THAN ONE [APPLICATOR TUBE] [TUBE] PER TREATMENT FOR ONE CAT REGARDLESS OF THE CAT'S WEIGHT.

DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT.

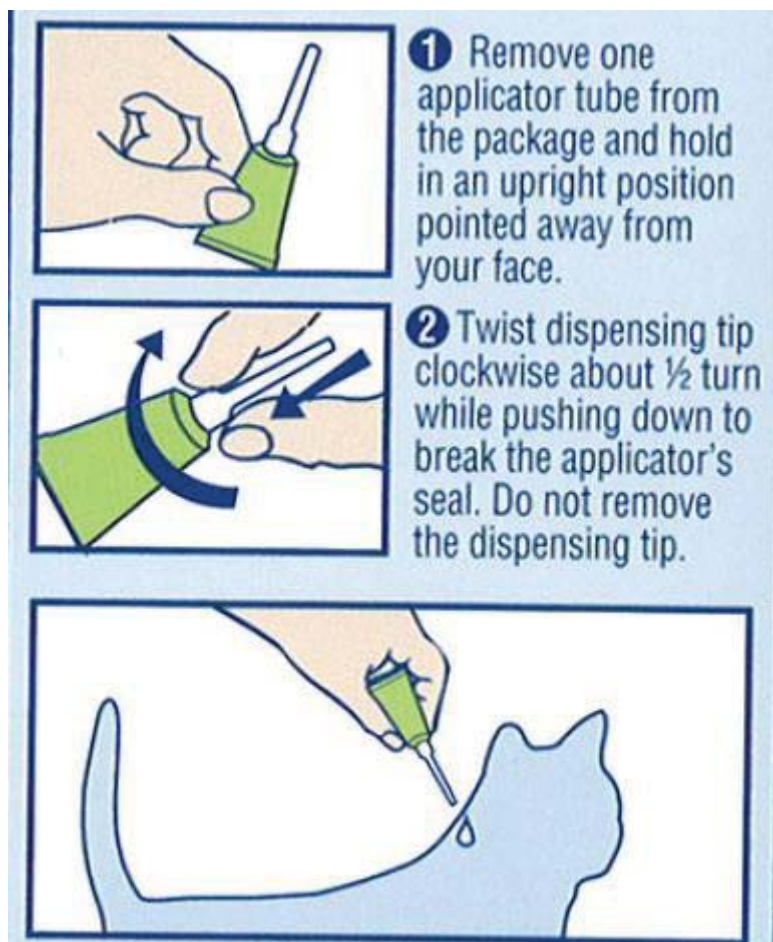
DO NOT ALLOW YOUR CAT TO GROOM ANY OTHER TREATED CATS UNTIL PRODUCT HAS DRIED.

FREQUENCY OF APPLICATION

{Alternate Brand Name} kills ticks for one month. A once monthly application is recommended where tick control is needed. Although {Alternate Brand Name} can control fleas for up to six weeks, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

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 and weighing 3 lbs. or more as follows:

{Note to Reviewer: CRP: free tubes; SAUE opening instructions apply to a long-tip applicator tube and will not change in text or format on the final printed label from that used in testing; Whenever this package is used, the term “applicator tube” or “tube” can be used, but whichever term is chosen, that term will be used consistently throughout the label.}



3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the [applicator tube][tube] to part the cat's hair so that the product will be applied at skin level. Squeeze [applicator tube][tube], applying entire contents in a single spot on the cat'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 {*Located in the lower right hand corner of the back panel*}

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

Do not contaminate water, food, or feed by storage or 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 reuse or refill this container. *If empty:* Place in trash or 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}

{*Alternate Brand 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 directions for use and precautions

EPA Reg. No. 2596-164

EPA Est. No. 2596-OH-1

{*Lot number to appear on tube crimp*}

{OPTIONAL/ALTERNATE LABEL TEXT}

{Note to Reviewer: Bullets have been added to certain Optional/Alternate Label Text and Non-Pesticide Related Claims & Other Optional Text sections whenever possible, to make it easier to itemize and review.}

With a monthly application of {*Alternate Brand Name*} kills mosquitoes within 48 hours for up to 28 days.

{*Alternate Brand Name*} remains effective even after bathing, water immersion, or exposure to sunlight. Do not reapply {*Alternate Brand Name*} for 30 days.

{*Alternate Brand Name*} can be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

{*Alternate Brand 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.

- 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 tapeworm] [for] [28 days] [30 days] [1 month] [4 weeks] [on cats]
- Kills [Adult] Fleas
- Kills fleas that may cause [flea allergy dermatitis] [and] [flea bite anemia] [for] [28 days] [30 days] [1 month] [4 weeks] [on cats]
- 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
- Controls existing infestations
- Prevents establishment of new infestations
- {*Alternate Brand Name*} effectively targets fleas.

{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

{Mosquitoes}

- Kills mosquitoes
- 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]

{Multiple}

- Kills Fleas, Ticks, Chewing Lice
- 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 adult Fleas
- Kills Fleas, Brown Dog Ticks, Deer Ticks, [after contact] [for] [28 days] [30 days] [1 month] [4 weeks]
- Controls Flea and Tick infestations [on cats] [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 and 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]
- Prevents re-infestation
- Prevents and controls re-infestation [s]
- Effective and convenient topical treatment
- Kills fleas [and ticks] through [after] contact
- Do not reapply product for 30 days
- Remains effective even after bathing, water immersion, or exposure to sunlight
- {Alternate Brand Name} remains effective even after bathing, water immersion, or exposure to sunlight.

- Can also be used on breeding, pregnant and lactating queens
- 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
- 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
- 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]

✓ Contains the same active ingredient used in Frontline® for cats.

{Note to Reviewer: whenever the claim immediately above (check marked) is included on product label, then the label will contain the appropriate disclaimers below (asterisked). The disclaimers will be placed in the same area of the label as the optional claim so that both are viewed together.}

- * {Alternate Brand Name} is not manufactured by or distributed by Merial
- * Frontline® is a registered trademark of Merial

{NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT}

- 1st dose, 2nd dose, 3rd dose
- First month, Second month, Third month Value pack 3 month supply
- 3 monthly treatment[s]
- Convenient [easy to use] applicator
- [3] Pro-cision Flo® Applicator[s] [With] Pro-cision Flo® Applicator
- 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 _____
- Fast acting
- Long lasting
- Convenient to use
- Contains Fipronil
- Waterproof
- Easy spot on topical applicator
- Stays on and doesn't rub off
- [With] patented applicator
- [With] patent pending applicator

{Alternate Brand Names}

{Product names are limited to Alternate Brand Names. 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.}

Hartz® UltraGuard® Flea [and] [&] Tick Topical Treatment for Cats [& Kittens]
Hartz® InControl® Flea [and] [&] Tick Topical Treatment for Cats [& Kittens]
Revo™ Flea [and] [&] Tick Topical Treatment for Cats [& Kittens]
Hartz® Revo™ 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]
Revo™ Flea [and] [&] Tick Topical Solution for Cats [& Kittens]
Hartz® Revo™ 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]