

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 31, 2015

Lance Hemsarth Senior Director Research & Development The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688

Subject: Notification per PRN 98-10 – Additional Marketing Statements & Net Contents Product Name: Hartz Reference #144 EPA Registration Number: 2596-179 Application Date: 12/4/2015 Decision Number: 511935

Dear Mr. Hemsarth:

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 <u>hollis.angela@epa.gov</u>.

Sincerely,

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

Hartz[®] Reference # 144

Alternate Brand Names

Hartz® Pro Force ProTM Triple Action Topical Treatment for Cats (& Kittens) Hartz® FieldForce ProTM Triple Action Topical Treatment for Cats (& Kittens) Hartz® First Defense ProTM Triple Action Topical Treatment for Cats (& Kittens) Hartz® First Defense ProTM Triple Active Topical Treatment for Cats (& Kittens)

Hartz® Pro ForceTM for Cats (& Kittens) Hartz® FieldForce ProTM for Cats (& Kittens) Hartz® First Defense ProTM for Cats (& Kittens)

Hartz® Pro ForceTM Triple Action Topical Solution for Cats (& Kittens) Hartz® FieldForce ProTM Triple Action Topical Solution for Cats (& Kittens) Hartz® First Defense ProTM Triple Action Topical Solution for Cats (& Kittens) Hartz® First Defense ProTM Triple Active Topical Solution for Cats (& Kittens)

FieldForce ProTM Triple Action Topical Treatment for Cats (& Kittens) First Defense ProTM Triple Action Topical Treatment for Cats (& Kittens) First Defense ProTM Triple Active Topical Treatment for Cats (& Kittens)

FieldForce ProTM for Cats (& Kittens)

First Defense ProTM for Cats (& Kittens) FieldForce ProTM Triple Action Topical Solution for Cats (& Kittens) First Defense ProTM Triple Action Topical Solution for Cats (& Kittens) First Defense ProTM Triple Active Topical Solution for Cats (& Kittens)

FRONT PANEL

ACTIVE INGREDIENTS:

Fipronil	9.80%
(S)-Methoprene	11.80%
Pyriproxyfen	0.25%
OTHER INGREDIENTS	78.15%
TOTAL	00.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS:

NOTIFICATION

2596-179

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:

12/31/2015

[For 1 applicator pack]	
(For use) ONLY (for use) on cats (& kittens) 8 weeks and older, weighing 3 lbs. or more.	0.017 FL. OZ. (0.5 ML) (Applicator)

[For 3 applicator pack]

(For use) ONLY (for use) on cats (&	0.051 FL. OZ. (1.5 ML),
kittens) 8 weeks and older, weighing 3	Contains 3 (-) (tubes, each) 0.017fl. oz. (0.5ml)
lbs. or more.	(Applicators)

[For 6 applicator pack]

[1 of o uppreator pacin]	
(For use) ONLY (for use) on cats (&	0.102 FL. OZ. (3.0 ML),
kittens) 8 weeks and older, weighing 3	Contains 6 (-) (tubes, each) 0.017fl. oz. (0.5ml)
lbs. or more.	(Applicators)

BACK PANEL

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.

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

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 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.

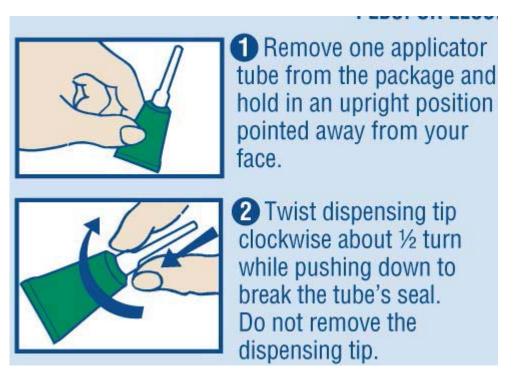
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. **IF IN EYES:** Hold eye 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. USE ON CATS ONLY. DO NOT USE ON RABBITS, DOGS, PUPPIES OR OTHER ANIMALS. DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR CATS

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:



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. Repeat once a 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.

PRODUCT NAME contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). PRODUCT NAME effectively targets all stages of 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, chewing lice and mosquitoes.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for at 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.)

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.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Do not use or store near heat or open flame.

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. *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.

EPA Reg. No. 2596-<mark>179</mark> EPA Est. No. 2596-OH-1

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INDIVIDUAL TUBE TEXT

(Product Name)
Only for use on cats 8 weeks and older weighing 3 lbs or more
0.017 fl oz (0.5ml)
Contains Fipronil 9.80%, (S)-Methoprene 11.80%, Pyriproxyfen (Nylar®) 0.25%
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2596-179
EPA Est. No. 2596-0H-1

OPTIONAL/ALTERNATE LABEL TEXT

Product Name contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and Pyriproxyfen (Nylar®). Product Name effectively targets all stages of 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, chewing lice and mosquitoes.

Stops and prevents infestations Kills adult fleas, flea eggs, and flea larvae Prevents all flea stages (eggs, larvae, pupae) from developing 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 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 Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis and flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) Kills fleas that may cause flea allergy dermatitis (for) (28 days) (30 days) (1 month) (4 weeks) 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) 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) 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 Stops existing infestations [Flea Eggs] Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) Prevents Flea Eggs from hatching Kills flea eggs on your (cat or kitten or cat and kitten) that live in your home Kills flea eggs on your (cat or kitten or cat and kitten) to prevent the eggs from hatching in your home [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, Flea eggs, (Flea larvae), Chewing Lice Kills Fleas, Ticks, Flea Eggs (for) (28 days) (30 days) (1 month) (4 weeks) Kills Fleas, Ticks, Flea Eggs, Flea larvae (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Flea larvae through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, Flea larvae after contact (for) (28 days) (30 days) (1 month) (4 weeks)

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) Kills flea eggs and flea larvae to help prevent future re-infestations Kills all stages of the flea life cycle Breaks the flea life cycle Prevents all flea stages (eggs, larvae, pupae) from developing

[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)

Hartz [®] Reference #144 EPA Reg. No.: 2596-<mark>179</mark> MASTER LABEL- -

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution) Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks) 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) Dual insect growth regulator (IGR) prevents re-infestation Contains two ingredients to prevent flea infestations 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 Patents Pending 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. Convenient to use

Contains Fipronil and the insect growth regulators (IGR) (S)-Methoprene and (Pyriproxyfen) (Nylar®). (Product name) effectively targets all stages of 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. (Also) Contains a second insect growth regulator (IGR) (Pyriproxyfen) (Nylar®)

(Also) Contains a third active ingredient (Pyriproxyfen) (Nylar®)

Triple Active Formula (contains one adulticide and two insect growth regulators) (IGRs) Triple Action Formula (contains one adulticide and two insect growth regulators) (IGRs)

- Fast-acting
- Long-lasting
- Waterproof

Only for cats and kittens 8 weeks of age or older weighing 3 lbs or more Specially formulated for cats and kittens 8 weeks of age or older weighing 3 lbs or more

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose

First month, second month, third month, fourth month, fifth month, sixth month Value pack 1 month supply 3 month supply 6 month supply 1 monthly treatment 3 monthly treatment(s) 6 monthly treatment(s) 1 monthly dose 3 monthly doses 6 monthly doses Apply monthly (every 30 days) Convenient (easy to use) applicator (3) Pro-cision Flo[®] Applicator(s) (included) 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) Made in the U.S.A Patent(s) Pending Formula

After application, the treated area may appear wet (or) (oily) for up to 24 hours You may bathe your cat 48 hours after application

(Single Dose Pack) (Single Unit Pack) (Individual Unit) (Not For Sale)

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_____Fourth Dose_____Fifth Dose_____Sixth Dose_____

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase (Brand name).

After treating your pet for the first time, peel off the sticker and place on your calendar that day. Place the remaining stickers on your calendar as a reminder to apply (Brand name) monthly.

Calendar Reminder Stickers Don't forget to re-purchase 6 months use all 6 stickers 3 months Hartz [®] Reference #144 EPA Reg. No.: 2596-<mark>179</mark> MASTER LABEL- -

[Individual stickers] Apply (Brand name) [Individual sticker] Re-purchase (Brand name)

Use these calendar stickers as a reminder for when to reapply (Apply) (First) (1st) Month (Brand Name) (Reapply) (Second) (2nd) Month (Brand Name) (Reapply) (Third) (3rd) Month (Brand Name) (Reapply) (Fourth) (4th) Month (Brand Name) (Reapply) (Fifth) (5th) Month (Brand Name) (Reapply) (Sixth) (6th) Month (Brand Name)

Questions? Contact your veterinarian or call our technical experts at 1-800-275-1414, twenty four (24) hours per day, seven (7) days per week. Consult veterinarian before use



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