



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 #128  
EPA Registration Number: 2596-163  
Application Date: 25-Jan-2018  
Decision Number: 537643

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

Page 2 of 2  
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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](mailto:Breeden-Alemi.Julie@epa.gov).

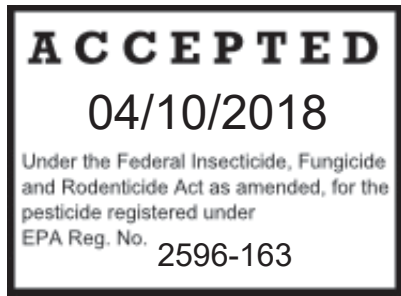
Sincerely,

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 #128  
 EPA Reg. No. 2596-163  
 MASTER LABEL -



March 20, 2018

**{FRONT PANEL}**  
**Hartz® Reference # 128**

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

*{Primary Brand Name not to be used on any product labels. The word Dog 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.}*

*{Alternate Brand Names are listed at end of document}*

*{Included on the front panel is a clear picture of a dog in the weight range for the product}*

**ACTIVE INGREDIENTS:**

Fipronil .....9.70%

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

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

**KEEP OUT OF REACH OF CHILDREN**

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

**NET CONTENTS:**

| For use ONLY on DOGS and Puppies<br>8 weeks and older Weighing: | Net Contents   |
|---|--|
| 5-22 lbs.   | 0.069 fl. oz. (2.01ml.),<br>Contains 3 [applicator tubes] [tube][s], each 0.023 fl.<br>oz. (0.67 ml.)  |
| 23 - 44 lbs.  | 0.135 fl. oz. (4.02 ml.),<br>Contains 3 [applicator tubes] [tube][s], each 0.045 fl.<br>oz. (1.34 ml.) |
| 45 - 88 lbs.  | 0.273 fl. oz. (8.04 ml.),<br>Contains 3 [applicator tubes] [tube][s], each 0.091 fl.<br>oz. (2.68 ml.) |
| 89 - 132 lbs.   | 0.408 fl. oz. (12.06 ml.),<br>Contains 3[applicator tubes] [tube][s], each 0.136 fl.<br>oz. (4.02 ml.) |

*{Cat Warning: A cat prohibition icon, 1.5 cm x 1.5cm, and warning text will appear on the lower right hand corner of the front panel and back panel in yellow and black images within a box.}*



**DO NOT USE ON CATS**

**{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. Avoid contact with treated area until dry.

**HAZARDS TO DOMESTIC ANIMALS**

For external use only. Do not use on puppies under 8 weeks of age or less than [5] [23] [45] [89] lbs. Sensitivities may occur after using ANY pesticide product for dogs. If signs of sensitivity occur bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Dogs 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 dogs. 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. Dog must be dry at time of application and remain dry for 48 hours after application.

**READ ENTIRE LABEL BEFORE EACH USE**

THIS PRODUCT CAN ONLY BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER AND WEIGHING {Insert product weight range} INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES.

**RESTRICTIONS:**

DO NOT USE ON DOGS OR PUPPIES LESS THAN 8 WEEKS OF AGE WEIGHING LESS THAN [5][23][45][89] LBS  
DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS.  
DO NOT EXCEED LABELED DOSAGE AMOUNT FOR DOGS.  
DO NOT APPLY MORE THAN ONCE PER MONTH.  
DO NOT BATHE FOR 48 HOURS AFTER APPLICATION.  
DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.  
DO NOT APPLY MORE THAN ONE TUBE PER TREATMENT FOR ONE DOG REGARDLESS OF THE DOG’S WEIGHT.

**SIDE EFFECTS**

Monitor your dog 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 1-800-275-1 414.

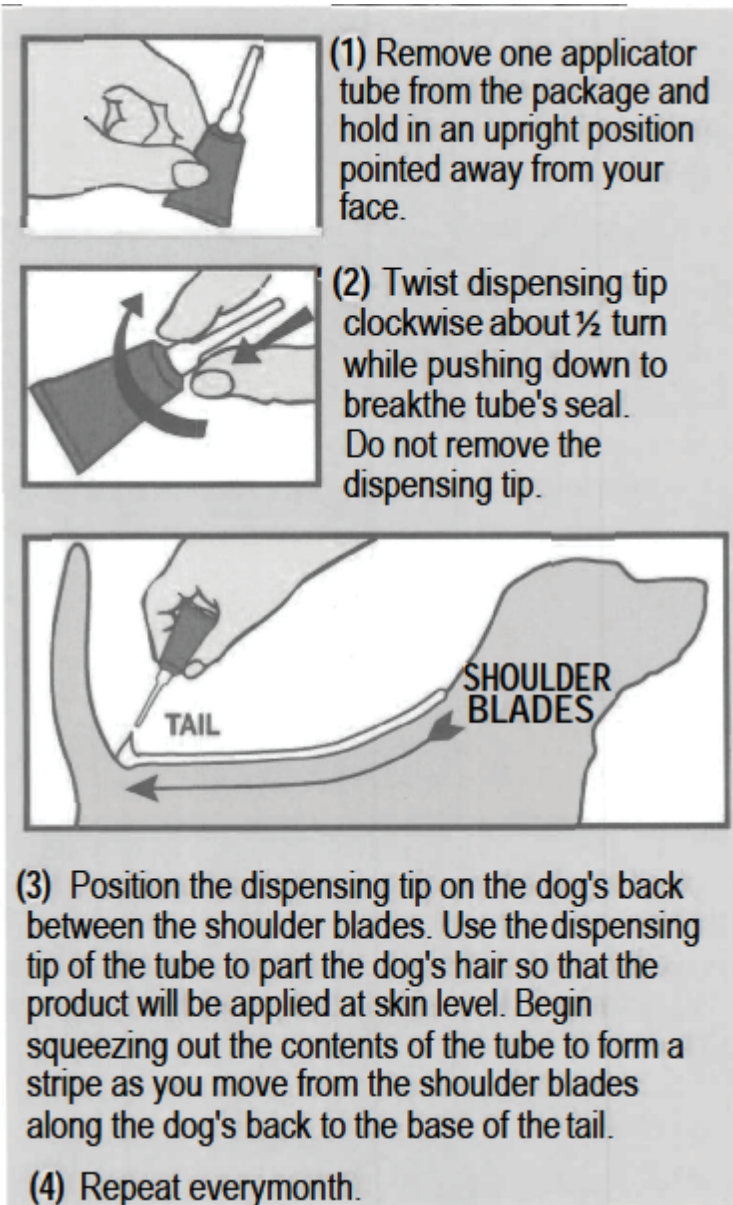
*{Box labeled “Side Effects” will be immediately above the cat warning text on the back panel.}*



*{A cat prohibition icon, 1.5 cm x 1.5 cm, and warning text will appear in a box located at the lower right hand corner of the back panel in yellow with black images.}*

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

*{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.}*



(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 tube's seal. Do not remove the dispensing tip.

(3) Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

(4) Repeat every month.

### 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-5pm E.S.T.]

EPA Reg. No. 2596-163 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 DOGS AND PUPPIES 8 WEEKS OR OLDER

*{The appropriate size and fill volume will be correctly used on each applicable dog's weight category}*

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),

23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),

45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),

89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains fipronil(9.70%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions EPA Reg. No. 2596-163

EPA Est. No. 2596-OH-1

*{Note: Cat Warning Icon: A cat prohibition icon will appear on the immediate container that holds the tube(s). Icon is 1.5 cm x 1.5 cm black image on a yellow background}*

*{Lot number to appear on tube crimp}*

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***{Note to Reviewer - Brackets used in this label are as follows: { } indicate Notes to Reviewer and/or Text***

***Location/Positioning, [ ] indicate Optional/Alternate text, ( ) indicate text that will be included on the label.}*** Page 5

**{OPTIONAL/ALTERNATE LABEL TEXT}**

**{Adult Fleas}**

- Kills Fleas [that may transmit tapeworm] [for] [28 days] [30 days] [1 month] [4 weeks][on dogs]
- Kills [Adult] Fleas
- Kills Fleas that may cause [flea allergy dermatitis] [and] [flea bite anemia] [for] [28 days] [30 days] [1 month] [4 weeks] [ondogs]
- 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
- Helps eliminate fleas

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] [4weeks]
- Kills [all stages of ] Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks [for] [28 days] [30 days] [1 month] [4weeks]
- Kills Deer Ticks [for] [28 days] [30 days] [1 month] [4weeks]
- Kills Deer Ticks [for] [28 days] [30 days] [1 month] [4 weeks] on dogs and puppies 8 weeks of age or older and weighing *{Insert product weight range}*
- Kills all stages of Deer Ticks [for] [28 days] [30 days] [1 month] [4 weeks]
- Kills all stages of Deer Ticks [for] [28 days] [30 days] [1 month] [4 weeks] on dogs and puppies 8 weeks of age or older and weighing *{Insert product weight range}*
- Kills Deer Ticks that may carry Lyme disease [for] [28 days] [30 days] [1 month] [4 weeks] Kills Deer Ticks that may carry Lyme disease [for] [28 days] [30 days] [1 month] [4 weeks] on dogs and puppies 8 weeks of age or older and *{Insert product weight range}*
- Kills all stages of Deer Ticks that may carry Lyme disease [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 dogs and puppies 8 weeks of age or older and *{Insert product weight range}*
- 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, [through contact] [for] [28 days] [30 days] [1 month] [4 weeks]
- Kills Fleas, Ticks, [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, [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 [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, and 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, Brown Dog Ticks, Deer Ticks, [after contact] [for] [28 days] [30 days] [1 month] [4 weeks]
- Controls Flea and Tick infestations [on dogs] [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 dogs and puppies 8 weeks of age or older and weighing {Insert product weight range}]
- 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 48 hours for up to 28 days
- Kills Mosquitoes that may transmit West Nile virus [for] [28 days] [1 month] [4 weeks][on dogs]
- Kills Mosquitoes that may transmit heartworm [for] [28 days] [1 month] [4 weeks] [on dogs]
- 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]
- Prevents infestation[s]
- Prevents and controls re-infestation[s]
- Effective and convenient topical treatment Kills fleas [and ticks] through [after] contact

**{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
  - 3monthly treatment[s]
  - Convenient [easy to use]applicator
  - Pro-cision Flo® Applicator
  - 3 Pro-cision Flo® Applicator[s] [included]
  - Direct to your dog'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 dog 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
  - Stays on and doesn't rub off
  - [With] patented applicator
  - [With] patent pending applicator
  - Waterproof
  - Easy spot on topical applicator
  - 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
  - Effective after bathing
  - Effective after exposure to water
  - Can be used on breeding, pregnant and lactating bitches
  - Convenient to use
  - 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 and chewing lice.
  - Only for use on dogs and puppies 8 weeks of age or older and weighing {Insert product weight range}
  - Formulated for dogs and puppies 8 weeks of age or older and weighing {Insert product weight range}
- 
- ✓ Contains the same active ingredient used in Frontline® for dogs.
  - ✓ Contains Fipronil [, the active ingredient used in Frontline ®].

*{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.

- Contains Fipronil
- 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.

EPA Reg. No. 2596-163  
EPA Est. No. 2596-OH-1

{ALTERNATE BRAND NAMES}

*{Product names limited to Alternate Brand Names only. The word Dog 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 Dogs [&] [and Puppies]  
Hartz® InControl® Flea [and] [&] Tick Topical Treatment for Dogs [&] [and Puppies]  
Hartz® Pro Force™ Topical Treatment for Dogs [&] [and Puppies]  
Hartz® FieldForce™ Topical Treatment for Dogs [&] [and Puppies]  
Hartz® First Defense™ Topical Treatment for Dogs [&] [and Puppies]  
Hartz® UltraGuard® Flea [and] [&] Tick Topical Solution for Dogs [&] [and] Puppies  
Hartz® InControl® Flea [and] [&] Tick Topical Solution for Dogs [&] [and Puppies]  
Hartz® Pro Force™ Topical Solution for Dogs [&] [and] Puppies  
Hartz® FieldForce™ Topical Solution for Dogs [&] [and Puppies]  
Hartz® First Defense™ Topical Solution for Dogs [&] [and Puppies]  
FieldForce™ Topical Treatment for Dogs [&] [and Puppies]  
First Defense™ Topical Treatment for Dogs [&] [and Puppies]  
FieldForce™ Topical Solution for Dogs [&] [and Puppies]  
First Defense™ Topical Solution for Dogs [&] [and Puppies]