

2596-163

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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 #128, EPA Reg. No. 2596-163
Your Submission Dated June 7, 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.

Sincerely yours,

FOR

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 5, 2013

002596-00163 D479787

Hartz® Reference # 128

Alternate Brand Names

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)

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

EPA. Reg. No: 2596-163

FRONT PANEL

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing 5 to 22 lbs.

Weighing 23 to 44 lbs.

Weighing 45 to 88 lbs.

Weighing 89 to 132 lbs.

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.

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NET CONTENTS:

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



[Cat Warning: A cat prohibition icon will appear on the front panel and back panel.] 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.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. 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 the 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

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(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 or advice.
DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS.

DIRECTIONS FOR USE

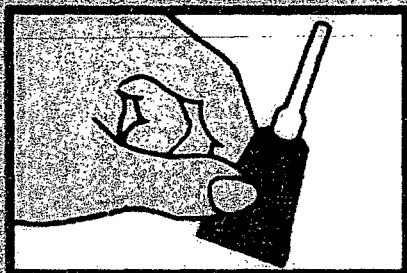
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

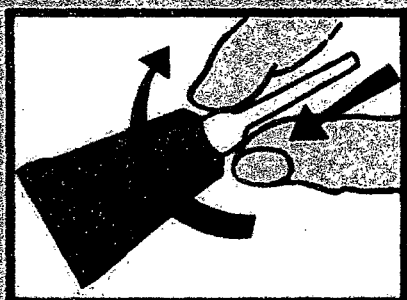
**USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER.
DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS.
DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.
THIS PRODUCT CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER,
INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES.**



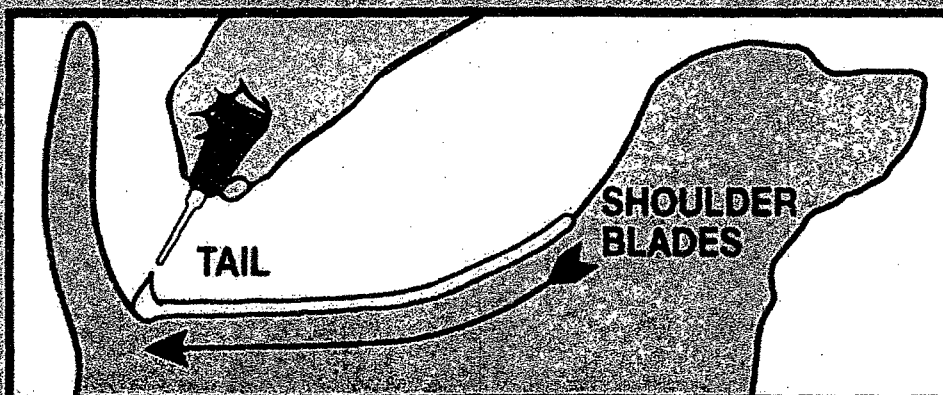
DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



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.

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 1-800-275-1414.

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. *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.

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. 2596-163
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

[Product 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

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 (for up to 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) (on dogs)
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
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 Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older
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
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
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

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, 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, (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)

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 dogs)

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

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

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
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.
Effective after bathing
Effective after exposure to water
Avoid contact with treated area until dry.
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.

Patent(s) Pending Formula

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 dogs and puppies 8 weeks of age or older
Formulated for dogs and puppies 8 weeks of age or older

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
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

Hartz® Reference #128
EPA Reg. No.: 2596-163
MASTER LABEL-

September 20, 2012
Revised February 25, 2014

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Applied:

First Dose _____
Second Dose _____
Third Dose _____

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Made in the U.S.A.

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