



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 2, 2016

Lance H. Hemsarth
Senior Director, R&D
The Hartz Mountain Corporation
400 Plaza Dr.
Secaucus, NJ 07094

Subject: PRIA Label Amendment – Addition of tube sizes to the label.
Product Name: Hartz Reference #131
EPA Registration Number: 2596-166
Application Date: July 28, 2016
Decision Number: 519998

Dear Mr. Hemsarth:

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, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

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

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

Enclosure

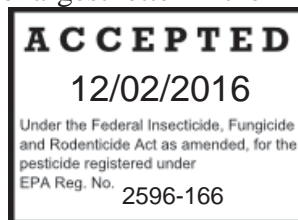
Hartz® Reference # 131

{ **Note to Reviewer** - Brackets used in this label are as follows : [] are for optional wording, { } are for notes to reviewer , () are for text location/positioning. }

(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 40% of the size of the largest letter in the Alternate Brand Name.)

(Alternate Brand Names list at end of document)

(FRONT PANEL)



(Included on the front panel is a clear picture of a cat in the weight range for the product.)

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	11.80%
OTHER INGREDIENTS	<u>78.40%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for First Aid and additional precautionary statements.

NET CONTENTS:

(For 1 applicator package)

[For use] ONLY [for use] on Cats {& Kittens} 8 weeks and older, Weighing 1.5 lbs or more	0.017 fl oz [0.5 mL] [Applicator]
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(For 3 applicator pack)

[For use] ONLY [for use] on Cats {& Kittens} 8 weeks and older Weighing 1.5 lbs or more	0.051 fl oz [1.5 mL], Contains 3 [-] [tubes, each] 0.017 fl oz [0.5 mL] [Applicators]
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(For 4 applicator pack)

[For use] ONLY [for use] on Cats {& Kittens} 8 weeks and older Weighing 1.5 lbs or more	0.068 fl oz [2.0 mL], Contains 3 [-] [tubes, each] 0.017 fl oz [0.5 mL] [Applicators]
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(For 6 applicator pack)

[For use] ONLY [for use] on Cats {& Kittens} 8 weeks and older Weighing 1.5 lbs or more	0.102 fl oz [3.0 mL], Contains 6 [-] [tubes, each] 0.017 fl oz [0.5 mL] [Applicators]
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[2 cartons of 0.051 fl oz [(1.5 mL)] [3 applicators each containing 0.017 fl oz [(0.5 mL)]; [3 doses per carton, 6 doses total]]]

[4 cartons of 0.051 fl oz [(1.5 mL)] [3 applicators each containing 0.017 fl oz [(0.5 mL)]; [3 doses per carton, 12 doses total]]]

(BACK PANEL)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. 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 kittens under 8 weeks of age or weighing less than 1.5 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. Consult a veterinarian before using this product on medicated, debilitated or aged cats. Call [1-XXX-XXX-XXXX] [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 the 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-XXX-XXX-XXXX] [1-800-275-1414], twenty-four [24] hours per day, seven [7] days per week.

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 CAT READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY.

RESTRICTIONS:

DO NOT APPLY TO CATS UNDER 8 WEEKS OF AGE AND WEIGHING LESS THAN 1.5 LBS

DO NOT EXCEED LISTED DOSAGE AMOUNT FOR CATS.

DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT.

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


DO NOT REAPPLY (Alternate Brand Name) FOR 30 DAYS.

DO NOT DOUBLE-DOSE OR APPLY MORE THAN ONE APPLICATOR TUBE PER TREATMENT FOR ONE CAT REGARDLESS OF THE CAT'S WEIGHT

DO NOT ALLOW CATS TO GROOM EACH OTHER UNTIL PRODUCT HAS DRIED.

To kill fleas, all stages of ticks [Brown Dog ticks, American Dog ticks, Lone Star ticks, and [&] Deer ticks [which may carry Lyme disease]], and chewing lice, apply to cats and kittens 8 weeks or older weighing 1.5 lbs or more as follows:

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.

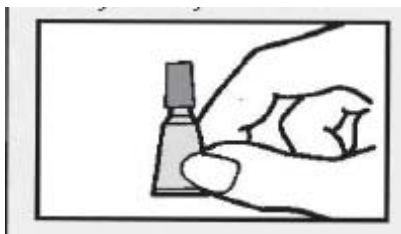


2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the 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
You may bathe your cat 48 hours after application.
4. Repeat [every] [once a] month.

DIRECTIONS FOR USE [ALTERNATE DIRECTIONS FOR CAP TUBE THROUGH STEP 5]

1. Remove one applicator tube from package and hold in an upright position pointed away from your face.



2. Pull off cap. Turn the cap around and place on top.



3. Simply press cap down to break the seal of the tube. Remove cap carefully.



4. Position the tip of the tube on the cat's back between the shoulder blades. Use the 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 cat's skin. Separate treated cat from other [dogs and cats] [pets] for 24 hours after treatment has been applied.



You may bathe your cat 48 hours after application

5. Repeat [every] [once a] month

FREQUENCY OF APPLICATION

[When used monthly, Alternate Brand Name completely breaks the flea life cycle and controls tick and chewing lice infestations]. [Research demonstrates that (Alternate Brand Name) kills adult fleas, flea eggs, and flea larvae for up to six weeks]. (Alternate Brand Name) [also] prevents development of all flea stages for up to six weeks. 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][apply (Alternate Brand

Name) once every 30 days].

(Alternate Brand Name) kills ticks for a least one month. A once monthly application is recommended where tick control is needed.

(Alternate Brand Name) kills chewing lice for 30 days. [Do not reapply product for 30 days.]

(Alternate Brand Name) remains effective even after bathing, [swimming,] water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply (Alternate Brand Name) for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or 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 HANDLING: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available or place in trash. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

SIDE EFFECTS (*Located in a box at the lower right hand corner of the back label.*)

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-XXX-XXX-XXXX] [1-800-275-1414].

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

EPA Reg. No. 2596-166
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.]]

INDIVIDUAL TUBE TEXT

(Alternate Brand Name)

[For use] Only [for use] on Cats 8 weeks and older weighing 1.5 lbs or more
0.017 fl oz (0.5mL)

Contains Fipronil 9.8%, (S)-Methoprene 11.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-166

EPA Est. No. 2596-OH-1

(Lot number to appear on tube)

(OPTIONAL/ALTERNATE LABEL TEXT)

(Alternate Brand Name) can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Controls and prevents flea 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

Eliminates infestations with chewing lice

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

Fast-acting

Long-lasting

Waterproof

[Convenient] [Easy] to use

(Adult Fleas)

Kills Fleas [that may transmit tapeworms] [for] [28 days] [30 days] [1 month] [4 weeks] [on cats]

Kills [Adult] Fleas [for up to 6 weeks]

[Kills][Controls] fleas that may cause [flea allergy dermatitis] [and] [flea bite anemia] [for] [28 days] [30 days] [1 month] [4 weeks] [6 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 flea infestations

Prevents establishment of new flea infestations

(Flea Eggs)

Kills Flea Eggs [and Flea Larvae] [for] [28 days] [30 days] [1 month] [4 weeks]

Prevents Flea Eggs from hatching

(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 Brown Dog ticks [*R. sanguineus*], American dog ticks [*D. variabilis*], Lone Star ticks [*Amblyomma americanum*], Deer ticks [*Ixodes scapularis*] [which may transmit Lyme disease]

Kills all stages of Ticks, [including those that may transmit Lyme disease]

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)

Eliminates chewing lice infestations

Controls infestations of chewing lice

Aids in Control of sarcoptic mange [mite] infestations

(Multiple)

Kills fleas, flea eggs [and] [&] larvae, [ticks], [and] [chewing lice]

Kills all stages of ticks [including those that may transmit Lyme disease]

Kills Fleas, Flea Eggs [and] Larvae [and][Chewing Lice]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, [Flea larvae]

Kills Fleas, Ticks, Flea eggs, [Flea larvae] [through contact] [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, [Flea larvae] [after contact] [for] [28 days] [30 days] [1 month] [4 weeks]

Prevents development of all flea stages for up to 6 weeks.

Prevents Flea eggs, larvae and pupae from hatching

Kills newly emerged flea eggs before they lay eggs

Kills adult Fleas, Flea Eggs and Larvae [for up to 6 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] [for] [28 days] [30 days] [1 month] [4 weeks]

Provides fast, effective and convenient treatment and control of [fleas,] [ticks], [and] [chewing lice] [for cats and kittens]

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

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]

Prevents flea eggs from developing into biting adults [for] [up to] [30 days] [1 month] [4 weeks]

Spreads with cat's natural skin oils

Kills fleas for 30 days [1 month] [4 weeks]

Controls and prevents infestations

Prevents flea re-infestation

Prevents and controls flea re-infestation[s]

Eliminates fleas

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]

(Alternate Brand Name) remains effective even after bathing, [swimming,] water immersion, or exposure to sunlight. Avoid contact with treated area until dry.

(Alternate Brand Name) can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

[(Alternate Brand Name)] Can [also] be used on breeding, pregnant and lactating queens

(Alternate Brand Name) contains Fipronil and the insect growth regulator [(IGR)] (S)-

Methoprene.

(Alternate Brand Name) effectively targets all stages of fleas.

(Alternate Brand Name) [is] fast-acting, long-lasting, waterproof, [and] [&] [convenient] [easy] [to use].

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.

Contains Fipronil and (S)-Methoprene [, the active ingredients used in Frontline Plus[®]].
(Alternate Brand Name) is not manufactured by or distributed by Merial. Frontline Plus[®] is a registered trademark of Merial.

Contains the same active ingredients fipronil and (S)-methoprene found in Frontline[®] Plus

Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline[®] Plus for Cats

Contains the same active ingredients as Frontline[®] Plus for Cats

{**Note to reviewer:** whenever any of the three claims immediately above are included on product labels, then the label will contain the appropriate disclaimers below. The disclaimers will be placed in the same area of the label as the optional claims so that both are viewed together. }

* (Alternate Brand Name) is not manufactured by or distributed by Merial Limited]

* [Frontline is a registered trademark of Merial Limited.]

Compare to Frontline Plus[®]

For cats and kittens [8 weeks of age or older weighing 1.5 lbs or more]

Formulated for cats and kittens

Do Not Use On Dogs

(NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT)

1st dose, 2nd dose, 3rd dose [Xth dose]

First month, second month, third month [Xth month]

Value pack

[X] month supply

[X] monthly treatment[s]

Fragrance-free

Unscented

Convenient [easy to use] applicator

X 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]

[New], easy to use applicator [tube]

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 _____

Xth Dose _____

[Calendar] [Reminder] stickers [inside]

[3] [4] [6] Doses Inside

[3 Pack] [3 Applicators] [3 Months Supply] [3 Doses]

[4 Pack] [4 Applicators] [4 Months Supply] [4 Doses]

[6 Pack] [6 Applicators] [6 Months Supply] [6 Doses]

6 Dose Value Pack

4 [doses][tubes][applicators][month supply]

12 [doses][tubes][applicators] [month supply] [fully year] [value pack]

12 [applicators] [tubes]

[12 month supply]

Bonus Pack

Buy 3 get 1 free

4 month supply

12 month [full year] supply

The first time you treat your cat, place the First Application Sticker on your calendar. Apply Stickers [2 and 3] [2 through 4] [2 through 6] to the calendar [30 and 60 days] [30, 60, 90 days] [30, 60, 90, 120, and 180 days] [at the end of each 30 day period] after the first application to remind you it's time to reapply Alternate Brand Name for Cats.

[First Application Sticker:] Apply (Alternate Brand Name) ~~for Cats~~

[Month 2 Sticker:] Apply (Alternate Brand Name) ~~for Cats~~

[Month 3 Sticker:] Apply (Alternate Brand Name) ~~for Cats~~

[Month 4 Sticker:] Apply (Alternate Brand Name) ~~for Cats~~

[Month 5 Sticker:] Apply (Alternate Brand Name) ~~for Cats~~

[Month 6 Sticker:] Apply (Alternate Brand Name) ~~for Cats~~

For Customer Service please call 1-xxx-xxx-xxxx

Questions or comments about this product?
Call [X-XXX-XXX-XXXX]
[Monday-Friday X am-Xpm EST]

(Alternate Brand Names)

Hartz® Force Plus™ Dual Action Topical Treatment for Cats [& Kittens]
Hartz® FieldForce Plus™ Dual Action Topical Treatment for Cats [& Kittens]
Hartz® First Defense Plus™ Dual Action Topical Treatment for Cats [& Kittens]
Hartz® First Defense Plus™ Dual Active Topical Treatment for Cats [& Kittens]

Hartz® Plus Force™ for Cats [& Kittens]
Hartz® FieldForce Plus™ for Cats [& Kittens]
Hartz® First Defense Plus™ for Cats [& Kittens]

Hartz® Plus Force™ Dual Action Topical Solution for Cats [& Kittens]
Hartz® FieldForce Plus™ Dual Action Topical Solution for Cats [& Kittens]
Hartz® First Defense Plus™ Dual Action Topical Solution for Cats [& Kittens]
Hartz® First Defense Plus™ Dual Active Topical Solution for Cats [& Kittens]

FieldForce Plus™ Dual Action Topical Treatment for Cats [& Kittens]
First Defense Plus™ Dual Action Topical Treatment for Cats [& Kittens]
First Defense Plus™ Dual Active Topical Treatment for Cats [& Kittens]

FieldForce Plus™ for Cats [& Kittens] First Defense Plus™ for Cats [& Kittens]
FieldForce Plus™ Dual Action Topical Solution for Cats [& Kittens]
First Defense Plus™ Dual Action Topical Solution for Cats [& Kittens]
First Defense Plus™ Dual Active Topical Solution for Cats [& Kittens]