

2596-183

12/11/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 11, 2014

Ms. Heather Masch
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Label Notification per PRN 98-10 – Nine Alternate Brand Names
Product Name: HARTZ Ref#148
EPA Registration Number: 2596-183
Application Date: November 10, 2014
Decision Number: 498022

Dear Ms. Masch:

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 alternate brand names: Hartz® Advanced™ for Cats, Hartz® Advanced™ for Kittens, Hartz® Advanced™ for Cats and Kittens, Hartz® Advanced™ Flea Treatment for Cats, Hartz® Advanced™ Flea Treatment for Cats and Kittens, Hartz® Advanced™ Flea Treatment for Kittens, Advanced™ Flea Treatment for Cats, Advanced™ Flea Treatment for Cats and Kittens, and Advanced™ Flea Treatment for Kittens has been added to the product records

If you have any questions, you may contact Melody Banks at 703 305 5413 or via email at banks.melody@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Venus Eagle", with a long horizontal line extending to the right.

Venus Eagle, Product Manager 1
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

[FRONT PANEL]
Hartz® Reference # 148

Alternate Brand Names

Hartz® Advanced™ for Cats

Hartz® Advanced™ for Kittens

Hartz® Advanced™ for Cats and Kittens

Hartz® Advanced™ Flea Treatment for Cats

Hartz® Advanced™ Flea Treatment for Cats and Kittens

Hartz® Advanced™ Flea Treatment for Kittens

Advanced™ Flea Treatment for Cats

Advanced™ Flea Treatment for Cats and Kittens

Advanced™ Flea Treatment for Kittens

Hartz First Defense Max for Cats [& or Kittens]

Hartz First Defense Advanced PLUS for Cats [& or Kittens]

Hartz First Defense Advanced PRO for Cats [& or Kittens]

Hartz First Defense Evolution for Cats [& or Kittens]

Hartz First Defense Guardian for Cats [& or Kittens]

Hartz Generic Topical Treatment for Cats [& or Kittens]

Hartz Generic Flea Topical for Cats [& or Kittens]

Hartz Generic for Cats [& or Kittens]

Hartz First Defense ADVANCED for Cats [& or Kittens]

Hartz ADVANCE PRO Flea Treatment for Cats [& or Kittens]

Hartz UltraGuard Sentinel for Cats [& or Kittens]

Hartz UltraGuard Sentinel MAX for Cats [& or Kittens]

Hartz UltraGuard Sentinel PLUS for Cats [& or Kittens]

Hartz UltraGuard Sentinel PRO for Cats [& or Kittens]

Hartz UltraGuard Defender for Cats [& or Kittens]

Hartz UltraShield for Cats [& or Kittens]

Hartz ImidaShield II for Cats [& or Kittens]

Hartz ImidaShield II MAX for Cats [& or Kittens]

Hartz ImidaShield II PLUS for Cats [& or Kittens]

Hartz ImidaShield II PRO for Cats [& or Kittens]

Hartz ImidaShield for Cats [& or Kittens]

Hartz ImidaShield MAX for Cats [& or Kittens]

Hartz ImidaShield PLUS for Cats [& or Kittens]

Hartz ImidaShield PRO for Cats [& or Kittens]

Hartz ImidaGuard II for Cats [& or Kittens]

Hartz ImidaGuard II MAX for Cats [& or Kittens]

Hartz ImidaGuard II PLUS for Cats [& or Kittens]

Hartz ImidaGuard II PRO for Cats [& or Kittens]

Hartz ImidaGuard for Cats [& or Kittens]

Hartz ImidaGuard MAX for Cats [& or Kittens]
 Hartz ImidaGuard PLUS for Cats [& or Kittens]
 Hartz ImidaGuard PRO for Cats [& or Kittens]
 Hartz ProCare for Cats [& or Kittens]
 Hartz FirstCare for Cats [& or Kittens]

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

For use ONLY on Cats 8 weeks and Older and Weighing 2 to 5 lbs.

or Weighing 5 to 9 lbs.
 or Weighing Over 9 lbs.

[FRONT PANEL (cont.)]

ACTIVE INGREDIENTS:

Imidacloprid	9.10%
Pyriproxyfen	0.46%
Other Ingredients	90.44%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for precautionary statements and directions for use.

NET CONTENTS:

[Large clear picture of a cat in appropriate weight range on front panel to be included]

For use ONLY on Cats 8 weeks and Older and Weighing:	Net Contents
2 to 5 lbs.	0.031 fl. oz. (0.92 ml), Contains 4 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.056 fl. oz. (1.6 ml), Contains 4 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.108 fl. oz. (3.2 ml), Contains 4 tubes, each 0.027 fl. oz. (0.8 ml)

For use ONLY on Cats 8 weeks and Older and Weighing:	
2 to 5 lbs.	0.046 fl. oz. (1.38 ml), Contains 6 tubes, each 0.0078 fl. oz. (0.23 ml)
5 to 9 lbs.	0.084 fl. oz. (2.4 ml), Contains 6 tubes, each 0.014 fl. oz. (0.4 ml)
over 9 lbs.	0.162 fl. oz. (4.8 ml), Contains 6 tubes, each 0.027 fl. oz. (0.8 ml)

Hartz® Reference #148
EPA Reg. No.: 2596-183
MASTER LABEL

Version: Nov 10, 2014

4/11

[BACK PANEL]

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies or consumer questions call 1-800-275-1414.

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.

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 warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not apply to cats or kittens under 8 weeks of age or weighing less than [2 lbs.; 5 lbs.; 9 lbs.] As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not store near heat or open flame.

[BACK PANEL (cont.)]

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

RESTRICTIONS

USE ONLY ON CATS OR KITTENS 8 WEEKS AND OLDER WEIGHING [2 to 5 lbs.; 5 to 9 lbs.; Over 9 lbs.]

DO NOT USE ON OTHER ANIMALS

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR CATS

DO NOT APPLY MORE THAN ONE (1) TUBE PER TREATMENT ON ANY CAT

DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY.

DO NOT USE ON CATS WEIGHING LESS THAN 2 LBS. [this line only required on product labeled for use on cats weighing 2 to 5 lbs.]

Side Effects (Cats): Monitor your cat after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call, 1-800-275-1414.

[BACK PANEL (cont.)]

[DIRECTIONS FOR USE (cont.)]

[APPLICATION INSTRUCTIONS:]

[Visuals Depicting How to Open Applicator Tube And Application To Animal]

[OPTION 1:]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. ***Do not get this product in your pet's eyes, or allow your pet to ingest this product. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.*** Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[OPTION 2:]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**.
3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. ***Do not get this product in your pet's eyes, or allow your pet to ingest this product. The product is bitter tasting and salivation may occur for a short time if the pet licks the product immediately after treatment.*** Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four (4) weeks. On cats, do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly treatment schedule.

[BACK PANEL (cont.)]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-274-1414 for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

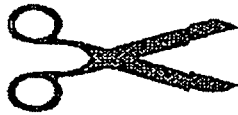
EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

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[INSTRUCTIONS FOR BLISTER PACK]

HOW TO OPEN



[OPTION 1:]

1. Being careful not to cut close to the blister cavities, take scissors and cut along dotted line.
2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
3. Follow application instructions.
4. Repeat steps 1 and 2 for each tube.

[OPTION 2:]

1. Separate [foil] [paper] from corner of blister package.
2. Peel back [foil] [paper] and take out the tube.

INDIVIDUAL TUBE TEXT

(Product name)

[The appropriate size and fill volume will be correctly used on each applicable cat's weight category]

ONLY FOR USE ON CATS AND KITTENS 8 WEEKS OR OLDER WEIGHING 2 to 5 lbs. -

0.0078 fl. oz. (0.23 ml)

or 5 to 9 lbs. - 0.014 fl. oz. (0.4 ml)

or 9 lbs. and Over - 0.027 fl. oz. (0.8 ml)

9.10% Imidacloprid

0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read The Entire Label Before Use

EPA Reg. No. 2596-

EPA Est. No. 2596-OH-1

(Lot no. is heat stamped in tube crimp – required on each)

OPTIONAL/ALTERNATE LABEL TEXT

For use on cats and kittens 8 weeks of age and older

(Insert Product Name) contains Imidacloprid, [and an/the] [insect growth regulator] [IGR] [Pyriproxyfen]

A single topical application remains effective for up to [4 weeks] [1 month]

Convenient, easy-to-apply topical solution

Convenient, easy-to-apply [and fragrance free] [monthly] [topical solution]

Once a month topical flea prevention and treatment for cats 8 weeks of age or older

(Insert Product Name) is indicated for the prevention and treatment of fleas on cats 8 weeks of age and older

For the prevention and treatment of flea infestations on cats

One treatment prevents further flea infestations for up to [4 weeks] [1 month] [30 days]

Kills fleas and continues to prevent infestations for up to [four weeks] [a month] [30 days]

Kills larval stages of fleas following contact with [a/an] [Product Name] treated cat

Stops existing flea infestations by killing adult fleas

Effectively breaks the flea life cycle

[Kills] [Controls] life stages

Comprehensive flea prevention and treatment

2-way flea protection ([kills] [controls]) adults and eggs

Treatment of cats with [Product Name] kills fleas and that may cause flea allergy dermatitis [FAD] [or flea bite hypersensitivity]

Flea adulticide and ovidicide

Kills flea eggs

Controls flea problems

Provides flea protection

Controls existing fleas and flea eggs plus [and] [prevents] future flea infestations

[Brand Name] may be used year-round for flea [prevention] [protection]

Contains an insect growth regulator (IGR) to kill flea eggs and prevent reinfestation

Monthly use of [Product Name] on cats kills fleas that may cause ([flea allergy dermatitis] [flea bite hypersensitivity])

Controls existing flea infestations on your cat and prevents further infestations

Prevents fleas on treated cats from infesting (reinfesting)

Fragrance-free

Prevents (establishment of) new infestations after application

Prevents all flea stages (eggs) from developing

Kills fleas (and flea eggs) [for] [4 weeks] [1 month] [30 days]

Stays on and doesn't rub off for 1 month

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation (reinfestation)

Effective and convenient topical treatment

(With) patented applicator

Easy spot on topical applicator
Remains effective even after bathing or water immersion.
(Product Name) remains effective even after bathing or water immersion.

Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (or Advantage® II)
Contains the (same) active ingredients used in Bayer Advantage® II (or Advantage® II) (products)
Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (or Advantage® II) (brand products)
[Product Name] is not manufactured by or distributed by Bayer. Advantage® II is a registered trademark of Bayer Healthcare LLC.

Only for cats and kittens 8 weeks of age or older
For cats and kittens 8 weeks of age or older

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] [2] [3] [4] [5] [6] month supply
[4 or 6] monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(4 or 6) Pro-cision Flo® Applicator(s) (included)
(4 or 6) Pro-glide® Applicator(s) (included)
(Pro-cision Flo® Applicator)
(Pro-Glide® Applicator)
Featuring [Pro-cision Flo®] [Pro-Glide®] Applicator (for easy application)
Direct to your cat's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Convenient to use

After application, the treated area may appear wet for up to 24 hours
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 _____