



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2596-181

Date of Issuance:

10/23/2014

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Hartz Reference #146

Name and Address of Registrant (include ZIP Code):

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

- 1. This registration is time-limited and expires two years from the date this product is first released for shipment.

You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.

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Signature of Approving Official:

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)

Date:

10/23/2014

2. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2015.

Please flag any Confidential Business Information as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - a. All incidents should be reported including all minor dermal and ocular irritation reports.

- b. Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label (if applicable).
 - g. A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).
 - h. Table showing number of incidents for each cat breed, where provided.
 - i. Table showing number of incidents in cats for each clinical sign.
 - j. Table showing number of incidents in cats for each organ system.
5. Report aggregate incidents, but do not combine moderate and minor incidents.
 6. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
 7. You are required to comply with the DCIs identified below:
 - a. Imidacloprid GDCI-129099-951, issued on 11/10/2010
 - b. Pyriproxyfen GDCI- 129032-1299, issued on 2/21/2014

If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

8. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
9. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 2596-181.”
10. Submit one copy of the final printed label for the record before you release the product for shipment.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/28/2014

If you have any questions, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division
(7505P)

Attachment – stamped label

[FRONT PANEL]

Hartz[®] Reference # 146

Alternate Brand Names

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*]

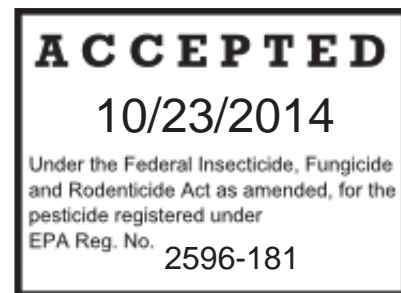
[Each of the above brands will be packaged in the weight classes designated below:]

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)

[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.

[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

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.)

[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 ovcide

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 _____