



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 4, 2014

David Jones
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Subject: Label Notification per PRN 98-10 – Addition of alternate brand names and correction of typographical error in dosage level
Product Name: HARTZ Reference # 145
EPA Registration Number: 2596-180
Application Date: November 19, 2014
Decision Number: 497731

Dear Mr. Jones:

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 label submitted with the application has been stamped “Notification” and will be placed in our records.

The alternate brand names Hartz Advanced Flea Treatment for Dogs, Hartz Advanced Flea Treatment for Dogs and Puppies, Advanced Flea Treatment for Dogs, and Advanced Flea Treatment for Dogs and Puppies have been added to the product record.

If you have any questions, you may contact Jennifer Urbanski at 703-347-0156 or via email at urbanski.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Venus Eagle".

Venus Eagle, PM 01
Invertebrate & Vertebrate Branch 3
Registration Division
Office of Pesticide Programs

[FRONT PANEL]

Hartz® Reference # 145

Alternate Brand Names

- Hartz® Advanced™ Flea Treatment for Dogs
- Hartz® Advanced™ Flea Treatment for Dogs and Puppies
- Advanced™ Flea Treatment for Dogs
- Advanced™ Flea Treatment for Dogs and Puppies

NOTIFICATION

2596-180

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/04/2014

- Hartz First Defense Max for Dogs [& or and Puppies]
- Hartz First Defense Advanced PLUS for Dogs [& or and Puppies]
- Hartz First Defense Advanced PRO for Dogs [& or and Puppies]
- Hartz First Defense Evolution for Dogs [& or and Puppies]
- Hartz First Defense Guardian for Dogs [& or and Puppies]
- Hartz Generic Flea Topical Treatment for Dogs [& or and Puppies]
- Hartz Generic Flea Topical for Dogs [& or and Puppies]
- Hartz First Defense ADVANCED for Dogs [& or and Puppies]
- Hartz ADVANCED for Dogs [& or and Puppies]
- Hartz ADVANCE PRO for Dogs [& or and Puppies]
- Hartz UltraGuard Sentinel MAX for Dogs [& or and Puppies]
- Hartz UltraGuard Sentinel PLUS for Dogs [& or and Puppies]
- Hartz UltraGuard Sentinel PRO for Dogs [& or and Puppies]
- Hartz UltraGuard Defender for Dogs [& or and Puppies]
- Hartz UltraShield for Dogs [& or and Puppies]
- Hartz ImidaShield MAX for Dogs [& or and Puppies]
- Hartz ImidaShield PLUS for Dogs [& or and Puppies]
- Hartz ImidaShield PRO for Dogs [& or and Puppies]
- Hartz ImidaShield II MAX for Dogs [& or and Puppies]
- Hartz ImidaShield II PLUS for Dogs [& or and Puppies]
- Hartz ImidaShield II PRO for Dogs [& or and Puppies]
- Hartz ImidaGuard MAX for Dogs [& or and Puppies]
- Hartz ImidaGuard PLUS for Dogs [& or and Puppies]
- Hartz ImidaGuard PRO for Dogs [& or and Puppies]
- Hartz ImidaGuard II MAX for Dogs [& or and Puppies]
- Hartz ImidaGuard II PLUS for Dogs [& or and Puppies]
- Hartz ImidaGuard II PRO for Dogs [& or and Puppies]
- Hartz ProCare for Dogs [& or and Puppies]
- Hartz FirstCare for Dogs [& or and Puppies]

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

For use ONLY on Dogs [and Puppies] 7 weeks and older weighing 3 - 10 lbs.

or weighing 11 - 20 lbs.

or weighing 21 - 55 lbs.

or weighing over 55 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.

[Large clear picture of dog in appropriate breed/weight class on front panel of product to be included]

NET CONTENTS:

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	Contains 1 tube, each 0.014 fl. oz. (0.4 ml)
11 to 20 lbs.	Contains 1 tube, each 0.034 fl. oz. (1.0 ml)
21 to 55 lbs.	Contains 1 tube, each 0.084 fl. oz. (2.5 ml)
55 lbs. and Over	Contains 1 tube, each 0.135 fl. oz. (4.0 ml)

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	0.042 fl. oz. (1.2 ml), Contains 3 tubes, each 0.014 fl. oz. (0.4 ml)
11 to 20 lbs.	0.102 fl. oz. (3.0 ml), Contains 3 tubes, each 0.034 fl. oz. (1.0 ml)
21 to 55 lbs.	0.252 fl. oz. (7.5 ml), Contains 3 tubes, each 0.084 fl. oz. (2.5 ml)
55 lbs. and Over	0.405 fl. oz. (12.0 ml), Contains 3 tubes, each 0.135 fl. oz. (4.0 ml)

[FRONT PANEL (cont.)]**NET CONTENTS (cont.):**

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	0.056 fl. oz. (1.6 ml), Contains 4 tubes, each 0.014 fl. oz. (0.4 ml)
11 to 20 lbs.	0.136 fl. oz. (4.0 ml), Contains 4 tubes, each 0.034 fl. oz. (1.0 ml)
21 to 55 lbs.	0.336 fl. oz. (10.0 ml), Contains 4 tubes, each 0.084 fl. oz. (2.5 ml)
55 lbs. and Over	0.540 fl. oz. (16.0 ml), Contains 4 tubes, each 0.135 fl. oz. (4.0 ml)

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	0.084 fl. oz. (2.4 ml), Contains 6 tubes, each 0.014 fl. oz. (0.4 ml)
11 to 20 lbs.	0.204 fl. oz. (4.0 ml), Contains 6 tubes, each 0.034 fl. oz. (1.0 ml)
21 to 55 lbs.	0.504 fl. oz. (15.0 ml), Contains 6 tubes, each 0.084 fl. oz. (2.5 ml)
55 lbs. and Over	0.810 fl. oz. (24.0 ml), Contains 6 tubes, each 0.135 fl. oz. (4.0 ml)



DO NOT USE ON CATS [1.5 x 1.5 cm black on yellow background]

[BACK PANEL]

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 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 7 weeks of age or weighing less than [3lbs.; 11lbs.; 21lbs.; 55lbs.] As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a Veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

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.

[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 DOGS OR ON PUPPIES 7 WEEKS OF AGE OR OLDER WEIGHING [3 to 10 lbs.; 11 to 20 lbs.; 21 to 55 lbs.; Over 55 lbs.]

DO NOT USE ON OTHER ANIMALS

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR DOGS

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

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

Side Effects: Monitor your dog 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 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.



[1.5 x 1.5 cm black on yellow background]

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 immediately.

[BACK PANEL (cont.)]

[DIRECTIONS FOR USE (CONT.)]

[APPLICATION INSTRUCTIONS:]

[Visuals Depicting How to Open Applicator Tube and Application to Animal]

[OPTION 1: for 3 to 10 lbs. or 11 to 20 lbs. packages]

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. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, 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 dog's eyes or allow your dog to ingest this 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 the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[OPTION 2: for 3 to 10 lbs. or 11 to 20 lbs. packages]

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. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, 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 dog's eyes or allow your dog to ingest this 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 the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[BACK PANEL (cont.)]**[DIRECTIONS FOR USE (CONT.)]**

[APPLICATION INSTRUCTIONS (cont.):]

[OPTION 3: for 21 to 55 lbs. and Over 55 lbs. packages]

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. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. ***Do not get this product in your dog's eyes or allow your dog to ingest this product.***
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[OPTION 4: for 21 to 55 lbs. and Over 55 lbs. packages]

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. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. ***Do not get this product in your dog's eyes or allow your dog to ingest this product.***
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment 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 1-800-275-1414 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. 2596-180

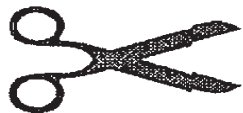
EPA Est. No. 2596-OH-1

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

Insert Product name

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

Only for Use on Dogs and Puppies 7 Weeks or Older Weighing *[insert text with weight and fill volume from a line immediately below]*

- 3 to 10 lbs. - 0.014 fl. oz. (0.4 ml)
- 11 to 20 lbs. - 0.034 fl. oz. (1.0 ml)
- 21 to 55 lbs. - 0.084 fl. oz. (2.5 ml)
- Over 55 lbs. - 0.135 fl. oz. (4.0 ml)

9.10% Imidacloprid
0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read the Entire Label before Use

EPA Reg. No. 2596-180

EPA Est. No. 2596-OH-1

(Lot No. is heat stamped in tube crimp- required number)

OPTIONAL/ALTERNATE LABEL TEXT

For use on dogs and puppies 7 weeks of age and older

(Product Name) contains Imidacloprid and (an/the) insect growth regulator *or* IGR *or* Pyriproxyfen

A single topical application remains effective for [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 treatment for dogs 7 weeks of age or older

(Product Name) is indicated for the prevention and treatment of fleas on dogs 7 weeks of age and older

For the treatment and prevention of flea [and lice] infestations

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

Kills larval stages of fleas

Stops existing flea infestations by killing adult fleas

[Prevents] [Stops] flea eggs from hatching [or developing] [into biting adults]

Effectively breaks the flea life cycle

Effectively targets all [life] stages of [fleas]

[Kills] [Controls] all flea life stages

3-way flea protection ([kills] [controls] adults, larvae, and eggs)

[Prevents] [Stops] flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas

Treatment with (Product Name) kills fleas which may cause flea allergic dermatitis [FAD] [or flea bite hypersensitivity]

Flea adulticide, larvicide, and ovicide

Kills flea eggs

Controls highly [irritating] [annoying] [flea] [insect] bites

Controls flea problems (on dogs *or* on dogs and puppies)

Provides flea protection (on dogs *or* on dogs and puppies)

Controls existing fleas and flea eggs [(plus) (and)] [prevents] future flea infestations in the home

Starts working through contact

Use flea [prevention] [protection] year-round

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

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

Multi-stage flea control

Prevents fleas on treated dogs from infesting (reinfesting) your home

Kills fleas which may serve as intermediate hosts for tapeworms

Kills [(biting) (chewing)] lice

For treatment and prevention of [(biting) (chewing)] lice [infestations] [on dogs *or* on dogs and puppies]

For the Prevention and Treatment of Flea and Lice Infestations on Dogs

Stops existing [(biting) (chewing)] lice infestations

Dual protection against fleas and lice

Treats, prevents and controls [(biting) (chewing)] lice [infestations]

Provides effective control of [(biting) (chewing)] lice [infestations]

Kills [(biting) (chewing)] lice and prevents further infestations
For treatment and prevention of infestations with [(biting) (chewing)] lice
Remains effective after bathing and/or swimming
Remains effective following swimming and/or shampooing
Waterproof
Remains effective after exposure to rain

Prevents (establishment of) new infestations after application

Prevents all flea stages (eggs, larvae) from developing
Prevents all flea stages (eggs, larvae, pupae) from developing
Kills fleas, flea eggs, larvae, pupae [for] [4 weeks] [1 month] [30 days]

Stays on and doesn't rub off for 1 month (*or* 4 weeks)

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

Stops and prevents infestations

Prevents re-infestation (reinfestation)

Prevents and controls re-infestation (reinfestations)

Eliminates fleas

Long lasting – 1 month *or* 4 weeks

Effective and convenient topical treatment

(With) patented applicator

Effective after bathing

Effective after exposure to water

Easy spot on topical applicator

Remains effective even after bathing and water immersion

(Product Name) remains effective even after bathing and 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 dogs and puppies 7 weeks of age or older

Specially formulated for dogs and puppies 7 weeks of age or older

Kills fleas within [12] hours of application

Kills fleas on dogs within [12] hours and continues to prevent infestations for [four weeks] [1 month] [30 days]

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 dog’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

You may bathe your dog 4 days 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 _____

Fourth Dose _____

Fifth Dose _____

Sixth Dose _____