

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

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

2596-191

EPA Reg.

Number:

Date of Issuance:

7/26/21

NOTICE OF PESTICIDE:

X Registration \_\_ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited Expires: 07/26/2023

Name of Pesticide Product:

Hartz Reference #167

Name and Address of Registrant (include ZIP Code):

Joe Conti, Senior Director Regulatory, Research & Development The Hartz Mountain Corp. 400 Plaza Dr 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. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
VE	7/26/21
Venus Eagle, Product Manager 01 Invertebrate and Vertebrate Branch 3, Registration Division (7505P)	

- 2. This registration is time-limited and expires 07/26/2023.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for dogs 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.
  - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs 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.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

- 5. You are required to comply with the data requirements described in the DCI identified below:
  - a. Imidacloprid GDCI-129099

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <a href="http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1">http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1</a>

- 6. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 2596-191."
- 7. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

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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 note that the record for this product currently contains the following CSFs:

- Basic CSF dated 5/8/2020
- Alternate CSF 1 dated 5/8/2020

If you have any questions, please contact Marianne Lewis by phone at (703) 308-8043, or via email at lewis.marianne@epa.gov.

Enclosure

Hartz Reference #167 EPA Registration # 2596-XXX MASTER LABEL

## **{FRONT PANEL}**

# ACCEPTED

Jul 26, 2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2596-191

July 22, 2021

# Hartz<sup>®</sup> Reference # 167

{The font size of the words "Dogs" and/or "Puppies" will be at least 75% of the height of the largest letter in the primary brand name used. A large clear picture of a dog in the respective weight class / breed will be on the front panel of the marketplace label.}"

{Alternate Brand Names are listed at the end of this document. Each Hartz market label will be packaged in a single weight class as designated below. The single weight class and age will appear on the market label prominently on the front panel, enclosed within a box, per the Agency's pet spot on mitigation measures.}"

For use ONLY on Dogs [and Puppies] 7 weeks and older weighing 3 - 10 lbs. [11 - 20 lbs.] [21 - 55 lbs.] [over 55 lbs.]

#### **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 [and insert] for First Aid, Precautionary Statements and Directions for Use.

{A large, clear picture of a dog in the respective weight class / breed will be on the front panel of the marketplace label.}

#### **NET CONTENTS:**

{1 Tube}

For use ONLY on Dogs and Puppies 7	Net Contents	
weeks and older Weighing:		
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)	
Over 55 lbs.	Contains 1 tube, each 0.135 fl. oz. (4.0 ml)	

## {FRONT PANEL - continued}

{2 Tubes}

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents
3 to 10 lbs.	0.028 fl. oz. (0.8 ml),
	Contains 2 tubes, each 0.014 fl. oz. (0.4 ml)
11 to 20 lbs.	0.068 fl. oz. (2.0 ml),
	Contains 2 tubes, each 0.034 fl. oz. (1.0 ml)
21 to 55 lbs.	0.168 fl. oz. (5.0 ml),
	Contains 2 tubes, each 0.084 fl. oz. (2.5 ml)
Over 55 lbs.	0.270 fl. oz. (8.0 ml),
	Contains 2 tubes, each 0.135 fl. oz. (4.0 ml)

## {3 Tubes}

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents
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)
Over 55 lbs.	0.405 fl. oz. (12.0 ml),
	Contains 3 tubes, each 0.135 fl. oz. (4.0 ml)

## {4 Tubes}

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents
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)
Over 55 lbs.	0.540 fl. oz. (16.0 ml),
	Contains 4 tubes, each 0.135 fl. oz. (4.0 ml)

## **FRONT PANEL** - continued

{6 Tubes}

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents
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)
Over 55 lbs.	0.810 fl. oz. (24.0 ml),
	Contains 6 tubes, each 0.135 fl. oz. (4.0 ml)

## {7 Tubes}

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents:
3 - 10 lbs.	0.098 fl. oz. (2.8 ml),
	Contains 7 tubes, each 0.014 fl. oz. (0.4 ml)
11 - 20 lbs.	0.238 fl. oz. (6 ml),
	Contains 7 tubes, each 0.034 fl. oz. (1.0 ml)
21 - 55 lbs.	0.588 fl. oz. (17.5 mL),
	Contains 7 tubes, each 0.084 fl. oz. (2.5 ml)
Over 55 lbs.	0.945 fl. oz. (28 ml)
	Contains 7 tubes, each 0.135 fl. oz. (4.0 ml)

## {8 Tubes}

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents:
3 - 10 lbs.	0.112 fl. oz. (3.2 ml),
	Contains 8 tubes, each 0.014 fl. oz. (0.4 ml)
11 - 20 lbs.	0.272 fl. oz. (8 mL),
	Contains 8 tubes, each 0.034 fl. oz. (1.0 ml)
21 - 55 lbs.	0.672 fl. oz. (20 mL),
	Contains 8 tubes, each 0.084 fl. oz. (2.5 ml)
Over 55 lbs.	1.08 fl. oz. <b>(</b> 32 mL),
	Contains 8 tubes, each 0.135 fl. oz. (4.0 ml)

{Cat Prohibition Icon: A cat prohibition icon will appear in a box on the front panel, located in the lower right corner of the package. Icon is 1.5 cm x 1.5 cm black image on a yellow background.}



## **{BACK PANEL}**

FIRST AID			
<u>If Swallowed</u>	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>		
<u>If in Eyes</u>	<ul> <li>Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>		
If on Skin or Clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>		

## **HOTLINE 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 1-800-275-1414, twenty-four [24] hours per day, seven [7] days per week.

## {BACK PANEL- continued}

## 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 dogs or puppies under 7 weeks of age or weighing less than 3 lbs. [11 lbs.] [21 lbs.] [55 lbs.] Consult your veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs. Individual sensitivities 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.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Weigh your dog to be sure you are applying the correct dose formulated for the weight of your dog. Use the entire contents of the applicator on each dog. Do not split one applicator between dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

#### 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 DOGS WEIGHING LESS THAN 3 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 FOR ONE DOG, REGARDLESS OF THE DOG'S WEIGHT.
- DO NOT ALLOW CHILDREN TO APPLY PRODUCT.
- DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY.

## {BACK PANEL- continued}

**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 (such as lethargy) occur, consult your veterinarian or call 1-800-275-1414.

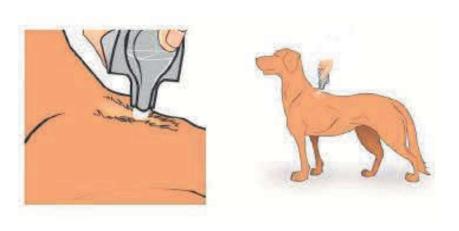


{1.5 X 1.5 cm black on yellow background}

Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

#### [APPLICATION INSTRUCTIONS:]

**(OPTION 1:** - Visuals depicting how to apply product to animal are **optional.** The numbers **underneath** the graphics correspond to the numbers in the How to Apply section below.}



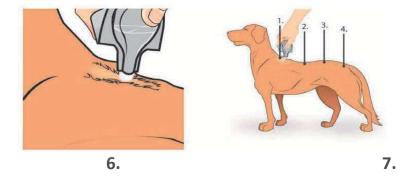
7. 8.

#### **HOW TO APPLY**

1. Dog should be dry prior to application and remain dry for 24 hours after application.

- 2. Remove one applicator tube from the package.
- 3. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.
- 4. Turn the cap around and place other end of cap back on tube.
- 5. Twist cap to break seal, then remove cap from tube.
- 6. The dog should be standing for easy application.
- 7. Part the hair on the dog's back, between the shoulder blades, until the skin is visible.
- 8. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin.
- 9. **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.
- 10. Discard empty tube as described in the Storage and Disposal section.
- 11. In case of severe pest infestations, you are able to retreat your dog earlier than [four][4] weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted, not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.
- 12. Do not bathe dog for 48 hours after product application.
- 13. Discard empty tube as described in the Storage and Disposal section.

{OPTION 2 - Visuals depicting how to open applicator tube and application to animal are optional. The numbers underneath the graphics correspond to the numbers in the How to Apply section below.}

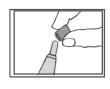


- 1. Dog should be dry prior to application and remain dry for 24 hours after application.
- 2. Remove one applicator tube from the package.
- 3. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
- 4. Twist cap to break seal, then remove cap from tube.
- 5. The dog should be standing for easy application.
- 6. Part the hair on the dog's back, between the shoulder blades, until the skin is visible.

- 7. 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*.
- 8. Discard empty tube as described in the Storage and Disposal section.
- 9. In case of severe pest infestations, you are able to retreat your dog earlier than (4) four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted, not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.
- 10. Do not bathe dog for 48 hours after product application.
- 11. Discard empty tube as described in the Storage and Disposal section.

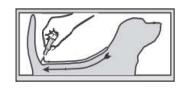
**{OPTION 3** - Visuals depicting how to open applicator tube and application to animal are **optional.** The numbers underneath the graphics correspond to the numbers in the How to Apply section below.}





4.





6.

- 1. Dog should be dry prior to application and remain dry for 24 hours after application.
- 2. Remove one applicator tube from the package.
- 3. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. The dog should be standing for easy application.
- 4. Pull off cap. Turn the cap around and place on top of the tube.
- 5. Simply press cap down to break the seal of the tube. Remove cap carefully.
- 6. Position the tip of the tube on the dog's back between the shoulder blades. Use the 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.
- 7. Separate treated dog from other dogs and cats [pets] for 24 hours after treatment has been applied.
- 8. Repeat every month. (Do not bathe your dog 48 hours prior to application.)
- 9. In case of severe pest infestations, you are able to retreat your dog earlier than [4] four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted, not to

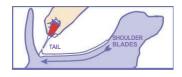
exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.

- 10. Do not bathe dog for 48 hours after product application.
- 11. Discard empty tube as described in the Storage and Disposal section.

**(OPTION 4:** Visuals Depicting How to Open Applicator Tube and Application to animal are **optional.** The numbers underneath the graphics correspond to the numbers in the How to Apply section below.}







2.

3.

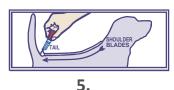
4.

- 1. Dog should be dry prior to application and remain dry for 24 hours after application.
- 2. Remove one applicator tube from the package and hold in an upright position **pointed away from your face.**
- 3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
- 4. 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.
- 5. Separate treated dog from other dogs and cats [pets] for 24 hours after treatment has been applied.
- 6. Repeat every month. (Do not bathe your dog 48 hours prior to application.)
- 7. In case of severe pest infestations, you are able to retreat your dog earlier than [4] four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted, not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.
- 8. Do not bathe dog for 48 hours after product application.
- 9. Discard empty tube as described in the Storage and Disposal section.

**{OPTION 5 -** Visuals depicting how to open applicator tube and application to animal are **optional.** The numbers underneath the graphics correspond to the numbers in the How to Apply section below.}





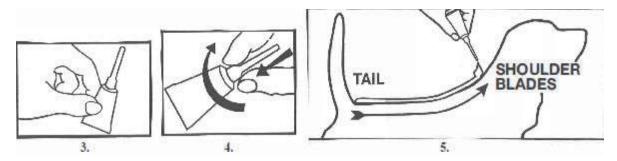


3

## [HOW TO APPLY]

- 1. Dog should be dry prior to application and remain dry for 24 hours after application.
- 2. Remove one applicator tube from the package.
- 3. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
- 4. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
- 5. The dog should be standing for easy application. 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 tale.
- 6. Separate treated dog from other pets for 24 hours after treatment has been applied.
- 7. Repeat every month. (Do not bathe your dog 48 hours prior to application.)
- 8. In case of severe pest infestations, you are able to retreat your dog earlier than [4] four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted, not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.
- 9. Do not bathe dog for 48 hours after product application.
- 10. Discard empty tube as described in the Storage and Disposal section.

**{OPTION 6 -** Visuals depicting how to open applicator tube and application to animal are **optional.** The numbers underneath the graphics correspond to the numbers in the How to Apply section below.}



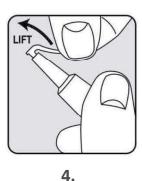
#### [HOW TO APPLY]

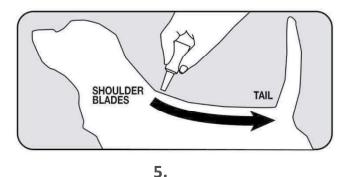
1. Dog should be dry prior to application and remain dry for 24 hours after application.

- 2. Remove one applicator tube from the package.
- 3. Hold applicator tube in an upright position facing away from you and your pet's face and eyes.
- 4. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
- 5. The dog should be standing for easy application. Part the hair at the base of the tail so skin is visible. Place the tip of the tube on the skin, and begin applying the product [Hartz Reference #167] in a continuous line from the base of tail along the center of the back moving forward to the shoulder blades, until tube is empty.
- 6. Separate treated dog from other dogs and cats [pets] for 24 hours after treatment has been applied.
- 7. Repeat every month. (Do not bathe your dog 48 hours prior to application.)
- 8. In case of severe pest infestations, you are able to retreat your dog earlier than [4] four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted, not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.
- 9. Do not bathe dog for 48 hours after product application.
- 10. Discard empty tube as described in the Storage and Disposal section.

**{Option 7}** - *Visuals depicting how to open applicator tube and application to animal are* **optional.** *The numbers underneath the graphics correspond to the numbers in the How to Apply section below.*}







- 1. Dog should be dry prior to application and remain dry for 24 hours after application.
- 2. Remove one applicator tube from the package.
- 3. Remove one applicator tube from the package and hold in an upright position at the neck of the tube (pointed away from your face).
- 4. Lift the applicator handle (lever) in an upward motion to separate (from the body of the tube).
- 5. The dog should be standing for easy application. Position the tip of the tube at the base of the dog's neck between the shoulders.

- 6. Using the tip of the applicator tube to part the dog's hair allowing for the product to be applied to the skin. Begin squeezing out the contents of the tube in a stripe as you move toward the dog's tail.
- 7. Separate treated dog from other dogs and cats [pets] for 24 hours after treatment has been applied.
- 8. Repeat every month. (Do not bathe your dog 48 hours prior to application.
- 9. In case of severe pest infestations, you are able to retreat your dog earlier than [4] four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted, not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.
- 10. Do not bathe dog for 48 hours after product application.
- 11. Discard empty tube as described in the Storage and Disposal section.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or 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.

#### **CONTAINER HANDLING:**

Non-refillable container. Do not reuse or refill 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] experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-xxx EPA Est. No. xxxx-

Hartz<sup>®</sup> 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.
- 3. Follow application instructions.
- 4. Repeat steps 1 and 2 for each tube.

{Note to Reviewer: Product may also be packaged in a tray without a paper or foil cover. In this case no instructions required for opening}

## {INDIVIDUAL TUBE TEXT / LABEL}

Hartz Reference #167

{Note: 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 FOR EXTERNAL USE ON DOGS ONLY

CAUTION
Read the Entire Label before Use

EPA Reg. No. 2596-xxx

## {INDIVIDUAL TUBE TEXT / LABEL - continued}

EPA Est. No. Xxx

{Note: Lot Number is heat stamped in tube crimp- required number}

## **{OPTIONAL/ALTERNATE LABEL MARKETING CLAIMS}**

- Hartz Reference #167 contains Imidacloprid and [an] [the] insect growth regulator [IGR] [ Pyriproxyfen]
- A single topical application remains effective for 4 weeks [1 month]
- Convenient, easy-to-apply [and fragrance free] [monthly] topical solution
- Once a month topical flea treatment for dogs 7 weeks of age or older weighing 3 to 10 lbs. [11 to 20 lbs.] [21 to 55 lbs.] [over 55 lbs.]
- Hartz Reference #167 is for the prevention and treatment of fleas on dogs 7 weeks of age and older weighing 3 to 10 lbs. [11 to 20 lbs.] [21 to 55 lbs.] [over 55 lbs.]
- For the treatment and prevention of flea [and[ [lice] infestations on dogs and puppies
- One treatment prevents re-infestations for 4 weeks [1 month] [30 days] on dogs and puppies
- Kills larval stage of fleas
- Kills existing flea infestations by killing adult fleas on dogs [and puppies]
- Prevents flea eggs from hatching [or developing] [into biting adults]
- Effectively breaks the flea life cycle
- Effectively targets multiple life stages of fleas on dogs [and] [puppies]
- Kills [Controls] multiple flea life stages on dogs and puppies
- 3-way protection against fleas [kills] [controls] adults, larvae, and eggs
- Prevents flea eggs [and flea larvae] from developing into biting adult fleas
- Flea adulticide, larvicide, and ovicide
- Kills flea eggs
- Controls fleas on dogs and puppies
- Provides protection against fleas on dogs and puppies
- Controls and provides protection against fleas on dogs and puppies
- Controls existing fleas and flea eggs on dogs and puppies
- Starts working through contact
- Use flea prevention [protection] year-round
- Year-Round Prevention when used on a monthly basis

- Contains an insecticide and an insect growth regulator [IGR] to kill flea eggs for 30 days [1 month][4 weeks]
- Monthly use of Hartz Reference #167 kills fleas which may cause flea allergy dermatitis [flea bite hypersensitivity]
- Treatment with Hartz Reference #167 kills fleas which may cause flea allergic dermatitis (FAD) [flea bite hypersensitivity]
- Multi-stage flea control for dogs and puppies
- 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 [and puppies]
- For the Prevention and Treatment of Flea and Lice Infestations on Dogs and Puppies
- Kills existing [biting] [chewing] lice infestations on dogs
- Dual protection against fleas and lice
- Treats, prevents and controls [biting] [chewing] lice [infestations] on dogs
- Provides effective control of [biting] [chewing] lice [infestations] on dogs
- Kills [biting][chewing] lice and prevents re-infestations for 30 days [1 month] [4 weeks]
- For treatment and prevention of infestations with biting [chewing] lice on dogs
- 48 hours after application, Hartz Reference # 167 remains effective [even] after bathing [and/or swimming] [and water immersion]
- Waterproof after 48 hours
- Prevents re-infestations for 30 days [1 month] [4 weeks] after application
- Prevents multiple flea stages [eggs, larvae] from developing on dogs and puppies
- Kills fleas, flea eggs, larvae for 30 days [1 month] [4 weeks]
- Stays on and doesn't rub off for 30 days [1 month] [4 weeks]
- Kills fleas for 30 days [1 month] [4 weeks]
- Prevents infestation [and] [re-infestation] for 30 days [1 month] [4 weeks]
- Prevents and controls infestation [and][re-infestations] for 30 days [1 month] [4 weeks]
- Long lasting 1 month [30 days] [4 weeks]
- Effective and convenient topical treatment
- [With] patented applicator {This claim only to be used on packages with Pro-Glide® applicator}
- Easy to use spot on topical applicator

- Only for dogs and puppies 7 weeks of age or older weighing 3 to 10 lbs. [11 to 20 lbs.] [21 to 55 lbs.] [over 55 lbs.]
- Formulated for dogs and puppies 7 weeks of age or older weighing 3 to 10 lbs. [11 to 20 lbs.] [21 to 55 lbs.] [over 55 lbs.]
- Kills fleas on dogs within 12 hours of application
- Kills fleas on dogs within 12 hours and continues to prevent infestations for 4 [four] weeks [1 month] [30 days]
- 1<sup>st</sup> dose [2<sup>nd</sup> dose] [3<sup>rd</sup> dose] [4<sup>th</sup> dose] [5<sup>th</sup> dose] [6<sup>th</sup> dose] [7<sup>th</sup> dose] [8<sup>th</sup> dose]
- First month [second month] [third month] [fourth month] [fifth month] [sixth month [seventh month] [eighth month]

## {Optional Active Ingredient Reference Statements}

Whenever any active ingredient reference statement listed below is used on the market label, the claim will not be set in a font side that is larger than the Signal word and it will not be bolded or highlighted or colored to cause the claim to stand out over the rest of the labeling text. This claim will not be presented in a way that will detract from the required precautionary labeling on the label.}

- Contains Imidacloprid and Pyriproxyfen, the active ingredients used [found] in Advantage® II
- Contains the active ingredients used [found] in Elanco Advantage® II [Advantage® II]
- Contains Imidacloprid and Pyriproxyfen, the active ingredients used [found] in Elanco Advantage® II [Advantage® II]

{Whenever any of the three Reference Statements immediately above are included on the market label, the label will also include one of the disclaimers below, which will be placed directly below the optional reference claim so that both are viewed together.}

- Elanco Advantage® is a registered trademark of Elanco Healthcare LLC
- Advantage<sup>®</sup> II is a registered trademark of Elanco Healthcare LLC

### **{NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL MARKETING CLAIMS}**

Value Pack {Optional Value Packs may be one of the following configurations:

- 1. Two Packages, each Package containing 2, 4, 6, 7, or 8 tubes. Packaged side by side, with no part of back or front labels to be covered or unreadable.
- 2. Two Packages, each Package containing 2, 4, 6, 7, or 8 tubes. Packages are wrapped together, with all mandatory front panel and back panel labeling to be clearly displayed.

{Note: Total Net Contents shown on Value Pack #2 as noted above is based on weight of dog or puppy and number of tubes in package. See Net Contents statements in front section of Master Label for all Value Pack #2 tube configurations.}

- 1 [2] [3] [4] [6] [7] [8] month supply
- 1 [2] [3] [4] [6] [7] [8] monthly treatment[s]
- Apply monthly [every 30 days]
- Convenient [easy to use] applicator
- 1 [2] [3] [4] [6] [7] [8] Pro-cision Flo® Applicator[s] [included]
- 1 [2] [3] [4] [6] [7] [8] Pro-glide Applicator[s] [included]
- Pro-cision Flo® Applicator
- Pro-Glide<sup>®</sup> Applicator
- Featuring Pro-cision Flo® [Pro-Glide®] Applicator [for easy application]
- Direct to your dog's skin
- Easy [Simple] to use [to handle] [to apply]
- Made in the U.S.A
- Convenient to use
- Easy to hold applicator [,with no drip and no splash]
- After application, the treated area may appear wet for up to 24 hours

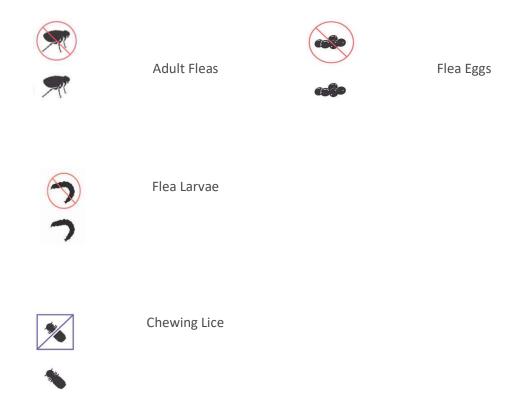
dose is applied:		
First Dose		
Second Dose		
Third Dose		
Fourth Dose		
Fifth Dose		
Sixth Dose		
Seventh Dose		
Eighth Dose		

To help remind you when you last applied treatment, simply write in the date when each

### [Reminder Stickers]

- The first time you treat your dog, place the first month sticker on your calendar.
- The first time you treat your dog, peel off a sticker and place it on your calendar that day.
- The first time you treat your dog, apply [Hartz Reference #167] monthly, every 30 days.
- Use these calendar stickers to remind you when your dog is due for the next application.
- Apply first month [Hartz Reference #167]
- Apply second month [Hartz Reference #167]
- Apply third month [Hartz Reference #167] [Repurchase]
- Apply fourth month [Hartz Reference #167] [Repurchase]
- Apply fifth month [Hartz Reference #167]
- Apply sixth month [Hartz Reference #167] [Repurchase]
- Apply seventh month [Hartz Reference #167] [Repurchase]
- Apply eighth month [Hartz Reference #167] [Repurchase]
- Manufactured for The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094.
- Hartz Reference #167 is not manufactured by or distributed by Elanco
- From the brand with over 90 years [of] experience caring for pets
- From the brand with over 90 years [of] experience devoted to pets
- From the brand with over 90 years [of] experience dedicated to pets
- From the brand with over 90 years of commitment to pets
- Hartz, the brand with over 90 years [of] experience caring for pets [devoted to pets]
- Caring for Pets [for] over 90 years
- Serving Pets [for] over 90 years
- Helping Pets [for] over 90 years

## **{OPTIONAL MARKETING ICONS}**



Hartz Reference #167
EPA Registration # 2596-XXX
MASTER LABEL

### {Alternate Brand Names}

Hartz® Advanced™ Flea Treatment for Dogs Advanced™ Flea Treatment for Dogs

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

Hartz ADVANCE PRO for Dogs [& [and] Puppies] ADVANCE PRO for Dogs [& [and] Puppies]

Hartz First Defense ADVANCED for Dogs [& [and] Puppies] First Defense ADVANCED for Dogs [& [and] Puppies]

Hartz First Defense Advanced PLUS for Dogs [& [and] Puppies] First Defense Advanced PLUS for Dogs [& [and] Puppies]

Hartz First Defense Advanced PRO for Dogs [& [and] Puppies] First Defense Advanced PRO for Dogs [& [and] Puppies]

Hartz First Defense Evolution for Dogs [& [and] Puppies] First Defense Evolution for Dogs [& [and] Puppies]

Hartz First Defense Guardian for Dogs [& [and] Puppies] First Defense Guardian for Dogs [& [and] Puppies]

Hartz First Defense for Dogs [& [and] Puppies]
First Defense for Dogs [& [and] Puppies]

Hartz FirstCare for Dogs [& [and] Puppies]
FirstCare for Dogs [& [and] Puppies]

Hartz Generic Flea Topical for Dogs [& [and] Puppies] Generic Flea Topical for Dogs [& [and] Puppies]

Hartz Generic Flea Topical Treatment for Dogs [& [and] Puppies] Generic Flea Topical Treatment for Dogs [& [and] Puppies]

Hartz ImidaGuard for Dogs [& [and] Puppies] ImidaGuard for Dogs [& [and] Puppies]

Hartz ImidaGuard PLUS for Dogs [& [and] Puppies] ImidaGuard PLUS for Dogs [& [and] Puppies]

Hartz ImidaGuard PRO for Dogs [& [and] Puppies] ImidaGuard PRO for Dogs [& [and] Puppies]

Hartz ImidaGuard II for Dogs [& [and] Puppies] ImidaGuard II for Dogs [& [and] Puppies]

Hartz ImidaGuard II PLUS for Dogs [& [and] Puppies] ImidaGuard II PLUS for Dogs [& [and] Puppies]

{Text in [ ] contain Optional or Alternate wording; Text in { } contain Notes to Reviewer; Text in ( ) will appear on marketplace label.}

July 22, 2021

Hartz ImidaGuard II PRO for Dogs [& [and] Puppies] ImidaGuard II PRO for Dogs [& [and] Puppies]

Hartz ImidaShield for Dogs [& [and] Puppies] ImidaShield for Dogs [& [and] Puppies]

Hartz ImidaShield PLUS for Dogs [& [and] Puppies] ImidaShield PLUS for Dogs [& [and] Puppies]

Hartz ImidaShield PRO for Dogs [& [and] Puppies] ImidaShield PRO for Dogs [& [and] Puppies]

Hartz ImidaShield II for Dogs [& [and] Puppies] ImidaShield II for Dogs [& [and] Puppies]

Hartz ImidaShield II PLUS for Dogs [& [and] Puppies] ImidaShield II PLUS for Dogs [& [and] Puppies]

Hartz ImidaShield II PRO for Dogs [& [and] Puppies] ImidaShield II PRO for Dogs [& [and] Puppies]

Hartz ProCare for Dogs [& [and] Puppies] ProCare for Dogs [& [and] Puppies]

Hartz UltraGuard Defender for Dogs [& [and] Puppies] UltraGuard Defender for Dogs [& [and] Puppies]

Hartz UltraGuard Sentinel for Dogs [& [and] Puppies] UltraGuard Sentinel for Dogs [& [and] Puppies]

Hartz UltraGuard Sentinel PLUS for Dogs [& [and] Puppies] UltraGuard Sentinel PLUS for Dogs [& [and] Puppies]

Hartz UltraGuard Sentinel PRO for Dogs [& [and] Puppies] UltraGuard Sentinel PRO for Dogs [& [and] Puppies]

Hartz UltraShield for Dogs [& [and] Puppies]
UltraShield for Dogs [& [and] Puppies]