

2596-150

7/13/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 13, 2010

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

Subject: Label Notification(s) for Pesticide Registration Notice 98-10  
Adding Alternate Brand Name and new EPA Est. No.

Dear Ms. Masch:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 98-10 dated June 14, 2010 for the following product(s):

**HARTZ Reference 118**

**EPA Reg. No. 2596-150**

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN-98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Regina Foushee'-Smith at 703-605-0780.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard J. Gebken  
Product Manager  
Insecticide Branch  
Registration Division (7505P)



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 2596-150	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Ref 118	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

"Addition of alternate brand names and addition of new EPA Est. No. per PR Notice 98-10"

"This notice is consistent with the provisions of PR Notices 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather Masch	Title Regulatory Affairs Associate	Telephone No. (Include Area Code) 201-271-4800, ext. 7036
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete; I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature 	3. Title Regulatory Affairs Associate	
4. Typed Name Heather Masch	5. Date 4/13/10	



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800  
REGULATORY AFFAIRS

June 14, 2010

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)  
**RE: Response to Letter June 2010 for Hartz Ref 118**  
**EPA Reg. No. 2596-150**  
Resubmission of alternate brand names and addition of new EPA Est.  
No. per PR Notice 98-10

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this notification to add alternate brand names and to add a new EPA Est. No. for the product **Hartz Ref 118, EPA Reg. No. 2596-150**. This is being done in conjunction with the filing of a new CSF for the new manufacturing location 2596-OH-1. This was the reason the previous notification was rejected.

The Hartz Mountain Corporation is submitting the following information:

- A completed application (EPA Form 8570-1) and;
- Three copies of the proposed notification label.

"This notice is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR §152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7036 or [hmasch@hartz.com](mailto:hmasch@hartz.com).

Sincerely,

Heather Masch  
Regulatory Affairs Associate

Handwritten notations consisting of groups of 'J' characters arranged in a grid-like pattern, possibly representing a signature or initials.

4/11

# Hartz® Reference 118

## Alternate Brand Names

Hartz® InControl™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (4 to 15 lbs.)  
 Hartz® InControl™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (16 to 30 lbs.)  
 Hartz® InControl™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (31 to 60 lbs.)  
 Hartz® InControl™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (over 60 lbs)

Hartz® InControl Advanced™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (4 to 15 lbs.)  
 Hartz® InControl Advanced™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (16 to 30 lbs.)  
 Hartz® InControl Advanced™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (31 to 60 lbs.)  
 Hartz® InControl Advanced™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing) (over 60 lbs)

- ✓ Hartz® InControl™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing 4 to 15 lbs.]
- ✓ Hartz® InControl™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing 16 to 30 lbs.]
- ✓ Hartz® InControl™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing 31 to 60 lbs.]
- ✓ Hartz® InControl™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing over 60 lbs]
  
- ✓ Hartz® InControl Advanced™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing 4 to 15 lbs.]
- ✓ Hartz® InControl Advanced™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing 16 to 30 lbs.]
- ✓ Hartz® InControl Advanced™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing 31 to 60 lbs.]
- Hartz® InControl Advanced™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies Weighing Over 60 lbs]

Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing 4 to 15 lbs.)  
 Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing 16 to 30 lbs.)  
 Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing 31 to 60 lbs.)  
 Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing > 60 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing 4 to 15 lbs.)  
 Hartz® UltraGuard Plus™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing 16 to 30 lbs.)  
 Hartz® UltraGuard Plus™ Flea & Tick Drops for Dogs (& (and) Puppies) (Weighing 31 to 60 lbs.)

5711

Hartz® Reference No. 118

4/13/2010

EPA Reg. No.: 2596-150

MASTER LABEL BASED ON 9/04/07 EPA STAMPED APPROVED LABEL

Hartz® UltraGuard Plus™ Flea & Tick Drops for Dogs (&) (and) (Puppies) (Weighing > 60 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing 4 to 15 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing 16 to 30 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing 31 to 60 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing >60 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing 4 to 15 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing 16 to 30 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing 31 to 60 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing >60 lbs.)

**ACTIVE INGREDIENTS**

Phenothrin.....85.7%

(S) – Methoprene.....2.3%

**OTHER INGREDIENTS** .....12.0%

**TOTAL** .....100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:** See (back) (side) panel for (ingredients and) additional precautionary statements.

**NET CONTENTS** Contains (*number*) tubes, each \_\_ fl. oz. ( \_\_ ml)

[*Note: Multiple packages containing from 1 tube to X tubes – each tube contains fl. oz. ( \_\_ ml)*]

<b>For Dogs and Puppies Weighing:</b>	<b>Net Contents (Each tube)</b>
4 to 15 lbs.	0.04 fl. oz. (1.1 ml)
16 to 30 lbs.	0.04 fl. oz. (1.3 ml)
31 to 60 lbs.	0.14 fl. oz. (4.1 ml)
> 60 lbs.	0.20 fl. oz. (5.9 ml)

EPA Reg. No. 2596-150

2596-NJ-01 = BI

2596-OH-01 = PP

See lot # for EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

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

**READ ENTIRE LABEL BEFORE EACH USE**  
**USE ONLY ON DOGS OR ON PUPPIES 12 WEEKS OF AGE OR OLDER**  
**DO NOT USE ON DOGS OR PUPPIES WEIGHING 4 LBS. OR LESS.**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

**HAZARDS TO DOMESTIC ANIMALS**

**DO NOT USE ON CATS OR KITTENS.** Do not use on puppies less than 12 weeks old. Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or on animals known to be sensitive to pesticide products without first consulting a veterinarian. Sensitivity, such as slight transitory redness of the skin at the site of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap, rinse with large amounts of water, and consult a veterinarian immediately.

**ENVIRONMENTAL HAZARDS**

This product is toxic to fish.

**FIRST AID**

**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. • You may also contact 1-800-275-1414 for emergency medical treatment information. • Have the product container or label with you when calling for advice or going for treatment.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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

[There are 4 closure options for the tube. The first represents the currently used cap. The following 3 closure options are proposed for use with this product.]

[Note: New text for opening new closures (option #1, #2 and #3) is highlighted.]

[Current cap]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). (Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully.) (Hold bottom of tube with one hand. With the other hand, snap cap off.)

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. Repeat every month.

[New optional cap #1]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

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. Repeat every month.

[New optional cap #2]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Squeeze the middle of the dispensing tip at the grooved pad to break the inner seal.

Position the dispensing 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. Repeat every month.

[New optional cap #3]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn until you feel it click into place. Push down to break the tube's seal. Do not remove the dispensing tip.

Position the dispensing 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. Repeat every month.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Store in a cool, dry place. **If empty:** Do not reuse the container. Place in trash or 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. **Container Disposal:** Nonrefillable container. Do not refill or reuse this container.

**INDIVIDUAL TUBE TEXT**

- Hartz® InControl™ Flea & Tick Drops for Dogs (& (and) Puppies)
- Hartz® InControl Advanced™ Flea & Tick Drops for Dogs (& (and) Puppies)
- Hartz® InControl™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies]
- Hartz® InControl Advanced™ Flea & Tick Drops for Dogs [for Dogs (& (and) Puppies]
- Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (& (and) Puppies)
- Hartz® UltraGuard Plus™ Flea & Tick Drops for Dogs (& (and) Puppies)
- Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (& (and) Puppies)
- Hartz® UltraGuard Plus™ Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (& (and) Puppies)

[Product name will be followed by weight of dog for which tube is intended]

[Active Ingredients:]

- Phenothrin .....85.7%
- (S) – Methoprene .....2.3%

*Range of volumes from 0.04 fl. oz. (1.1 ml) to 0.20 fl. oz (5.9 ml) depending upon size of dog*

*[Note: Multiple packages containing from 1 tube to X tubes – each tube contains fl. oz. ( \_ ml)]*

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION:**

Read accompanying label before use

EPA Reg. No. 2596-150

2596-NJ-01 = BL

2596-OH-01 = PP

See lot # for EPA Est. No.

The Hartz Mountain Corp.

**OPTIONAL/ALTERNATE LABEL TEXT**

- (Kills) (and) (&) (Repels) Fleas (and) (&) Ticks for (up to) (30 days) (1 month)
- Kills (fleas) (ticks) (mosquitoes) (flea eggs) (&) (and) (flea larvae) (for up to 30 days)
- Prevents flea eggs from hatching (for 30 days) (1 month)(4 weeks)
- Starts killing through contact
- Flea egg and (&) (flea) larvae treatment
- Contains an insect growth regulator
- Kills hatching flea eggs



Kills mosquitoes  
Contains an adulticide  
Flea and tick control  
Flea and tick (and mosquito) topical treatment  
Kills pre-adult stages of the flea life cycle  
Kills all stages of the flea life cycle  
Kills (and repels) fleas which may cause (flea bite anemia)(and)(or)(flea allergy dermatitis)  
Prevents mosquitoes from feeding on dogs for up to (one month) (4 weeks)(30 days) (per application)  
A single female flea can lay (and average of) 25 eggs per day (on average)  
Flea (and)(&) tick control  
Once fleas are (visible)(apparent) on your pet, there is already an infestation in your home.

For use on dogs and puppies 12 weeks of age or older only  
For dogs and puppies at least 12 weeks old  
For dogs and puppies over 4 lbs.



[The above graphic will be used to depict “do not use on cats” language]

One tube gives (provides) (30 days) (one month) (4 weeks) protection

Hartz® UltraGuard (alternate brand name) flea and tick products are most effective when used as part of a total program aimed at reducing fleas and ticks (in the dog’s environment)

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

Convenient (easy to use) applicator

X Pro-Glide™ Applicator(s)

(Now) (featuring the angled) Pro-Glide™ Applicator easily gets through fur, for gentle on-skin application

(Now) (featuring the angled) Pro-Glide™ Applicator quickly gets through fur, for on-skin application

(Now) (featuring the angled) Pro-Glide™ Applicator easily penetrates fur, for gentle on-skin application

(Now) (featuring the angled) Pro-Glide™ Applicator quickly penetrates fur, for on-skin

application

New Pro-Glide™ Applicator (*To be used only for the first 6 months*)

Pro-Glide™ Applicator gently glides through the fur

Pro-Glide™ Applicator easily gets through fur to minimize (oily) residue

Pro-Glide™ Applicator easily penetrates fur to minimize (oily) residue

Pro-Glide™ Applicator features rounded edges for gentle on-skin application

Pro-Glide™ Applicator glides smoothly through the fur

Pro-Glide™ Applicator features an angled tip to help guide the application

Easy to use Pro-Glide™ Applicator

Easy to (use)(handle) (apply)

Simple to (use)(handle) (apply)

(Featuring the) (with) EZC™ tube

(Featuring the) (with) EZ2C™ tube

(Featuring the) (with) EZView™ tube

(Featuring the) (with) Clearview™ tube

(Clearview™) (EZC™) (EZ2C™) (EZView™) tube (visually) ensures all product has been dispensed

(Clearview™) (EZC™) (EZ2C™) (EZView™) tubes give you the assurance all the product has been applied

(Patent pending)

(X) Pro-cision Flo™ Applicator(s)

(Pro-cision Flo™ Applicator)(Applicator) for (direct-to-skin) (direct to skin) application

(Pro-cision Flo™ Applicator)(Applicator) for direct application

Pro-cision Flo™ Applicator

Applicator (easily penetrates fur) (coat) for direct application

Applicator (easily penetrates fur) (coat) for application directly to your dog's skin

Direct to your dog's skin

For Dogs and Puppies (weighing) (4-15 lbs.) (16-30 lbs.) (31-60 lbs.) (> 60 lbs.)

This product contains three (four) monthly doses (one monthly dose), each X (fl. oz.) (cc) 1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose (X<sup>th</sup> dose)

First month, second month, third month (Xth month)

Triple pack

X-pack

X-tubes

Value pack

X monthly treatments

Fresh (scent) (fragrance)

Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

Spreads naturally with dog's (movement) (skin and hair oils)

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

No mess

Wait 48 hours after applying before bathing your dog.

Do not bathe your dog for 48 hours after application.

May stain leather and suede fabrics for (24) (24 to 48) hours after application.

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

applied:

First Dose \_\_\_\_\_

Second Dose \_\_\_\_\_

Third Dose \_\_\_\_\_

Xth Dose \_\_\_\_\_

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

VISIT (OUR)(WEBSITE)

(www.hartz.com)(www.hartzultraguard.com)(www.hartzincontrol.com)

Hartz recommends that you visit your veterinarian twice a year.

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