

2596-150

12/18/2009

1/11

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

PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 18 2009

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

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request To Add (>4 to 15 lbs.) to Alternate Brand Names:
Hartz® InControl Flea & Tick Drops for Dogs (&) (and) (Puppies) (Weighing
>4 to 15 lbs.)
Hartz® InControl Advanced Flea & Tick Drops for Dogs (&) (and) (Puppies)
(Weighing) (>4 to 15 lbs.)
Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (&) (and) (Puppies)
(Weighing > 4 to 15 lbs.)
Hartz® UltraGuard Plus Flea & Tick Drops 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 > 4 to 15 lbs.)
Hartz® UltraGuard Pro® Flea & Tick Drops with (Pro-cision Flo Applicator) for
Dogs (&) (and) (Puppies) (Weighing > 4 to 15 lbs.)
EPA. Reg. No. 2596-150
Application Dated October 12, 2009

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 10/12/09 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 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 Reference 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 _____	NOTIFICATION DEC 18 2009
<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 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:

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	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions

6. Manner in Which Label is Affixed to Product
 Lithograph Paper, glued Stenciled 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.

2. Signature 	3. Title Regulatory Affairs Associate	6. Date Application Received (Stamped)
4. Typed Name Heather Masch	5. Date 10/12/09	

Hartz® Reference 118

NOTIFICATION

DEC 18 2009

Alternate Brand Names

Hartz® InControl™ Flea & Tick Drops for Dogs (&) (and) (Puppies) (Weighing) (~~>4 to 15 lbs.~~)

Hartz® InControl Advanced™ Flea & Tick Drops for Dogs (&) (and) (Puppies) (Weighing) (~~>4 to 15 lbs.~~)

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

Hartz® UltraGuard Plus™ Flea & Tick Drops 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 >4 to 15 lbs.~~)

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

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® 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.)

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.)

4/11

5/11

Hartz® Reference No. 111

10/12/09

EPA Reg. No.: 2596-150

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

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

Phenothrin85.7%

(S) – Methoprene.....2.3%

OTHER INGREDIENTS12.0%

TOTAL100.0%

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)*]

For Dogs and Puppies Weighing:	Net Contents (Each tube)
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

EPA Est. No. 2596-NJ-1

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 reuse or refill 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® 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:]

- Phenothrin85.7%
- (S) – Methoprene2.3%

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

EPA Est. No. 2596-NJ-1

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)

(Plus) Kills (keeps killing) pre-adult flea stages (too)

(Plus) Kills (fleas) (and) (&) (ticks) and pre-adult fleas (before they grow into biting adults)

(Plus) halts the flea life cycle by killing flea eggs (and flea larvae)

(Plus) Prevents Fleas Eggs (and flea larvae) from hatching [for (one month) (30 days) (4 weeks)]

(Plus) Kills (flea eggs) (and flea larvae) before they (can) hatch

A single female flea can lay (and average of) 25 eggs per day (on average)

Controls flea (and) (&) tick infestations (on dogs)

Flea (and)(&) tick control

(Plus) kills (adult ticks) (larvae) (and) (&) (nymphs)

Kills (pre-adult) ticks

(Plus) kills (adult ticks) (larvae) (and) (&) (nymphs)

Kills (pre-adult) ticks

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]

(Why use Hartz® Ref. 118 (this product)(alternate name brand)?) Why is it important to kill flea eggs and flea larvae? Once you see fleas on your pet, there is already an infestation of pre-adult flea stages in your home.

Hartz® Ref. 118 (this product) (alternate brand name) is a monthly treatment that controls flea and tick infestations.

Hartz® Ref. 118 (alternate brand name) contains [(both) (an insecticide to kill adult fleas and ticks) (and mosquitoes) and an insect growth regulator (IGR) to kill flea eggs before

9/11

they hatch]

Once fleas are apparent on your pet, there is already an infestation of their pre-adult stages in your home. Hartz® Ref. 118 (this product) (alternate brand name) is designed to kill both the adult flea (and adult mosquito) and flea eggs and flea larvae, thereby breaking the flea (and adult mosquito) life cycle.]

Hartz® Ref. 118 (this product) (alternate brand name) kills the adult flea, (and) its eggs and larvae, thereby breaking the flea life cycle.

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

(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)

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)

1st dose, 2nd dose, 3rd dose (Xth 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

10
11

Hartz® Reference No. 118

10/12/09

EPA Reg. No.: 2596-150

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

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.)