

2596-137

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Robert Rosenwasser
Product Registration
The Hartz Mountain Corp.
400 Plaza Drive
Secaucus, NJ 07094-3688

SEP 26 2008

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request Alternate Brand Name(s)

- "Hartz Control Pet Care System® One Spot Repellent for Dogs"
- "Hartz® Control Pet Care System ®Once Flea & Tick Treatment for Dogs and Puppies Under 30 lbs."
- "Hartz ®Control Pet Care Systems ®Once Flea & Tick Treatment for Dogs and Puppies Over 30 lbs."
- "Hartz UltraGuard ®IV Flea & Tick Drops for [Dogs (&) (Puppies) (Weighing Under 30 lbs.)"]
- "Hartz UltraGuard® IV Flea & Tick Drops for [Dogs (&) (Puppies) (Weighing Over 30 lbs.)"]
- "Hartz ®UltraGuard Basic™ Flea & Tick Drops [for Dogs (&) (Puppies) (Weighing Under 30 lbs.)"]
- "Hartz ®UltraGuard Basic™ Flea & Tick Drops [for Dogs (&) (Puppies) (Weighing Over 30 lbs.)"]
- "Hartz® Advanced Care® Once Flea & Tick Treatment for Dogs & Puppies"

EPA Reg. No. 2596-137
Application Dated July 17 2008

Dear Mr. Rosenwasser:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 07/17/08 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.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,



Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

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Use read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



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 2596-137	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ One Spot Repellent for Dogs	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. NOTIFICATION Product Name SEP 26 2008	

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 optional marketing statements 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 of 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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
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 checked="" 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 Robert Rosenwasser	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) 201-271-4800 ext. 7202
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 Director, Regulatory Affairs	
4. Typed Name Robert Rosenwasser	5. Date 7/17/08	



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

July 17, 2008

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: HARTZ One Spot Repellent for Dogs
EPA Reg. No. 2596-137
Addition of alternate brand names and optional marketing
statements 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 new alternate brand names and optional marketing statements for the product.

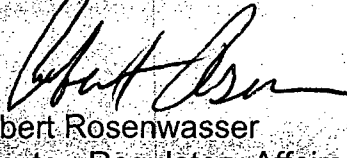
The Hartz Mountain Corporation is submitting the following information:

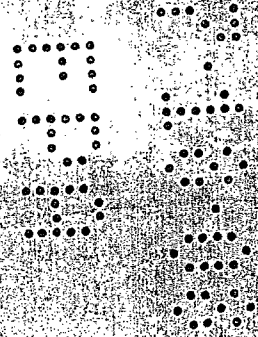
- A completed application (EPA Form 8570-1) and;
- Three copies of the proposed notification label.

"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. 7202 or mailto:rosenwasser@hartz.com

Sincerely,


Robert Rosenwasser
Director, Regulatory Affairs



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Hartz® One Spot Repellent for Dogs

7/17/08

EPA Reg. No.: 2596-137

MASTER LABEL BASED ON 2/20/07 EPA STAMPED APPROVED LABEL

Hartz® One Spot Repellent for Dogs

Alternate Brand Names

Hartz Control Pet Care System® One Spot Repellent for Dogs

Hartz® Control Pet Care System® Once Flea & Tick Treatment for Dogs and Puppies Under 30 lbs.

Hartz® Control Pet Care System® Once Flea & Tick Treatment for Dogs and Puppies Over 30 lbs.

Hartz UltraGuard® IV Flea & Tick Drops [for Dogs (& (and) Puppies) (Weighing under 30 lbs.)]

Hartz UltraGuard® IV Flea & Tick Drops [for Dogs (& (and) Puppies) (Weighing over 30 lbs.)]

Hartz® UltraGuard Basic™ Flea & Tick Drops [for Dogs (& (and) Puppies) (Weighing under 30 lbs.)]

Hartz® UltraGuard Basic™ Flea & Tick Drops [for Dogs (& (and) Puppies) (Weighing over 30 lbs.)]

Hartz® Advanced Care® Once Flea & Tick Treatment for Dogs and Puppies

IMPORTANT: USE ONLY ON DOGS OVER 6 MONTHS OF AGE

DO NOT USE ON CATS



NOTIFICATION

SEP 26 2008

ACTIVE INGREDIENT:

Permethrin 45.0%

OTHER INGREDIENTS:..... 55.0%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

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

NET CONTENTS: X tubes, XX fl. oz. (X cc) each XX fl. oz. (X cc) total]

EPA Reg. No. 2596-137

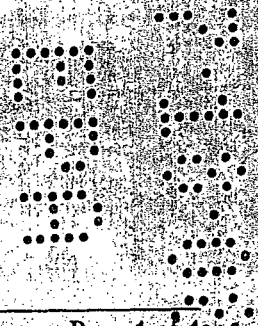
EPA Est. No. 2596-NJ-1

[(Made in (the) U.S.A (by)]

©The Hartz Mountain Corporation

400 Plaza Drive

Secaucus, NJ 07094 (U.S.A.)



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Hartz® One Spot Repellent for Dogs

7/17/08

EPA Reg. No.: 2596-137

MASTER LABEL BASED ON 2/20/07 EPA STAMPED APPROVED LABEL

READ ENTIRE LABEL BEFORE (EACH) USE

USE ONLY ON DOGS AND PUPPIES OVER 6 MONTHS OF AGE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS

CAUTION: DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. Cats which actively groom or come in close physical contact with treated dogs may be at risk of toxic exposure. Do not use on puppies less than 6 months old. Do not use this product in households with both dogs and cats. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity, such as slight transient irritation or hair loss 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 and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and other aquatic organisms.

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. • 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.

DO NOT USE ON CATS. May be toxic or potentially fatal if applied to or ingested by cats.

Directions Option 1 (for use on any size package)

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

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.) [(reapply) every 30 days if necessary.]

Directions Option 2 (for use on packages intended for those up to 30 lbs)

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

(This product is packaged in single dosage ampules. One ampule (1 cc) is the correct dosage for a small dog.) (This product contains an ampule inside a vial.) Point tip (of ampule) up and away

Hartz® One Spot Repellent for Dogs

7/17/08

EPA Reg. No.: 2596-137

MASTER LABEL BASED ON 2/20/07 EPA STAMPED APPROVED LABEL

from your face. Squeeze the middle of the tube to break the ampule. Position (Press) the tip of the tube on the dog's back between the shoulder blades and squeeze tube (to apply entire contents of the ampule (1 cc) to the animal) (to push the entire contents of the ampule (1 cc) through tip of the tube onto the animal). (Repeat every month.) [(reapply) every 30 days if necessary.]

Directions Option 3 (for use on packages intended for dogs over 30 lbs.

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

(This product is packaged in single dosage ampules. One ampule is the correct dosage for a large dog.) (This product contains an ampule inside a vial.) Point the tip (of the entire vial) up and away from your face. Squeeze the middle of the tube to break the ampule. Position (Press) the tip of the tube on the dog's back between the shoulder blades and squeeze the tube to apply the contents from the ampule to the dog until the contents level reaches the ¼ mark indicated on the tube. Invert the vial upright (tip pointing up) and go to the dog's tail. Position the tip of the tube at the base of the tail and apply the remaining contents of the tube to the base of the dog's tail. (Repeat every month.) [(reapply) every 30 days if necessary.]

Directions Option 4 (use in warehouse club packaging. This product contains 6 monthly dosages, each 1 cc)

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

For Dogs Over 30 lbs. Remove one applicator tube from the package and hold in an upright position. Pull off cap. Turn the cap around and place on top of tube. [press (twist) cap (down) to break the seal of tube.] (Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.) (Hold bottom of tube with one hand. With other hand, snap cap off) Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades and squeeze out the contents (of the tube) (from the tube to the dog). Remove second applicator tube from package and hold in an upright position. Pull off cap. Turn the cap around and place on top of tube. [press (twist) cap (down) to break the seal of tube.] (Hold bottom of tube with one hand. With other hand, remove cap and snap off tip.) (Hold bottom of tube with one hand. With other hand, snap cap off) Remove cap carefully. Invert the applicator tube upright and to to the dog's tail. Position the tip of the tube at the base of the tail and apply the contents of the tube to the base of the dog's tail. (Repeat every month.) (Repeat every 30 days if necessary.)

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal. Store in a cool, dry place. If empty. Do not re-use empty tube. Wrap and discard in trash.

OPTIONAL/ALTERNATE LABEL TEXT

Kills and repels the Deer tick, (which may carry Lyme disease) (a vector of Lyme disease)

Apply to one spot for (head to tail) (total body) flea and tick protection (control)

Kills fleas before they lay eggs

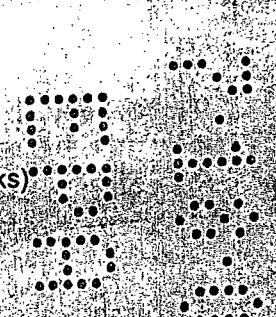
Kills fleas

Kills Ticks

Controls (Kills) (and) (Repels) fleas and ticks for up to 30 days (1 month) (4 weeks)

Kills and repels ticks (the American dog tick) (Brown dog tick)

(Lasts)(Works)(Protects) for 30 days (1 month)(4 weeks)



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Hartz® One Spot Repellent for Dogs

7/17/08

EPA Reg. No.: 2596-137

MASTER LABEL BASED ON 2/20/07 EPA STAMPED APPROVED LABEL

90% control of fleas and ticks in 48 hours (2 days)

Repels 95% of ticks within 3 days (72 hours)

Repels 90% of fleas within 3 days (72 hours)

Prevents re-infestation for 1 month (30 days)(4 weeks)

Hartz® (Control Pet Care System) products are designed to com each other in an integrated program for flea and tick management. We recommend use of Hartz (Control Pet Care System) products.

[with all flea and tick products, they are] [Spot] (this product) (alternate brand name) (is)] most effective when used as part of a total program aimed at reducing fleas and ticks in the dog's environment.

Be sure to treat the animal's bedding and surroundings with product registered for these uses, such as [the Hartz® (Control Pet Care System) line.]

Be sure to read the frill directions and precautions on the label of each product you use. Rabon® is a registered trademark for tetrachlorvinphos

vIGRen® is a registered trademark of Wellmark International

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Value Pack

3 (6) (11) (12) month supply

First (Second) (Third) Month

X Monthly Treatments

This product contains three monthly dosages, each (X fl. oz) (0.65) (1) (2) (3) (cc)(ml)

For Dogs and Puppies Over 30 lbs.

For Dogs and Puppies Up to 30 lbs.

(Convenient) (Easy) to use applicator

Easy (Simple) to use (handle) (apply)

Easy and convenient to use

No-mess

Disposable applicator

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

Apply to one spot—spreads over the dog's complete body (from head to tail) through the natural motion of the animal

Hartz Every Pet's Best Friend™

VISIT [OUR WEBSITE]

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

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