

2596-147

6-26-2007

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUN 26 2007

Robert Rosenwasser
Director, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

SUBJECT: Application for Pesticide Notification – Addition of Optional Marketing Statements
Hartz® Ref #114
EPA Reg. No. 2596-147
Application Dated June 5, 2007

Dear Mr. Rosenwasser:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 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 actions 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 contact me directly at 703-305-6249 or Terri Stowe of my staff at 703-305-6117.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

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



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

June 5, 2007

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

NOTIFICATION

JUN 26 2007

Attention: Mr. Richard Gebken (PM # 10)
RE: HARTZ REF #114
EPA Reg. No. 2596-147
Addition of 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 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

cc: [illegible]



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United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-147	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ REF #114	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 JUN 26 2007
<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 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 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	If "Yes" Unit Packaging wgt. No. per 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" Package 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 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 both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Director, Regulatory Affairs	
4. Typed Name Robert Rosenwasser	5. Date 6/5/07	

NOTIFICATION

Hartz® Ref. 114

JUN 26 2007

Alternate Brand Names

- Hartz® Advanced Care™ OneSpot® Flea Egg and Larvae Treatment for Cats and Kittens
- Control Pet Care System® OneSpot® Flea Egg and Larvae Treatment for Cats and Kittens
- Hartz® Control Pet Care System® OneSpot® Flea Egg and Larvae Treatment for Cats and Kittens
- Hartz® Advanced Care™ 2 in 1 Drops for Cats and Kittens
- Hartz® Advanced Care™ 4 in 1 Drops for Cats and Kittens
- Hartz® OneSpot® Flea Egg and Larvae Treatment
- Hartz® OneSpot® Flea Egg and Larvae Treatment for Cats and Kittens
- Hartz® UltraGuard™ OneSpot® Flea Egg and Larvae Treatment for Cats (&) (and) Kittens
- Hartz® UltraGuard™ OneSpot® Treatment for Cats (&) (and) Kittens

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6).....	2.9%
OTHER INGREDIENTS	97.1%
(TOTAL)	100.0%

Note: CAS numbers may or may not be included in ingredient statement

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for (ingredients and) additional precautionary statements.
See (side) (back) panel for ingredients and additional precautions

Net Contents: Note: Multiple packages containing from 1 tube to 150 tubes – each tube contains 0.03 fl. oz. (1-ee) (1 ml)

EPA Reg. No. 2596-147
EPA Est. No. 2596-NJ-1

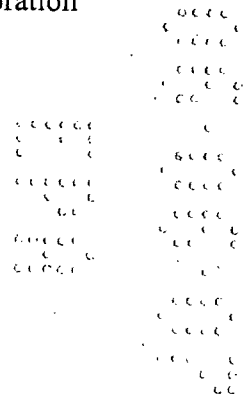
Hartz® and other trademarks are trademarks of the Hartz Mountain Corporation

Made (in the USA) by

©The Hartz Mountain Corporation

Secaucus, NJ 07094

(1-800-275-1414)



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: Do not use on kittens less than twelve weeks old. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity 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.

FIRST AID	
Have label with you when obtaining treatment advice.	
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, doctor, or 1-800-275-1414 immediately for treatment advice.

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON CATS OR KITTENS OVER 12 WEEKS OF AGE.

DIRECTIONS FOR USE

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

This product contains three monthly doses (dosages) (one monthly dose), each 0.03 fl. oz. (1 cc) (1 ml).

1. Use ONLY on cats or kittens over 12 weeks of age. DO NOT USE ON OTHER ANIMALS.
2. Remove one applicator tube from package and hold in an upright position.
3. (Simply press cap down to break the seal of tube.) [Hold bottom of tube with one hand. With other hand, (snap cap off) (remove cap and snap off tip)]
4. Remove cap carefully. {Position the tip of the tube on the cat's back between the shoulder blades and squeeze out [the (entire) contents] [(approximately) half the contents] of the tube}}
5. Repeat every month. (Repeat every 30 days if necessary.)

To see a (visual) demonstration of this application, visit our website at www.hartz.com

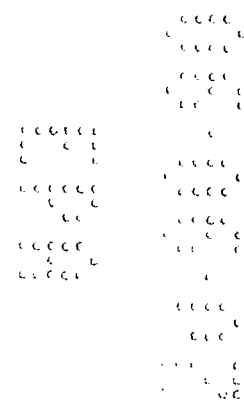
Alternate packaging directions:

Use ONLY on cats or kittens over 12 weeks of age. Remove one applicator tube from package and hold in an upright position. Simply press (twist) cap down to break the seal of tube. (Hold bottom of tube with one hand. With other hand, snap cap off.) Remove cap carefully. Position the tip of the tube on the cat's back between the shoulder blades and squeeze out (the entire contents) [(approximately) half the contents] of the tube. 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 this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800 CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information (or) (in case of emergency) (help at any step) call our flea and tick experts at (telephone number), (time) [1-800-275-1414 weekdays, 9am-5pm (E.S.T.) (Eastern Time)]



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OPTIONAL/ALTERNATE LABEL TEXT

Actively kills (flea eggs) (&) (and) (larvae) for up to 30 days
Starts working on contact
Powerful results when you need it
Clean fresh scent

[All bolded text below represents one label statement with any selected line bulleted.]

When your cat has fleas, your family and pet may be exposed to:

- (Fleas that may cause)**
- Flea allergy dermatitis**
- Flea bite anemia**
- Tapeworm infestation**

To learn more about treating current infestations and preventing future outbreaks please visit our website www.hartz.com

To learn more visit www.hartz.com

Hartz recommends that you visit your veterinarian twice a year.

Be sure to read full directions and precautions on the label of every product you use.

Special formula for cats

Specially formulated for cats

For cats and kittens

Flea egg and larvae treatment

Kills and prevents flea eggs (and) (&) larvae (for up to 30 days)

3 Months Protection, first month, second month, third month

~~X-monthly treatments~~

~~X-Pack~~

~~X-Tubes~~

Advanced flea egg and larvae topical treatment that's easy and convenient to use

Prevents flea eggs (from hatching) (for 30 days) (1 month) (4 weeks)

Kills flea eggs before they hatch

Kills flea eggs and larvae for 30 days

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

Kills flea eggs (and larvae)

Kills hatching eggs

Contains an insect growth regulator

Stops the flea life cycle

Controls (Kills) (Repels)(Lasts) (Works)(Protects) (Eliminates) up to 30 days (1 month) (4 weeks)

Apply to one spot for (total body) flea protection (control)

One tube gives 30 days protection

Flea control for cats with (PRECOR®) (vIGRen®) Insect Growth Regulator (IGR)

(S) – Methoprene (CAS # 65733-16-6)

Advanced flea (egg and larvae) treatment

Hartz® Ref. 114 (alternate name) provides relief from flea populations on cats and kittens by controlling and preventing flea eggs and larvae.

OPTIONAL/ALTERNATE LABEL TEXT (con't)

The Hartz® Ref. 114 (alternate name) contains [an insect growth regulator (IGR) to kill flea eggs before they hatch.] [a long lasting insect growth regulator which prevents flea eggs and larvae from maturing into adults.]

Adult fleas spend virtually all of their time on your pet, but they produce vast numbers of eggs which drop off the pet and develop in the environment.

Once fleas are apparent on your pet, there is already an infestation of their pre-adult stages in your home.

Hartz Ref. 114 (alternate name) is designed to kill flea eggs and larvae, thereby breaking the flea life cycle.

As with all flea products, (they are) (Hartz Ref. 114 is) (alternate name is) most effective when used as part of a total program aimed at reducing fleas in the cat's environment.

Be sure to treat the animal's bedding and surroundings with products registered for these uses.

Hartz Ref. 114 (alternate name) provides relief from flea infestations for one month by controlling and preventing flea eggs and larvae on your cat and kitten.

Hartz Ref. 114 (alternate name) kills flea eggs and larvae, thereby breaking the flea life cycle.

After application, through its natural movement, your cat's skin and hair oils carry Hartz Ref. 114 (alternate name) over the pet's body for protection against flea eggs and larvae.

To kill existing (eggs and larvae) (and kill) (adult flea populations), you may need to treat the (your) (pet), home, pet's bed and yard with traditional flea products approved for use on pets, around the home, or in your yard (such as home sprays, foggers and/or yard and kennel spray).

Hartz Ref. 114 (alternate name) can be used in conjunction with the entire Control Pet Care System (alternate name) product line.

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

3 Month supply, 1st dose, 2nd dose, 3rd dose

Triple pack

Convenient, easy to use applicator

Easy (simple) to use (handle) (apply)

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

DO NOT spread across cat/kitten fur and/or skin.

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

No mess

Disposable applicator

Satisfaction guaranteed

Money back guarantee

Guaranteed to work (or your money back)

If not completely satisfied, return unused portion for a full refund

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

Hartz® Every Pet's Best Friend™

VISIT OUR WEBSITE

www.hartz.com

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