

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

June 17, 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

Dear Ms. Masch:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 98-10 dated May 5, 2010 for the following product(s):

HARTZ Reference 119

EPA Reg. No. 2596-151

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 <u>nonrefillable</u> 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,

Richard J. Gebken Product Manager

Insecticide Branch

Registration Division (7505P)

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oires 2-28-95	

Please read instructions (on re	verse before comple	ung torm.			Form Apr	9400	./ OMB N	o. 2070)-00 gc). Approvel expires 2-28-9
O FDA United States							Regist	tratio	n	OPP Identifier Number	
Environmental Protection Age				ncy			Amen	dmer	nt		
Washington, DC 20460			460			V	Other				
Application for Pesticide - Section I											
1. Company/Product Num	ber			<u> </u>	1	roduct Man		1. Lu		3. Pro	posed Classification
2596-151				R Gebken					None Restricted		
4. Company/Product (Nar					PM#						
HARTZ Reference 119			10								
5. Name and Address of Applicant (Include ZIP Code)			6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling								
The Hartz Mountaii 400 Plaza Drive	n C	orporation		to: NOTIFICATION							
Secaucus, NJ 0709	94-3	3688			EPA Reg. No.						
		is a new address		Product Name JUN 1 7 2010							
				Sec	tion - II						
Amendment - Exp	lain I	below.			ſĵ	Final printed	l label	ls in repso	nse to	······································	
·						Agency lett	er dat	ed			
Kesubmission in re	espo	inse to Agency letter	dated	· · · · · · · · · · · · · · · · · · ·	- 🔲	"Me Too" A	Applica	ation.			
✓ Notification - Expl.	ain b	elow.				Other - Expl	lain be	elow.			
Explanation: Use addi	tione	al page(s) if necessar	y. (For section	on I and Se	ction II.)						
"Addition of new EPA Est	. No.	per PR Notice 98-10"	•								
"This notice is consistent	with	the provisions of PR N	Notices 98-10 a	and EPA re	gulations a	t 40 CFR 152	2.46, a	ind no othe	er chang	es hav	ve been made to the
labeling or the Confidentia to EPA. I further understa	al Sta	atement of Formula of	this product. I	understand	that it is a	violation of 1	18 U.S	i.C. Sec. 10	001 to w	rillfully s.nrode	make any false statement
FIFRA and I may be subje									2.10, 17.	o prod.	
				Sect	ion - II						
1. Material This Product	$\neg \tau$		· · · · · · · · · · · · · · · · · · ·					·r			
r 1	Child-Resistant Packaging Unit Packaging						of Container				
Yes		Yes		Yes				Metal Plastic			
No No				No				Glass			
* Certification must If "Yes" No. per Unit Packaging wgt. container			No. per . container	If "Yes" No. per Package wgt container			Paper Other (Specify)				
be submitted											
3. Location of Net Conter	nts Ir	nformation	4. Size(s) Re	tail Contai	ner		5. Lo	cation of l	Label Di	irectio	ns
Label Container											
6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled											
					ion - IV	/	•				
1. Contact Point (Comple	ete i	tems directly below I	for identificati				if nec	essary, to	proces.	s this	application.)
Name				Title		· 	4		Tele	phone	No. (Include Area Code)
Heather Masch			Regulatory Affairs Associate				201	-271-4	800, ext. 7036		
Certificati			ation	tion					ĺ	6. Date Application	
I certify that the statements I have made on this form and al			d all attach	all attachments thereto are true, accurate and complete.				3)) 3.3	Řepoliveo)		
l acknowledge that any knowlinglly false or misleading state both under applicable law.			atement may be punishable by tine or imprisonment or عدد د				- 1	(Stamped)			
2. Signature			3 Title				3				
			Regulatory Affairs Associate			- 1	,,,, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
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4. Typed Name				5. Date))))) ;)		
Heather Masch				5/5/10				l	زروو		



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

May 5, 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: Hartz Ref 119 EPA Reg. No. 2596-151

Addition of 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 a new EPA Est. No. for the product **Hartz Ref 119, EPA Reg. No. 2596-151**.

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.

Sincerely,

Heather Masch

Regulatory Affairs Associate

11/9/09

Hartz[®] Reference 119 EPA Reg. No.: 2596-151

MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

Hartz® Reference 119

NOTIFICATION

Alternate Brand Names

JUN 17 2010

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

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

Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (16 to 30 lbs.)

Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (31 to 60 lbs.)

Hartz® InControl® Flea & Tick Topical Drops for Dogs (&) (and) (Puppies) (Weighing) (over 60 lbs)

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

Hartz[®] UltraGuard[™] Flea (&) (and) Tick Drops for Dogs [for Dogs (&) (and) (Puppies) (Weighing) 4 to 15 lbs.)]

Hartz[®] UltraGuard[™] Flea (&) (and) Tick Drops for Dogs [for Dogs (&) (and) (Puppies) (Weighing) 16 to 30 lbs.)]

Hartz[®] UltraGuard[™] Flea (&) (and) Tick Drops for Dogs [for Dogs (&) (and) (Puppies) (Weighing) 31 to 60 lbs.)]

Hartz[®] UltraGuard[™] Flea (&) (and) Tick Drops for Dogs [for Dogs [(&) (and) Puppies (Weighing) Over 60 lbs.)]

ACTIVE INGREDIENT

Phenothrin	85.7%
OTHER INGREDIENTS	14.3%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back 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. 2596-151

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Hartz[®] Reference 119 EPA Reg. No.: 2596-151

MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

EPA Est. No. 2596-NJ-01 = BL 2596-OH-01 = PP See lot# for EPA Est. No.

[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. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. 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 and rinse with large amounts of water. If signs continue, 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 charging 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

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Hartz[®] Reference 119 EPA Reg. No.: 2596-151

MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

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.

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 sold 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 Topical Drops for Dogs (&) (and) (Puppies)
Hartz® UltraGuard™ Flea (&) (and) Tick Drops for Dogs (&) (and) (Puppies)

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

KEEP OUT OF REACH OF CHILDREN

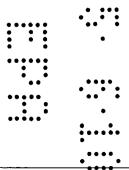
CAUTION: Read accompanying label before use.

[Active Ingredient:]	
Phenothrin	85 7%

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

EPA Reg. No. 2596-151 EPA Est. No. 2596-NJ-01 = BL 2596-OH-01 = PP See lot # for EPA Est. No.

The Hartz Mountain Corp.



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Hartz[®] Reference 119 EPA Reg. No.: 2596-151

MASTER LABEL BASED ON 9/6/07 EPA STAMPED APPROVED LABEL

OPTIONAL/ALTERNATE LABEL TEXT

(Kills) (&) (and) (Repels) (Fleas) (&) (and) (Ticks) for (up to) (30 days) (1 month) (4 weeks) Kills (Fleas) (&) (and) (Ticks) (&) (and) (mosquitoes) for (up to) (30 days) (1 month) (4 weeks) Controls (Fleas) (&) (and) (Ticks) (&) (and) (mosquitoes)

Contains an adulticide

Kills adult (Fleas) (&) (and) (Ticks) (&) (and) (mosquitoes)

Kills fleas before they lay eggs

Kills (and) (&) (repels) fleas which may cause (flea bite anemia) (and)(or)(flea allergy dermatitis)

Flea (and) (&) tick topical treatment

(Controls) (kills) (repels) adult fleas (and)(&) ticks (mosquitoes) round-the-clock for up to (30 days)

(1 month) (4 weeks)

Controls (kills) (repels) up to (30 days) (1 month) (4 weeks)

Flea & tick control

Controls flea and tick infestations

Flea tick (and mosquito) control for (dogs) (and) (or) (puppies)

Flea control for dogs



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

For Dogs (&) (and) Puppies weighing over 4 lbs.

For (dogs) (and) (or) puppies) over 12 weeks of age

For (dogs) (and) (or) puppies) over 4 lbs.

Hartz Ref. 119 (alternate name brand) contains (an insecticide to kill adult fleas and ticks) (and mosquitoes) [an insecticide that kills adult fleas and ticks (and mosquitoes)].

(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 a product registered for these uses, such as Hartz® (UltraGuard) (alternate brand name)

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NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Fresh scent X month supply 1st dose, 2nd dose, 3rd dose, Xth dose first month, second month, third month, Xth month X monthly treatments Triple pack Value pack No mess This product (package) contains X monthly doses, each fl. oz. (ml) Hartz (brand name) products are designed to complement each other in an integrated program for flea & tick management. To assure proper treatment, we recommend use of (only) Hartz (Brand name) products After application, the treated area may appear wet or oily for up to 24 hours. (As with all flea and tick products, they are)[Hartz Ref. 119 (alternate name brand) is] most effective when used as a part of a total program aimed at reducing fleas and ticks (and mosquitoes) in the (dog's) (and) (or) (puppy's) environment. Be sure to treat the animal's bedding and surroundings with products registered for these uses, such as the Hartz (alternate name brand) Line. Adult fleas spend virtually all of their time on your pet. Once fleas are (apparent) (visible) on your pet, there is already an infestation of their pre-adult stages in your home. Spreads naturally with (dog's) movement (skin and hair oils) Initially, to kill existing adult flea populations, you may need to treat the home, pet's bed and yard with traditional flea products such as home sprays, foggers, and/or yard & kennel sprays. Hartz Ref. 119 (alternate name brand) can be used in conjunction with the entire (brand name) product line. Wait 48 hours after applying before bathing your dog. Do not bathe your cat for 48 hours after application. May stain leather and suede fabrics for (24)(24 to 48) hours after application

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Hartz[®] Reference 119 EPA Reg. No.: 2596-151

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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:

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

VISIT (OUR) (WEBSITE) (www.hartz.com)(www.hartzincontrol.com)

Hartz recommends that you visit your veterinarian twice a year.

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