

2596-151

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

JAN 13 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Robert Rosenwasser
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Dear Mr. Rosenwasser:

Subject: Hartz Ref 119
EPA Reg. No. 2596-151
Submission dated 1/9/09

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

In accordance with PR Notice 2007-4, add the following statement to the Storage and Disposal statements:

Container disposal: Nonrefillable container. Do not refill or reuse this container.

In accordance with PR Notice 2007-4, the label must bear a batch code.

To avoid misuse, the product names on the tubes must match the names on the outer box.

The following statements are required to be on the front panel. They may not be displaced by marketing claims.

- Product name
- Ingredient Statement
- Keep out of Reach of Children
- Signal Word
- Net Contents

Delete all life cycle claims. Life cycle claims are related to insect growth regulators, and this product does not contain an IGR.

Delete the following claims, which require you to submit or cite efficacy data:

(Kills) (&) (and) (Repels) (Fleas) (&) (and) (Ticks) through contact for (up to) (30 days) (1 month) (4 weeks)
 Kills (Fleas) (&) (and) (Ticks) (&) (and) (mosquitoes) through contact for (up to) (30 days) (1 month) (4 weeks)
 (Starts killing) (fleas) (&) (and) (ticks) (and) (&) (mosquitoes) (through contact)
 (Starts to kill) (fleas) (&) (and) (ticks) (and) (&) (mosquitoes) (through contact)
 Controls...mosquitoes
 Kills (and) (&) (repels) fleas that may transmit tapeworm infestation
 Water Resistant

Delete the following enhanced efficacy claims:

One tube gives (provides) (30 days)(4 weeks)(one month of) protection
 Controls (kills) (repels) up to (30 days) (1 month) (4 weeks)
 This formula kills and prevents adult fleas, ticks, and mosquitoes.
 Hartz Ref. 119 (alternate brand name) provides relief from flea infestations for one month by controlling (killing) and preventing adult fleas on your (dog) (and) (puppy).
 (30 days) (1 month) Protection
 (Provides)(X Months)(X Days)(X Weeks) Protection
 Apply as a stripe from head to tail (total body) flea and tick (and mosquito) protection (control)
 spreads over the dog's complete body
 for protection against fleas (and) ticks, (and)(mosquitoes).
 Immediately the (dog's) (and) (or) (puppy's) skin and hair oils will begin to carry this solution over the (dog's) (and) (or) (puppy's) entire body, killing fleas (and) ticks, (and)(mosquitoes).
 Prevents re-infestation for (30 days) (1 month) (4 weeks)

Delete the following implied safety claims:

(Baby) Fresh
 (Baby) Powder
 (baby) fresh
 (Baby) Clean
 Traditional flea products

Delete the following claim which contradicts the package sizes:

For Dogs (and) Puppies (weighing) (4-15 lbs) (4-30 lbs) (16 - 30 lbs.) (31 - 45 lbs.) (46-60 lbs.) (61 - 90 lbs.) (over 90 lbs.)

Delete the following comparative claims:

Special formula for dogs
 Specially formulated for dogs
 Advanced Care™
 Special formula for (dogs) (and) (or) (puppies)
 Specially formulated for (dogs) (and) (or) (puppies)

Delete the following claims which detract from the precautionary statements and directions for use:

- Convenient (easy to use) applicator
- Easy (simple) to use (handle) (apply)
- Topical treatment that's easy and convenient to use

Delete the following claim which is false and misleading as fleas on average lay 25 eggs. They produce vast numbers of eggs that drop off the pet and develop in the environment.

Delete the following claims, which refer to ingredients not contained in this product:

- Rabon® is a registered trademark for tetrachlorvinphos
- vIGRen® is a registered trademark of Wellmark Intl.

Move the following claims to a section entitled "Use Restrictions" in the Directions for Use, and delete the statement "for best results"

- ~~(For best results)~~ wait 48 hours after applying before bathing your dog.
- ~~(For best results)~~ do not bathe your cat for 48 hours after application.
- Water Resistant
- May stain leather and suede fabrics for (24)(24 to 48) hours after application.

Delete the following claim or modify it to refer user to the Storage and Disposal section of the label:

- Disposable applicator

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance. As an alternative, you may refer consumers to the company's phone number or e:mail address.

Acceptance of this label does not constitute approval of claims appearing on this label that are made for other Hartz products. Label claims for other Hartz products must be qualified by a statement referring the user to the labels for those products.

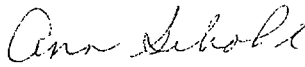
Changes in package size must be submitted as an amendment and not as a notification, as they may affect both efficacy and margins of exposure for the treated dog.

Please note that a notice of availability of EPA's reregistration eligibility document (RED) for products containing phenothrin was published in the Federal Register on March 14, 2008.

Additional data and/or labeling changes may be required for products containing phenothrin. For more information, see the following website:
<http://www.epa.gov/pesticides/reregistration/status.htm>.

If you have questions, please call Richard Gebken at 703 305-6701.

Sincerely,


for Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505P)

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Hartz® Reference 119

1/9/09

EPA Reg. No.: 2596-151

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

Hartz® Reference 119

Alternate Brand Names

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

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.)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 13 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2596-151

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 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.

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.

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Hartz® Reference 119

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

INDIVIDUAL TUBE TEXT

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-1

The Hartz Mountain Corp.

OPTIONAL/ALTERNATE LABEL TEXT

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

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

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

(Starts killing) (fleas) (&) (and) (ticks) (and) (&) (mosquitoes) (through contact)

(Starts to kill) (fleas) (&) (and) (ticks) (and) (&) (mosquitoes) (through contact)

Controls (Fleas) (&) (and) (Ticks) (&) (and) (mosquitoes)

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

Contains an adulticide

Stops (Flea) (&) (and) (Tick) (&) (and) (mosquito) life cycle by killing the adult form of these pests

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

Kills (pre-adult) ticks

Kills fleas before they lay eggs

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

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

Kills (and) (&) (repels) fleas that may transmit tapeworm infestation

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

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

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]

Hartz Ref. 119 (alternate brand name) is the monthly treatment that controls flea & tick infestations. This formula kills and prevents adult fleas, ticks, and mosquitoes. (It also repels and kills mosquitoes.)

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

Hartz Ref. 119 (alternate brand name) provides relief from flea infestations for one month by controlling (killing) and preventing adult fleas on your (dog) (and) (puppy).

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

For Dogs (and) Puppies (weighing) (4-15 lbs) (4-30 lbs) (16 - 30 lbs.) (31 - 45 lbs.) (46-60 lbs.) (61 - 90 lbs.) (over 90 lbs.)

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

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

~~Special formula for dogs~~

~~Specially formulated for dogs~~

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)

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

~~(30 days) (1 month) Protection~~

Fresh scent

~~(Provides)(X Months)(X Days)(X Weeks) Protection~~

~~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

Advanced Care™

(Baby) Fresh (scent) (fragrance)

(Baby) Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

(baby) fresh (scent) (fragrance)

(Baby) Clean (scent) (fragrance)

Convenient (easy to use) applicator

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

Topical treatment that's easy and convenient to use

Disposable applicator

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

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

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. They produce vast numbers of eggs that drop off the pet and develop in the environment.

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

Apply as a stripe from head to tail (total body) flea and tick (and mosquito) protection (control)
Apply as a stripe - spreads over the dog's complete body from head to tail through the natural motion of the animal
Spreads naturally with (dog's) movement (skin and hair oils)
Special formula for (dogs) (and) (or) (puppies)
Specially formulated for (dogs) (and) (or) (puppies)

After application, through its natural movement, your pet's skin and hair oils carry Hartz Ref. 119 (alternate name brand) over the pet's body for protection against fleas (and) ticks, (and)(mosquitoes).

Immediately the (dog's) (and) (or) (puppy's) skin and hair oils will begin to carry this solution over the (dog's) (and) (or) (puppy's) entire body, killing fleas (and) ticks, (and)(mosquitoes).

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.

(For best results) wait 48 hours after applying before bathing your dog.

(For best results) do not bathe your cat for 48 hours after application.

Water Resistant

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® Reference 119

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EPA Reg. No.: 2596-151

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

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

Rabon® is a registered trademark for tetrachlorvinphos

vIGRen® is a registered trademark of Wellmark Intl.

VISIT (OUR) (WEBSITE)

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

Hartz recommends that you visit your veterinarian twice a year.

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