



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 12, 2014

Mr. David Jones
Manager, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Subject: Amended Labeling; Label Review for Incorporation of Required Dog Spot-On Mitigation Hartz® Reference #119, EPA Reg. No. 2596-151

Dear Mr. Jones:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

Amendments to Dog Spot-On Product Registrations:

1. **This registration is now time-limited, and will expire 2 years from the date of this letter. More specifically, this registration will expire on March 12, 2016.**
2. If the Agency determines that future mitigation measures are necessary for all pet spot-on products, EPA will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.
3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future. In addition, it is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning July 1, 2014. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (Attn: Kaitlin Keller). The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: Internet, store, veterinarian.
 - Active ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (Standard 2 letter abbreviation)
 - Registrant case #
 - Species: Dog, cat, other (specify).
 - Breed: (As reported by pet owner)
 - Age: Months or years.
 - Sex: M, F, or neutered.
 - Weight: Pounds.

Conditions of Acceptance/Amendments to Dog Spot-On Product Registrations, continued:

- Primary Route of Exposure: Dermal, oral, other animal, inhalation, other.
- Body System: Neurological, dermatological, GI, respiratory, ocular, other.
- Major signs noted with separate column for each sign, using standard terminology.
- Time to Onset: (Hours, days)
- Treated by veterinarian: Yes or No
- First time product used: Yes or No
- Misuse: Use on incorrect species, overdose, too frequent dosing, other (describe).
- Any known pre-condition.
- EPA Severity Code: Death, major, moderate, minor.
- Outcome: Died, recovered, still treated, unknown.

5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported, including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- Summary table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

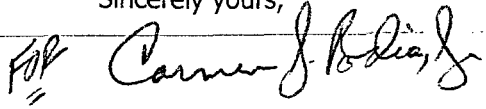
Should you wish to add/retain a reference to the company's website, smart phone/tablet app and/or a QR code reader on your product label, please be aware that the website, smart phone/tablet app and/or a QR code reader becomes labeling under FIFRA and is subject to review by the Agency. If the website, smart phone/tablet app, and/or a QR code reader is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website, smart phone/tablet app, and/or a QR code reader is referenced on a product's label, claims made on the website, smart phone/tablet app, and/or a QR code reader may not be 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, smart phone/tablet app, and/or a QR code reader contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website, smart phone/tablet app, and/or a QR code reader will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Copies of your label stamped "Accepted with Comments" as well as a copy of the review for minimum treated weight that was completed for the referenced product are enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

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Please note that this letter does not supersede anything contained within the Agency's letter dated September 30, 2011. If you have any questions related to this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Carmen J. Rodia". To the left of the signature, there are some initials "RJR" written in a similar style.

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted with Comments," dated March 12, 2014*
Review for Minimum Treatment Weight, dated January 8, 2014

002596-00151 D468743 & D481077

Front Panel

Hartz® Reference 119

Alternate Brand Names

Hartz® InControl® Flea & Tick Topical Drops for Dogs [for Dogs (&) (and) (Puppies)
 (Weighing _ to _ lbs.)]

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

ACCEPTED
 With COMMENTS
 In EPA Letter Dated:
March 12, 2014
 Under the Federal Insecticide, Fungicide
 and Rodenticide Act, As amended, for the
 pesticide Registered under EPA Reg. No:
2596-151

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)*]

Only For Dogs and Puppies Weighing:	Net Contents (Each tube)
5 to 14 lbs.	0.021 fl. oz. (0.65 ml)
14.1 to 30 lbs.	0.043 fl. oz. (1.3 ml)
30.1 to 60 lbs.	0.138 fl. oz. (4.1 ml)
> 60 lbs.	0.199 fl. oz. (5.9 ml)



DO NOT USE ON CATS

[*Cat Warning: A cat prohibition icon will appear on the front panel and back panel.*]

MASTER LABEL BASED ON 1/9/09 EPA STAMPED APPROVED LABEL

Back Panel

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 or using the toilet. Remove and wash contaminated clothing before reuse.

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 highly toxic to fish and 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. • 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.

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS OR PUPPIES 12 WEEKS OF AGE OR OLDER.

DO NOT USE ON DOGS OR PUPPIES WEIGHING UNDER 5 LBS. (*Use on the 5 – 14 lbs. dog and puppy weight range package only*)

DO NOT EXCEED RECOMMENDED DOSAGE AMOUNT FOR DOGS.

DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT

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 dogs back to the base of the tail. Repeat every month.

MASTER LABEL BASED ON 1/9/09 EPA STAMPED APPROVED LABEL

SIDE EFFECTS

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1414.



[Cat Warning: A cat prohibition icon will appear on the back panel.]

DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

EPA Reg. No. 2596-151
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.)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* 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.

MASTER LABEL BASED ON 1/9/09 EPA STAMPED APPROVED LABEL

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 0.021 fl. oz. (0.65 ml) to 0.199 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.

OPTIONAL/ALTERNATE LABEL TEXT

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

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

(Repels) (Fleas) for (up to) (25 days)

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

Kills (Fleas) (&) (and) (Ticks) (&) (and) (mosquitoes) for (up to) (28 days)

Kills (Fleas) (&) (and) (mosquitoes) for (up to) (28 days)

Kills (Ticks) (&) (and) (mosquitoes) for (up to) (28 days)

Kills (Fleas) (&) (and) (Ticks) (&) (and) (mosquitoes) (through contact) for (up to) (28 days)

(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 by ticks for (30 days) (1 month) (4 weeks)

Prevents re-infestation for 30 days

Contains an adulticide

Stops (Flea) (&) (and) (Tick) (&) (and) (mosquito) infestations 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 (or provides) 30 days of protection (fleas) (ticks)

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) (28 days)

Controls (kills) (repels) up to (28 days)

Flea & tick control

Controls flea and tick infestations

Controls (kills) (repels) up to 28 days

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

Flea control for dogs

Only for Dogs (&) (and) Puppies weighing 5 lbs. and over

Only for (dogs) (and) (or) puppies over 12 weeks of age

Only for (dogs) (and) (or) puppies 5 lbs. and over

MASTER LABEL BASED ON 1/9/09 EPA STAMPED APPROVED LABEL

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

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(s).

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.

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: _____

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

Hartz recommends that you visit your veterinarian twice a year.

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Producing establishment will add manufacturing site identifiers, lot codes and other traceability elements to all packages.