



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 23, 2010

Ms. Heather Masch,
Regulatory Affairs Associate
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

**Subject: Amended Labeling, Addition of New Optional Marketing Statements & Revised Text
Hartz® Reference 118, EPA Reg. No. 2596-150
Your Submission Dated March 31, 2010 & E-Mail Re-Submission Dated April 28, 2010**

Dear Ms. Masch:

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 June 23, 2012.**
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 October 1, 2010. 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, Immediate Office (Attn: Kimberly Nesci). 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.

First Aid section comment(s):

6. Replace the last 2 bulleted statements within this section with: **"HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center, doctor or veterinarian, or going for treatment. **For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414."** Please note that the "1-800-275-1414" telephone number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

Directions for Use section comment(s):

7. Add the statements **"READ ENTIRE LABEL BEFORE EACH USE."** and **"USE ONLY ON DOGS OR PUPPIES 12 WEEKS OF AGE OR OLDER."** and **"DO NOT USE ON DOGS OR PUPPIES WEIGHING 4 LBS. OR LESS."** immediately following the statement "It is a violation of ..." These statements must be bolded and capitalized.

Storage and Disposal section comment(s):

8. To facilitate inclusion of language from PR Notice 2007-4, revise this section to read:

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 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.

Optional/Alternate Label Text section comment(s), page 5 of 7:

- 9. Revise the 6th optional/alternate label claim to read "Contains an adulticide and an insect growth regulator."
- 10. Immediately following the last word of the 14th optional/alternate label claim, insert the words "on dogs."
- 11. Within the 18th optional/alternate label claim, replace the word "pet" with the word "dog."

Non-Pesticide Related Claims and Other Optional Text section comment(s), page 6 of 7:

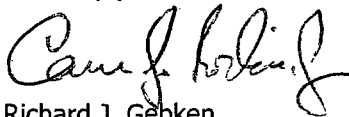
- 12. Within the 3rd, 4th, 5th, 6th, 8th, 9th, 10th and 12th optional/alternate label claims, insert the word "dog's" immediately preceding the word "fur" and delete the word "gentle" or "gently," since it is an implied safety claim that detracts from the precautionary statements listed on this label.
- 13. Within the 18th, 20th and 21st optional/alternate label claims, insert the word "dog's" immediately preceding the word "skin"

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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 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 is referenced on your product's label, claims made on the website 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 contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website 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.

A copy of your label stamped "Accepted with Comments" is 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.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov. If you have any questions about the listed amendments to dog spot-on product registrations, please contact Ms. Kimberly Nesci at (703) 308-8059 or via e-mail at Nesci.Kimberly@epa.gov.

Sincerely yours,

For 

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

Enclosure: *Label stamped "Accepted with Comments"*
002596-00150 D431712

Hartz® Reference No. 118

EPA Reg. No.: 2596-150

MASTER LABEL BASED ON 1/13/09 EPA STAMPED APPROVED LABEL

4/28/2010

ACCEPTED
With COMMENTS
In EPA Letter Dated:

June 23, 2010

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

2596-150

Hartz® Reference 118

Alternate Brand Names

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

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

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

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

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

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

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

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

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

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

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

Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (&) (and) (Puppies) (Weighing > 60 lbs.)

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

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

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

Hartz® UltraGuard Plus™ Flea & Tick Drops for Dogs (&) (and) (Puppies) (Weighing > 60 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing 4 to 15 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing 16 to 30 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing 31 to 60 lbs.)

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies] (Weighing >60 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing 4 to 15 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing 16 to 30 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing 31 to 60 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops with (Pro-cision Flo™ Applicator) for Dogs (&) (and) Puppies (Weighing >60 lbs.)

ACTIVE INGREDIENTS

Phenothrin.....85.7%

(S) – Methoprene.....2.3%

OTHER INGREDIENTS12.0%

TOTAL100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See (back) (side) 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. 2596-150

EPA Est. No. 2596-NJ-1

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

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. Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or on animals known to be sensitive to pesticide products without first consulting a

veterinarian. 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, rinse with large amounts of water, and 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)

[There are 4 closure options for the tube. The first represents the currently used cap. The following 3 closure options are proposed for use with this product.]

[Note: New text for opening ~~new~~ closures (option #1, #2 and #3) is highlighted.]

[Current cap]

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.

[New optional cap #1]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing 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.

[New optional cap #2]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Squeeze the middle of the dispensing tip at the grooved pad to break the inner seal.

Position the dispensing 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.

[New optional cap #3]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about 1/2 turn until you feel it click into place. Push down to break the tube's seal. Do not remove the dispensing tip.

Position the dispensing 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. **Container Disposal:** Nonrefillable container. Do not refill or reuse this container.

INDIVIDUAL TUBE TEXT

Hartz® InControl™ Flea & Tick Drops for Dogs (&) (and) (Puppies)

Hartz® InControl Advanced™ Flea & Tick Drops for Dogs (&) (and) (Puppies)

Hartz® UltraGuard Pro® Flea & Tick Drops for Dogs (&) (and) (Puppies)

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

Hartz® UltraGuard Pro® Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) (Puppies)

Hartz® UltraGuard Plus™ Flea & Tick Drops (with Pro-cision Flo™ Applicator) for Dogs (&) (and) (Puppies)

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

[Active Ingredients:]

Phenothrin85.7%

(S) – Methoprene2.3%

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

[Note: Multiple packages containing from 1 tube to X tubes – each tube contains fl. oz. (__ ml)]

KEEP OUT OF REACH OF CHILDREN

CAUTION:

Read accompanying label before use

EPA Reg. No. 2596-150

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)

Kills (fleas) (ticks) (mosquitoes) (flea eggs) (&) (and) (flea larvae) (for up to 30 days)

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

Starts killing through contact

Flea egg and (&) (flea) larvae treatment

6. Contains an insect growth regulator

Kills hatching flea eggs

Kills mosquitoes

~~Contains an adulticide~~

Flea and tick control

Flea and tick (and mosquito) topical treatment

Kills pre-adult stages of the flea life cycle

Kills all stages of the flea life cycle

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

Prevents mosquitoes from feeding on dogs for up to (one month) (4 weeks)(30 days) (per application)

A single female flea can lay (and average of) 25 eggs per day (on average)

Flea (and)(&) tick control

18. Once fleas are (visible)(apparent) on your pet, there is already an infestation in your home.

For use on dogs and puppies 12 weeks of age or older only

For dogs and puppies at least 12 weeks old

For dogs and puppies over 4 lbs.



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

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

Hartz® UltraGuard (alternate brand name) flea and tick products are most effective when used as part of a total program aimed at reducing fleas and ticks (in the dog's environment)

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Convenient (easy to use) applicator

X Pro-Glide™ Applicator(s)

3. (Now) (featuring the angled) Pro-Glide™ Applicator easily gets through fur, for ~~gentle~~ on-skin application
4. (Now) (featuring the angled) Pro-Glide™ Applicator quickly gets through fur, for on-skin application
5. (Now) (featuring the angled) Pro-Glide™ Applicator easily penetrates fur, for ~~gentle~~ on-skin application
6. (Now) (featuring the angled) Pro-Glide™ Applicator quickly penetrates fur, for on-skin application

New Pro- Glide™ Applicator *(To be used only for the first 6 months)*

8. Pro-Glide™ Applicator ~~gently~~ glides through the fur
9. Pro-Glide™ Applicator easily gets through fur to minimize (oily) residue
10. Pro-Glide™ Applicator easily penetrates fur to minimize (oily) residue
Pro-Glide™ Applicator features rounded edges for ~~gentle~~ on-skin application
11. Pro-Glide™ Applicator glides smoothly through the fur
Pro-Glide™ Applicator features an angled tip to help guide the application
Easy to use Pro-Glide™ Applicator
15. Easy to (use) ~~(handle)~~ (apply)
16. Simple to (use) ~~(handle)~~ (apply)
(Featuring the) (with) Clearview™ tube
18. Passes easily through the coat to the skin.
Glides quickly through coat
20. Applies smoothly on skin
21. Applies directly on skin

(Clearview™) tube (visually) ensures all product has been dispensed

(Clearview™) tubes give you the assurance all the product has been applied

Stops (and) (&) prevents re-infestations

Stops (and) (&) prevents re-infestations for 30 days

Prevents re-infestations

Prevents re-infestations for 30 days

(Patent pending)

(X) Pro-cision Flo™ Applicator(s)

(Pro-cision Flo™ Applicator)(Applicator) for (direct-to-skin) (direct to skin) application

(Pro-cision Flo™ Applicator)(Applicator) for direct application

Pro-cision Flo™ Applicator

Applicator (easily penetrates fur) (coat) for direct application

Applicator (easily penetrates fur) (coat) for application directly to your dog's skin

Direct to your dog's skin

For Dogs and Puppies (weighing) (4-15 lbs.) (16-30 lbs.) (31-60 lbs.) (> 60 lbs.)

This product contains three (four) monthly doses (one monthly dose), each X (fl. oz.) (cc)

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Triple pack

X-pack

X-tubes

Value pack

X monthly treatments

Fresh (scent) (fragrance)

Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

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

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

No mess

Wait 48 hours after applying before bathing your dog.

Do not bathe your dog for 48 hours after application.

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 _____

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VISIT (OUR)(WEBSITE)

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

Hartz recommends that you visit your veterinarian twice a year.

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