

2596-150

4/26/2012

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



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Sean McNear  
Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094

APR 26 2012

Subject: Amended Reregistration Label  
Product Name: Hartz Reference 118  
EPA Registration Number: 2596-150  
EPA Decision Number: 427070

Dear Mr. McNear,

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Phenothrin RED, and has concluded that your submission is acceptable.

NOTE: This product is **not** being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time. Furthermore, any required mitigation language for pet spot-on products must be addressed in a separate amendment.

Please be aware that the record for this product currently contains the Confidential Statement of Formulation (CSF) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated July 14, 2011
- Alternate CSF #1, dated July 14, 2011

Please also note that, should you wish to add/retain a reference to the company's website on your label (i.e., [www.hartz.com](http://www.hartz.com), [www.hartzultraguard.com](http://www.hartzultraguard.com), and [www.hartzincontrol.com](http://www.hartzincontrol.com)), 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" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Per 40 CFR 156.10(6), submit one copy of your final printed labeling before you release the product for shipment. As defined in 40 CFR 152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold." Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or [chao.julie@epa.gov](mailto:chao.julie@epa.gov).

Sincerely,



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

*Enclosures: Label stamped "Accepted" APR 26 2012  
Acute Toxicity Reviews, dated April 12, 2011 and January 5, 2012  
Product Chemistry Reviews, dated June 8 and November 1, 2011*

Hartz® Reference No. 118

EPA Reg. No.: 2596-150

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

4/17/2012

ACCEPTED

APR 26 2012

30 of 10

# Hartz® Reference 118

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for the  
pesticide registered under:

## Alternate Brand Names

EPA Reg. No: 2596-150

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.)

4 of 10

Hartz® Reference No. 118

4/17/2012

EPA Reg. No.: 2596-150

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

**ACTIVE INGREDIENTS**

Phenothrin.....85.7%

(S) – Methoprene.....2.3%

**OTHER INGREDIENTS** .....12.0%

**TOTAL** .....100.0%

**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)*]

<b>For Dogs and Puppies Weighing:</b>	<b>Net Contents (Each tube)</b>
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, using tobacco or using the toilet.

**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 dog(s) or on dog(s) 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 dog(s). If signs of sensitivity occur, bathe your dog(s) with mild soap, rinse with large amounts of water, and consult a veterinarian immediately.



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

**ENVIRONMENTAL HAZARDS**

This product is highly toxic to fish and aquatic invertebrates. Do not apply directly to water.

**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.

Do not apply this product in a way that will contact children, either directly or through drift/runoff.

(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 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

leaf 10

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 1/2 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**

**Pesticide Storage:** Store in a cool, dry place that is inaccessible to children.  
**Container Handling:** Nonrefillable container. Do not refill or reuse this container.  
**If empty:** 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.

**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:]

Phenothrin .....85.7%  
 (S) – Methoprene .....2.3%

*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  
 Contains an adulticide and an insect growth regulator  
 Kills hatching flea eggs  
 Kills mosquitoes  
 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  
 Kills (and repels) fleas which may cause (flea bite anemia)(and)(or)(flea allergy dermatitis) on dogs  
 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

Once fleas are (visible)(apparent) on your dog, there may already be 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.

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)

(Now) (featuring the angled) Pro-Glide™ Applicator easily gets through dog's fur, for on-skin application

(Now) (featuring the angled) Pro-Glide™ Applicator quickly gets through dog's fur, for on-skin application

(Now) (featuring the angled) Pro-Glide™ Applicator easily penetrates dog's fur, for on-skin application

(Now) (featuring the angled) Pro-Glide™ Applicator quickly penetrates dog's fur, for on-skin application

Pro-Glide™ Applicator gently glides through the dog's fur

Pro-Glide™ Applicator easily gets through dog's fur to minimize (oily) residue

Pro-Glide™ Applicator easily penetrates dog's fur to minimize (oily) residue

Pro-Glide™ Applicator features rounded edges for on-skin application

Pro-Glide™ Applicator glides smoothly through the dog's fur

Pro-Glide™ Applicator features an angled tip to help guide the application

Easy to use Pro-Glide™ Applicator

Easy to (use)() (apply)

Simple to (use)() (apply)

(Featuring the) (with) Clearview™ tube

Passes easily through the dog's coat to the skin.

Glides quickly through dog's coat

Applies smoothly on dog's skin

Applies directly on dog's 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 for 30 days

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 dog's fur) (dog's coat) for direct application

Applicator (easily penetrates dog's fur) (dog's 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)

1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose (X<sup>th</sup> 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)

10 of 10

Hartz<sup>®</sup> Reference No. 118

4/17/2012

EPA Reg. No.: 2596-150

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

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.)