

2596-156

08/21/2012

1/16

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG 21 2012

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

Subject: Amended Reregistration Label
Product Name: Hartz Reference 124
EPA Registration Number: 2596-156
EPA Decision Number: 427074

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 Any previously dated CSFs are superseded.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 11, 2011

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. 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.

Sincerely,



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

Enclosures: Label stamped "Accepted" AUG 21 2012
Acute Toxicity Reviews, dated April 13, 2011 and August 3, 2011
Product Chemistry Reviews, dated June 6, 2011 and May 11, 2012

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Hartz® Reference 124

Alternate Brand Names

Hartz® UltraGuard Plus™ Flea & Tick Drops I for Dogs [(&) (and) Puppies] Weighing 4 to 15 lbs.
Hartz® UltraGuard Plus™ Flea & Tick Drops I for Dogs [(&) (and) Puppies] Weighing 16 to 30 lbs.
Hartz® UltraGuard Plus™ Flea & Tick Drops I for Dogs [(&) (and) Puppies] Weighing 31 to 60 lbs.
Hartz® UltraGuard Plus™ Flea & Tick Drops I for Dogs [(&) (and) Puppies] Weighing > 60 lbs

Hartz® UltraGuard Plus+™ Flea & Tick Drops for Dogs [(&) (and) Puppies] Weighing 4 to 15 lbs.
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Hartz® InControl™ Flea & Tick Drops I for Dogs [(&) (and) Puppies] Weighing 4 to 15 lbs.
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Hartz® UltraGuard Plus™ Flea & Tick Drops I with (Precision Flo™ Applicator) for Dogs [(&) (and) Puppies] (Weighing 4 to 15 lbs.)
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ACCEPTED

AUG 21 2012
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

4/16

Hartz® Reference No. 124
EPA Reg. No.: 2596-156
MASTER LABEL

August 21, 2012

Hartz® UltraGuard Plus™ Flea & Tick Drops I with (Precision Pro™ Applicator for Dogs [(&) (and) Puppies] (Weighing 4 to 15 lbs.)
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7/16

Hartz® Reference No. 124

August 21, 2012

EPA Reg. No.: 2596-156

MASTER LABEL

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ACTIVE INGREDIENTS:

Phenothrin (CAS #26002-80-1).....85.7%

Pyriproxyfen (CAS # 95737-68-1).....0.5%

OTHER INGREDIENTS13.8%

TOTAL100.0%

Note: CAS numbers may or may not appear on product label

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for (ingredients and) additional precautionary statements.

See (side) (back) panel for ingredients and additional precautions.

NET CONTENTS: Contains (number) tubes, (_ fl. oz., _ ml) applicators

Only For Dogs and Puppies Weighing:	Net Contents (Each tube)
4 to 15 lbs.	0.04 fl. oz. (1.1 ml)
16 to 30 lbs.	0.06 fl. oz. (1.9 ml)
31 to 60 lbs.	0.14 fl. oz. (4.1 ml)
> 60 lbs.	0.21 fl. oz. (6.3 ml)

EPA Reg. No. 2596-RLA

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

Secaucus, NJ 07094 (U.S.A.)



[Cat Warning: A cat prohibition icon will appear on the front panel and back panel.] DO NOT USE ON CATS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, 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. 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.

FIRST AID

If on Skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. **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 4 LBS OR LESS. (Use on the 4 – 15 lbs package only)

DO NOT EXCEED SPECIFIED DOSAGE AMOUNT FOR DOGS.

DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT

(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.]

[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 dogs 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 dogs 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 dogs 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 ½ 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 dogs back to the base of the tail. Repeat every month.

Do not reapply more frequently than once every 30 days.

Do not get this product in your dog's eyes or mouth.

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.

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:* Do not reuse the container. 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.

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

INDIVIDUAL TUBE TEXT

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

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4/16

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

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

Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Flo™ Applicator) for Dogs [(&) (and) Puppies] (Weighing > 60 lbs.)

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MASTER LABEL

August 21, 2012

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.)

Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Pro™ Applicator) for Dogs [(&) (and) Puppies] (Weighing 4 to 15 lbs.)
Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Pro™ Applicator) for Dogs [(&) (and) Puppies] (Weighing 16 to 30 lbs.)
Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Pro™ Applicator) for Dogs [(&) (and) Puppies] (Weighing 31 to 60 lbs.)
Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Pro™ Applicator) for Dogs [(&) (and) Puppies] (Weighing > 60 lbs.)

Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Point™ Applicator) for Dogs [(&) (and) Puppies] (Weighing 4 to 15 lbs.)
Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Point™ Applicator) for Dogs [(&) (and) Puppies] (Weighing 16 to 30 lbs.)
Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Point™ Applicator) for Dogs [(&) (and) Puppies] (Weighing 31 to 60 lbs.)
Hartz® UltraGuard Plus™ Flea & Tick Drops (with Precision Point™ Applicator) for Dogs [(&) (and) Puppies] (Weighing > 60 lbs.)

Hartz® InControl™ Flea & Tick Drops with (Precision Flo™ Applicator for Dogs [(&) (and) Puppies] (Weighing 4 to 15 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Flo™ Applicator for Dogs [(&) (and) Puppies] (Weighing 16 to 30 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Flo™ Applicator for Dogs [(&) (and) Puppies] (Weighing 31 to 60 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Flo™ Applicator for Dog [(&) (and) Puppies] (Weighing > 60 lbs.)

Hartz® InControl™ Flea & Tick Drops with (Pro-cision Flo™ Applicator for Dogs [(&) (and) Puppies] (Weighing 4 to 15 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Pro-cision Flo™ Applicator for Dogs [(&) (and) Puppies] (Weighing 16 to 30 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Pro-cision Flo™ Applicator for Dogs [(&) (and) Puppies] (Weighing 31 to 60 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Pro-cision Flo™ Applicator for Dogs [(&) (and) Puppies] (Weighing > 60 lbs.)

Hartz® InControl™ Flea & Tick Drops with (Precision Pro™ Applicator for Dogs [(&) (and) Puppies] (Weighing 4 to 15 lbs.)

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Hartz® Reference No. 124
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August 21, 2012

Hartz® InControl™ Flea & Tick Drops with (Precision Pro™ Applicator) for Dogs [(&) (and) Puppies]
(Weighing 16 to 30 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Pro™ Applicator) for Dogs [(&) (and) Puppies]
(Weighing 31 to 60 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Pro™ Applicator) for Dogs [(&) (and) Puppies]
(Weighing > 60 lbs.)

Hartz® InControl™ Flea & Tick Drops with (Precision Point™ Applicator) for Dogs [(&) (and) Puppies]
(Weighing 4 to 15 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Point™ Applicator) for Dogs [(&) (and) Puppies]
(Weighing 16 to 30 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Point™ Applicator) for Dogs [(&) (and) Puppies]
(Weighing 31 to 60 lbs.)
Hartz® InControl™ Flea & Tick Drops with (Precision Point™ Applicator) for Dogs [(&) (and) Puppies]
(Weighing > 60 lbs.)

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

[Active Ingredients:]

Phenothrin85.7%
Pyriproxyfen.....0.5%

Keep Out of Reach of Children
Caution
Read accompanying label before use

Range of volumes from 0.04 fl. oz. (1.1 ml) to 0.21 fl. oz (6.3 ml) depending upon weight of dog
EPA Reg. No. 2596-156
EPA Est. No. 2596-NJ-1
The Hartz Mountain Corp.

OPTIONAL/ALTERNATE LABEL TEXT

Kills (Fleas) (Flea eggs) (Flea larvae) for up to 30 days
Kills ticks up to 2 weeks
Kills flea eggs and flea larvae helping to prevent re-infestations
Kills and helps prevent flea eggs and flea larvae

(Clean Fresh Scent)
Fresh Scent
Spring Fresh Scent

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Hartz recommends that you visit your veterinarian twice a year.
Be sure to read full directions and precautions on the label of every product you use.

(Precision Flo™ Applicator) (Precision Pro™ Applicator) (Pro-cision Flo™ Applicator)
(Patent pending)

(New) (X) (Precision Flo™ Applicator) (Precision Pro™ Applicator) (Pro-cision Flo™ Applicator) (Precision Point™ Applicator) (Precision Point™ Applicator) (s) (tubes)

Direct to your dog's skin

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

Controls flea and tick infestations on dogs
flea and tick control

Flea and tick topical treatment

Flea egg and flea larvae topical treatment that's easy and convenient to use

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

OPTIONAL/ALTERNATE LABEL TEXT, continued

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

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

Triple pack

Four-pack

X-pack

X-tubes

Value pack

X monthly treatments

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

Kills flea eggs before they hatch

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

Kills (and prevents) flea eggs (and flea larvae)

Flea egg and flea larvae treatment

Contains an insect growth regulator

Kills hatching flea eggs

Breaks the flea life cycle

Kills all stages of the flea life cycle

Kills fleas that may transmit tapeworm

Special formula only for dogs

Specially formulated only for dogs

Only for use on dogs and puppies 12 weeks of age or older
Only for dogs and puppies 12 weeks of age or older
Only for dogs and puppies weighing over 4 lbs.

Hartz® (Control Pet Care System) products are designed to complement each other in an integrated program for flea and tick management. To assure proper treatment, we recommend use of only Hartz® (Control Pet Care System) products.

OPTIONAL/ALTERNATE LABEL TEXT, continued

A single female flea can lay [an average of] 25 eggs per day [on average]
Controls flea population growth.
Controls flea (population growth) (infestation).
Controls flea infestation where it starts.
Complete your prevention program with products that kill both adult and pre adult fleas.

Be sure to treat the animal's bedding and surroundings with product registered for these uses, such as the Hartz® (Control Pet Care System) line.

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Hartz recommends that you visit your veterinarian twice a year.
Be sure to read full directions and precautions on the label of every product you use.
Fresh (scent) (fragrance)
Powder (scent) (fragrance)
Pleasant (scent) (fragrance)
Convenient (easy to use) applicator
Easy (simple) to (use) (handle) (apply)
Spreads naturally with dog's (movement) (skin and hair oils)
Apply as a stripe—spreads over the dog's complete body (from head to tail) through the natural motion of the animal
After application, the treated area may appear wet or oily for up to 24 hours
No mess
Disposable applicator

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 (or in case of emergency) (or for help during any step) call our flea and tick experts at 1-800-275-1414

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Hartz[®] Every Pet's Best Friend[™]

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