



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

DEC 14 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Joseph Conti
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Dear Mr. Conti:

Subject: Hartz Ref 118
EPA Reg. No. 2596-150
Submission dated 8/24/06

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.

The package for dogs 31 to 60 lbs with a dose of 0.09 fl. oz. is not approved. The dose for dogs 31 to 45 pounds must be packaged in 0.09 fl. oz. size tubes and the dose for dogs 46 to 60 pounds must be packaged in 0.14 fl. oz. size tubes. The label must reflect these package size changes.

Revise the packaging for the smallest weight classes as follows:

For dogs and puppies weighing 4 to 15 lbs (0.04 fl. oz.)
For dogs and puppies weighing 4 to 30 lbs. (0.04 fl. oz.)

Add to the label the following:

Do not use on dogs or puppies weighing 4 lbs or less.

Within one year you must submit data (with the appropriate PRLA fee) to support mosquito claims or remove mosquito claims from the label.

Within one year you must submit data (with the appropriate PRLA fee) to support claims against the Rocky Mountain wood tick or remove these claims from the label.

Revise the Precautionary Statements to read as follows:

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.

In accordance with the efficacy review, remove the following enhanced efficacy claims:
"Advanced" "Advanced Care", and "Advanced Care Plus" unless trademarked.
Fast Acting
Long Lasting

Claims against mosquitoes that may transmit West Nile Virus are not permitted at this time for dogs due to a lack of available evidence to demonstrate that dogs (1) become clinically ill due to West Nile Virus infection or (2) they serve as either a reservoir or alternative host for the virus.

As set forth in the label review manual, the individual tubes must bear the following labeling: Product name, including the weight of dog for which the product is intended, ingredient statement, signal word, child hazard warning, EPA registration number, EPA establishment number, net contents, and a statement referring the user to the accompanying label. The product name must match the name on the exterior package.

The product names "Ultraguard," "Omni Force," "Ultra Force" and "5 in 1," unless trademarked, are enhanced efficacy claims and must be deleted.

The "4 in 1" and "5 in 1" claims when not appearing as a trademarked product name must be qualified by an explanation. Otherwise they are enhanced efficacy claims and must be deleted.

The claim "3(4) month protection" must be qualified to explain what pests it refers to and how you get this length of protection.

Revise the claim "Stops the adult tick life cycle" to read as follows:
Stops the adult tick life cycle by killing the adult form of this pest.

Delete claims that the product is waterproof. You have not submitted data to support this claim.

Delete "gentle formula". This is an implied safety claim.

Add to the Hazards to domestic animals statements the following:
Do not use on cats or kittens.

Delete claims that the insect growth regulator controls ticks.

Add at the end of the First Aid statements the following:
You may also contact 1-800 xxx-xxxx for emergency medical treatment information.

3 8 12

Delete claims that the product lasts works protects adult fleas and ticks.

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

All future changes in package size must be submitted as an amendment and not as a notification.

A copy of the efficacy and companion animal safety reviews are enclosed.

If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

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

ACCEPTED
with COMMENTS
In EPA Letter Dated:

Hartz® Reference 118

DEC 14 2006
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
2596-150

Alternate Brand Names

Hartz® Advanced Care Brand® Flea & Tick Drops Plus + for Dogs and Puppies

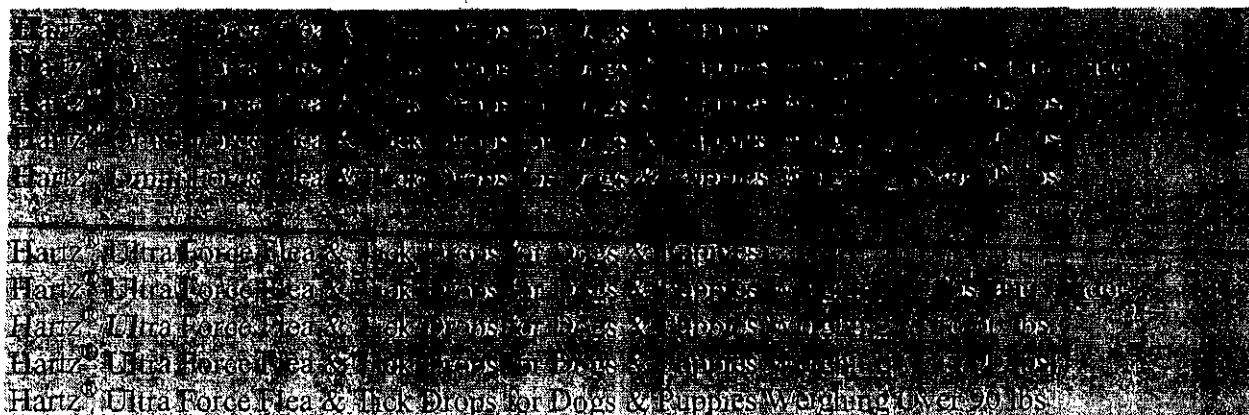
- Hartz® Advanced Care® 4 in 1® Flea & Tick Drops Plus + for Dogs and Puppies
- Hartz® Advanced Care® 4 in 1® Flea & Tick Drops Plus + for Dogs and Puppies Weighing 4 to 15 lbs.
- Hartz® Advanced Care® 4 in 1® Flea & Tick Drops Plus + for Dogs and Puppies Weighing 16 to 30 lbs.
- Hartz® Advanced Care® 4 in 1® Flea & Tick Drops Plus + for Dogs and Puppies Weighing 31 to 45 lbs.
- Hartz® Advanced Care® 4 in 1® Flea & Tick Drops Plus + for Dogs and Puppies Weighing 46 to 60 lbs.
- Hartz® Advanced Care® 4 in 1® Flea & Tick Drops Plus + for Dogs and Puppies Weighing 61 to 90 lbs.
- Hartz® Advanced Care® 4 in 1® Flea & Tick Drops Plus + for Dogs and Puppies Weighing Over 90 lbs.
- Hartz® Advanced Care® 5 in 1 Flea & Tick Drops Plus + for Dogs and Puppies

Hartz® UltraGuard plus Drops for Dogs and Puppies

- Hartz® UltraGuard plus Drops for Dogs and Puppies Weighing 30 lbs. and Under
- Hartz® UltraGuard plus Drops for Dogs and Puppies Weighing 31 to 60 lbs.
- Hartz® UltraGuard plus Drops for Dogs and Puppies Weighing 61 to 90 lbs.
- Hartz® UltraGuard plus Drops for Dogs and Puppies Weighing Over 90 lbs.

Pet Principles by Hartz® Flea & Tick Drops for Dogs & Puppies

- Pet Principles by Hartz® Flea & Tick Drops for Dogs & Puppies Weighing 30 lbs. and Under
- Pet Principles by Hartz® Flea & Tick Drops for Dogs & Puppies Weighing 31 to 60 lbs.
- Pet Principles by Hartz® Flea & Tick Drops for Dogs & Puppies Weighing 61 to 90 lbs.
- Pet Principles by Hartz® Flea & Tick Drops for Dogs & Puppies Weighing Over 90 lbs



ACTIVE INGREDIENT:

Phenothrin (CAS #26002-80-1).....	85.7%
(S) - Methoprene (CAS #65733-16-6).....	2.3%
OTHER INGREDIENTS	<u>12.0%</u>
TOTAL	100.0%

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.

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

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
30 lbs. and under	0.04 fl. oz., 1.3 mL
31 to 45 lbs.	0.09 fl. oz., 2.6 mL
31 to 60 lbs.	0.09 fl. oz., 2.6 mL
46 to 60 lbs.	0.14 fl. oz., 4.1 mL
61 to 90 lbs.	0.16 fl. oz., 4.6 mL
Over 90 lbs.	0.19 fl. oz., 5.9 mL

EPA Reg. No. 2596-150
EPA Est. No. 2596-NJ-1

[Made in (the) U.S.A. (by)]

©The Hartz Mountain Corporation
Secaucus, NJ 07094 (U.S.A.)
(and St. Thomas, Ontario N5P 3W7 Canada)

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS OR ON PUPPIES 12 WEEKS OF AGE OR OLDER

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

CAUTION: May cause eye irritation. Avoid contact with eyes or (and) clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS

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. • 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)

Use only on dogs or puppies 12 weeks of age or older.

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.

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.

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 or 1-800-CLEANUP 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.)

OPTIONAL/ALTERNATE LABEL TEXT

Controls flea and tick infestations
Effective flea and tick control
Integrated program for fleas & ticks
Protect your pet
Advanced flea and tick (and mosquito) topical treatment
Advanced flea egg and larvae topical treatment that's easy and convenient to use
Flea control for dogs with (PRECOR®)(VIGRen®) Insect Growth Regulator
This product contains three (four) monthly doses (one monthly dose), each X (fl. oz.) (cc)
Monthly protection against (fleas) (ticks) (mosquitoes) (flea eggs) (and) (flea larvae)
One tube gives (provides) 30 days protection
3 month supply
4 month supply
1st dose, 2nd dose, 3rd dose (4th dose)
3 (4) month protection
First month, second month, third month (fourth month)
Triple pack
Four-pack
1 month supply
6 month supply
12 month supply
Value pack
3 (4) monthly treatments
Fast Acting
Long lasting
4 in 1 (protection)
Kills & prevents (fleas)(ticks)(flea eggs) (larvae)
5 in 1 (protection)
(One product) kills fleas, ticks and (adult) mosquitoes plus flea eggs (and larvae)
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 larvae)
Flea egg and larvae treatment
Contains an insect growth regulator
Kills hatching flea eggs
Kills mosquitoes
Contains an adulticide
Stops the flea life cycle
Kills all stages of the flea life cycle
Stops the adult tick (and adult mosquito) life cycle
Breaks the (tick) (mosquito) life cycle by killing the adult form of these pests

OPTIONAL/ALTERNATE LABEL TEXT, continued

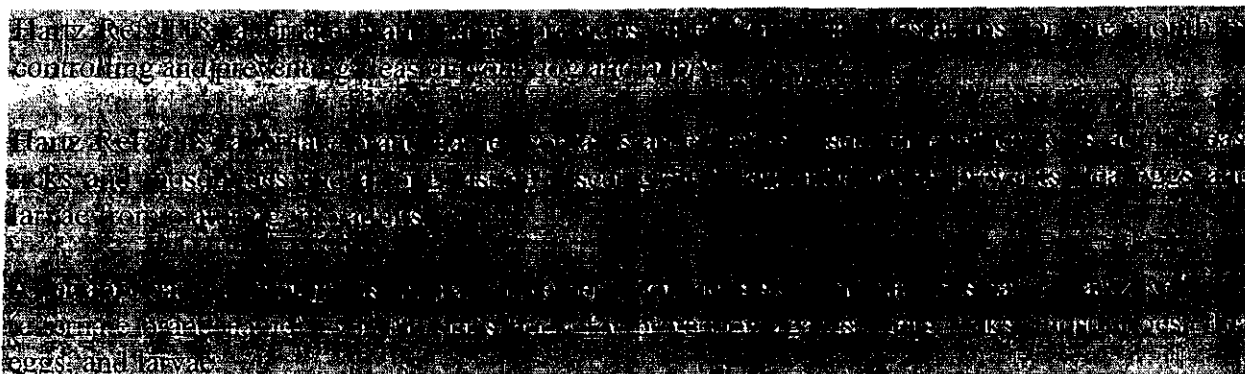
Kills the Rocky Mountain wood tick, which may carry Rocky Mountain spotted fever
Kills and repels the Deer tick which may carry Lyme disease
Prevents mosquitoes that could (can) transmit West Nile virus from feeding on dogs for up to one month (per application)

Controls (kills) (repels) (lasts) (works) (protects) (eliminates) fleas, ticks (and mosquitoes on treated dogs) round-the-clock for up to 30 days (1 month) (4 weeks)

Controls (kills) 95% of fleas and 81% of ticks in 24 hours (1 day)

Repels 96% of ticks within 1 day (24 hours)

Repels 95% of fleas within 1 day (24 hours)



Special formula for dogs

Specially formulated for dogs

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

For all dogs and puppies 12 weeks of age or older

Hartz Ref. 118 (this product)(alternate brand name) provides relief from flea and tick infestation (from flea and tick populations) on dogs and puppies by controlling and preventing (adult fleas) (ticks) (flea eggs) and (larvae)

Apply as a stripe for head to tail (total body) flea and tick (and mosquito) protection (control)

(Why use Hartz® Ref. 118 (this product)(alternate name brand)?) Hartz® Ref. 118 (this product)(alternate name brand) contains two (2) special (active) ingredients. The first (active) ingredient, phenothrin, is specifically designed to kill adult fleas, ticks, and mosquitoes. The second (active) ingredient, (S)-methoprene, is designed to kill flea eggs and larvae. This combination provides your pet with complete protection. Why is it important to kill flea eggs and larvae? Fleas spend virtually all their life on your pet and they produce a vast number of eggs, which drop off the pet and develop in the environment. Once you see fleas on your pet, there is already an infestation of pre-adult flea stages in your home. Hartz® Ref. 118 (this product)(alternate name brand) is specifically designed to kill adult fleas, flea eggs, and larvae, thereby breaking the flea life cycle and making your pet flea-free.

OPTIONAL/ALTERNATE LABEL TEXT, continued

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.

Hartz® Ref. 118 (this product) (alternate brand name) with (PRECOR®) (vIGRen®) – Insect Growth Regulator is the monthly treatment that effectively controls flea and tick infestations. Hartz Ref. 118 (this product) (alternate brand name) kills and prevents adult fleas and ticks (adult mosquitoes) plus flea eggs and larvae. It also repels and kills mosquitoes.

As with all flea and tick products, they are (Hartz Ref. 118 (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 product registered for these uses, such as the Hartz® (Control Pet Care System) line.

Hartz® Ref. 118 (this product) (alternate brand name) contains [(both) (an insecticide to kill adult fleas and ticks) (and mosquitoes) and an insect growth regulator (IGR) to kill flea eggs before they hatch] [a powerful effective insecticide which kills adult fleas and ticks (and mosquitoes) and a long-lasting insect growth regulator which prevents flea eggs and larvae from maturing into adults] (Adult fleas spend virtually all of their time on your pet, but they produce vast numbers of eggs which drop off the pet and develop in the environment.) [Once fleas are apparent on your pet, there is already an infestation of their pre-adult stages in your home. Hartz® Ref. 118 (this product) (alternate brand name) is designed to kill both the adult flea (and adult mosquito) and flea eggs and larvae, thereby breaking the flea (and adult mosquito) life cycle.] [Hartz® Ref. 118 (this product) (alternate brand name) will also break the tick life cycle by killing adult ticks, including the Deer Tick, which may carry Lyme disease, and the Rocky Mountain Wood Tick, which may carry Rocky Mountain spotted fever.]

Hartz® Ref. 118 (this product) (alternate brand name) provides relief from flea infestations for one month (30 days) (4 weeks) by controlling and preventing fleas on your dog or puppy. Adult fleas can live on your pet while also producing vast numbers of eggs, which drop off your pet and develop in the surrounding environment. Hartz® Ref. 118 (this product) (alternate brand name) kills the adult flea, (and) its eggs and larvae, thereby breaking the flea life cycle. Hartz® Ref. 118 (this product) (alternate brand name) breaks the tick life cycle by killing the adult ticks, including the Rocky Mountain Wood Tick and the Deer Tick (which may carry Lyme disease). Hartz® Ref. 118 (this product) (alternate brand name) also kills and repels mosquitoes, (which may carry canine heartworms.)

Important Information:

The ABC's of Flea and Tick Management

A—Treat Your Pet to kill fleas and ticks living on your pet

B—Protect Your Pet to keep fleas and ticks from re-infesting your pet

C—Treat Your Home both indoors and outdoors, to protect your entire home and guard against re-infestation.

OPTIONAL/ALTERNATE LABEL TEXT, continued

Be sure to read the full directions and precautions on the label of each product you use.

Step A—Treat Your Pet with one of the Hartz® (Control Pet Care System) on-animal products, such as conditioning shampoo, dip, powder or spray, to kill fleas and ticks living on your pet. Use a Hartz® (Control Pet Care System) product containing (PRECOR®) (vIGRen®), an insect growth regulator (IGR) to also stop hatching flea eggs from developing into biting adults.

Step B—Protect Your Pet with a Hartz® (Control Pet Care System) repellent or flea and tick collar to keep fleas and ticks from re-infesting your pet. The (Hartz® Control Pet Care System Ultimate Flea Collar with vIGRen® and Rabon®) (alternate brand name) will also prevent flea eggs from hatching.

Step C—Treat Your Home both indoors and outdoors, with (Control Pet Care System Home Flea and Tick Killer or Fogger with vIGRen®) (alternate brand names) and (Control Pet Care System Yard and Kennel Spray) (alternate brand name) to protect your entire home and guard against re-infestation. [The (Control Pet Care System) (alternate brand name) Flea Trap will also serve to help break the flea life cycle (by killing fleas) in hard to reach areas of your home.]

Rabon® is a registered trademark for tetrachlorvinphos
vIGRen® is a registered trademark of Wellmark International

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Waterproof
It is also waterproof
Fresh (scent) (fragrance)
Powder (scent) (fragrance)
Pleasant (scent) (fragrance)
Clean (scent) (fragrance)
Clean, fresh (scent) (fragrance)
Gentle formula
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

12 8 12

Hartz® Reference No. 118
EPA Reg. No.: 2596-150
MASTER LABEL

8/22/2006

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT, cont'd

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 _____
Fourth Dose _____

Satisfaction guaranteed
Money back guarantee (by Hartz®)
Guaranteed to work (or your money back)
If not completely satisfied (with this product,) return (unused portion) (it to place of purchase with your receipt) for a full refund

To see a visual demonstration of this application (ask our online experts) (visit our website) at [www. Hartz.com](http://www.Hartz.com)
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

Hartz® Every Pet's Best Friend™
VISIT OUR WEBSITE
www.hartz.com
Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation
PRECOR® (and vIGRen®)(is a) (are) registered trademark(s) of Wellmark Intl.