

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460 EPA Reg. Number:

Date of Issuance:

09/29/2011

2596-169

Term of Issuance:

Conditional

Name of Pesticide Product:

Hartz Reference #134

NOTICE OF PESTICIDE: x Registration

Reregistration (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is registered in accordance with FIFRA sec 3(c)(7)(A), contingent on the following:

1. Make the following labeling changes before releasing the product for shipment: a. Revise the EPA Registration Number to read: "EPA Registration No. 2596-169".

Signature of Approving Official:

Date:

See page 4

September 29, 2011

Richard Gebken, Product Manager (RM 10) Insecticide Branch Registration Division (MC 7505P)

EPA Form 8570-6

2. This registration is time-limited and expires two years from the date this product is first released for shipment.

You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.

- 3. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
- 4. You must submit the following data within the timeframe described below:

 Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
- 5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on January 1, 2012.

The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information CBI) 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 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 precondition

EPA Severity Code: death, major, moderate, minor Outcome: died, recovered, still treated, unknown

- 6. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. 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.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. 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.
 - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - g. 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.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dogs for each clinical sign.
 - i. Table showing number of incidents in dogs for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.
- 7. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for re-registration (registration review) of your product under FIFRA section 4.

If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with the above stated conditions, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact me or Dr. B. A. Akinlosotu via (703) 605-0653 or akinlosotu.bonaventure@epa.gov.

Sincerely,

Richard Gebken,

Product Manager (RM 10)

Insecticide Branch

Registration Division (MC 7505P)

Enclosures Stamped Label Hartz ® Reference #134 EPA Reg. No.: 2596-RAO /169 MASTER LABEL-

September 29, 2011

Hartz[®] Reference #134

Alternate Brand Names

Hartz[®] UltraGuard PRO[®] Triple Active Flea & Tick Drops [for Dogs [(&) (and) Puppies] Hartz[®] UltraGuard PRO[®] Triple Action Flea & Tick Drops [for Dogs [(&) (and) Puppies] Hartz[®] UltraGuard PRO[®] Topical Flea & Tick Prevention [for Dogs [(&) (and) Puppies] Hartz[®] UltraGuard PRO[®] Topical Flea & Tick Treatment [for Dogs. [(&) (and) Puppies] Hartz[®] UltraGuard PRO[®] Topical Flea & Tick Control [for Dogs [(&) (and) Puppies] Hartz[®] UltraGuard PRO[®] Topical Flea & Tick Solution [for Dogs [(&) (and) Puppies] Hartz[®] InControl Advanced® Triple Active Flea & Tick Drops [for Dogs [(&) (and) Puppies] Hartz[®] InControl Advanced® Triple Action Flea & Tick Drops [for Dogs [(&) (and) Puppies] Hartz[®] InControl Advanced® Topical Flea & Tick Prevention [for Dogs [(&) (and) Puppies] Hartz[®] InControl Advanced® Topical Flea & Tick Treatment [for Dogs [(&) (and) Puppies] Hartz[®] InControl Advanced® Topical Flea & Tick Control [for Dogs [(&) (and) Puppies] Hartz[®] InControl Advanced® Topical Flea & Tick Solution [for Dogs [(&) (and) Puppies]

Hartz® Pro Force™ Triple Active Topical Solution for Dogs (& Puppies) Pro Force™ Triple Active Topical Solution for Dogs (& Puppies)

Hartz® FieldForce™ Triple Active Topical Solution for Dogs (& Puppies) FieldForceTM Triple Action Topical Solution for Dogs (& Puppies)

First Defense™ Triple Active Topical Solution for Dogs (& Puppies)

ACCEPTED With COMMENTS In EPA Letter Dated: SEP 2 9 2011

Under the Federal Insecticide, Fungicide Hartz® First Defense™ Triple Active Topical Solution for Dogs (& Puppies and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

2596-169

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing 5 to 14 lbs.

Weighing 15 to 30 lbs.

Weighing 31 to 60 lbs.

Weighing 61-150 lbs.

ACTIVE INGREDIENTS:

Etofenprox	55.0%
*Piperonyl Butoxide (PBO)	10.0%
**n-octyl bicycloheptene dicarboximide (MGK 264)	. 1.0%
Pyriproxyfen (Nylar)	0.5%
S-Methoprene	0.25%
OTHER INGREDIENTS	33.25%
TOTAL	100.0%

^{*(}butylcarbityl)(6-propylpiperonyl) ether and related compounds

EVERCIDE, NYLAR, MGK®- Registered trademarks of McGlaughlin Gormley King Company

KEEP OUT OF REACH OF CHILDREN

^{**}MGK®264, Insecticide Synergist

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CAUTION: See back panel for additional precautionary statements.

NET CONTENT: Contains (number) tubes, each __ fl. oz. (__ml)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
5 to 14 lbs.	0.031 fl. oz. (0.91 ml.)
15 to 30 lbs.	0.066 fl. oz. (1.95 ml.)
31 to 60 lbs.	0.132 fl. oz. (3.90 ml.)
61 to 150 lbs.	0.220 fl. oz. (6.50 ml.)

EPA Reg. No. 2596-RAG? RAO? EPA Est. No. 2596-OH-1

Hartz[®] and other trademarks are trademarks of The Hartz Mountain Corporation. Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]

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 LESS THAN 5LBS.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin 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 OTHER ANIMALS. Do not use on dogs or puppies less than 12 weeks old or weighing less than 5lbs. 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

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poison control center or doctor for treatment advice. 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.

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 ON PUPPIES 12 WEEKS OF AGE OR OLDER DO NOT USE ON DOGS OR PUPPIES WEIGHING LESS THAN 5LBS.

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)

[Option 1]

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. 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. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

[Option 2]

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) (glide) from the shoulder blades along the dog's back to the base of the tail. Repeat every month. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

[Option 3]

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. Position the tip of the tube on the dog's back at the base of the dog's tail. 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 base of the tail along the dog's back to the shoulder blades. Repeat every month. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from

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other (dogs and cats) (pets) for 24 hours after treatment has been applied.

[Option 4]

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 at the base of the dog's tail. 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) (glide) from the base of the tail along the dog's back to the shoulder blades. Repeat every month. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

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 inaccesible 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.

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[®] Triple Active Flea & Tick Drops [for Dogs [(&) (and) Puppies] Weighing 5 to 14 lbs.]

Hartz[®] UltraGuard PRO[®] Triple Active Flea & Tick Drops [for Dogs [(&) (and) Puppies] Weighing 15 to 30 lbs.]

Hartz[®] UltraGuard PRO[®] Triple Active Flea & Tick Drops [for Dogs [(&) (and) Puppies] Weighing 31 to 60 lbs.]

Hartz[®] UltraGuard PRO[®] Triple Active Flea & Tick Drops [for Dogs [(&) (and) Puppies] Weighing 61-150 lbs.]

Hartz[®] UltraGuard PRO[®] Triple Action Flea & Tick Drops [for Dogs [(&) (and) Puppies] Weighing 5 to 14 lbs.l

Hartz[®] UltraGuard PRO[®] Triple Action Flea & Tick Drops [for Dogs [(&) (and) Puppies] Weighing 15 to 30 lbs.l

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Hartz[®] Reference #134 EPA Reg. No.: 2596-RAO MASTER LABEL- -

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Hartz® Pro Force™ Triple Active Topical Solution for Dogs (& Puppies)
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Hartz® FieldForce™ Triple Active Topical Solution for Dogs (& Puppies) FieldForce™ Triple Active Topical Solution for Dogs (& Puppies)

Hartz® First DefenseTM Triple Active Topical Solution for Dogs (& Puppies) First DefenseTM Triple Active Topical Solution for Dogs (& Puppies)

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

[A second weight class designation may be printed on the tube]

[Active Ingredients:] Etofenprox 55.0% PBO10.0% MGK 264 1.0% Nylar 0.5% S-Methoprene 0.25%

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

Range of volumes from 0.031 fl. oz. (.91 ml) to 0.220 fl. oz (6.5 ml) depending upon weight of dog EPA Reg. No. 2596-RAO \checkmark EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Weighing 5 to 14 lbs. Weighing 15 to 30 lbs. Weighing 31 to 60 lbs. Weighing 61-150 lbs.

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks)(on dogs) Kills fleas that may cause flea allergy dermatitis (and flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills Brown Dog Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs) Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

Kills Brown Dog Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks)(on dogs)

Kills all biting stages of Brown Dog Ticks and Deer Ticks

Kills adult Brown Dog Ticks and Deer Ticks, nymphs and larvae

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae)

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Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea (and) (Brown Dog Tick) (and) (Deer Tick) infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent re-infestation of fleas (and) (Brown Dog Tick) (and) (Deer Tick) (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea (and) (Brown Dog Tick) (and) (Deer Tick) re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Repels Mosquitoes (before they bite) (for) (28 days) (1 month) (4 weeks)

Repels (and controls) Mosquitoes (for) (28 days) (1 month) (4 weeks)

Controls mosquitoes (for) (28 days) (1 month) (4 weeks).

Repels Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)

Repels Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs) Once-a month Flea (and Brown Dog Tick, and Deer Tick)(Prevention) (Treatment) (Control) (Solution)

Monthly Flea (and Brown Dog Tick, and Deer Tick)(Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 weeks)Flea (and Brown Dog Tick, and Deer Tick) (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks) Gentle protection for dogs (and puppies)

Quick drying formula

Dries quickly

Quick drying

Stays on and doesn't rub off

Spreads with dog's natural skin oils

Starts killing fleas within 15 minutes

Starts killing fleas within 15 minutes and lasts for 30 days (1 month) (4 weeks)

Kills fleas for 30 days (1 month) (4 weeks)

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

Prevents and controls re-infestation(s)

Long lasting

Effective and convenient topical treatment

Kills fleas (and Brown Dog, Deer Ticks) through (after) contact

(With) patented applicator

(With) patent pending applicator

Easy spot on topical applicator

Waterproof control of flea eggs (and larvae)

Waterproof (control) to help prevent future flea infestation(s) (in the home) (by breaking their

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lifecycle)

Waterproof (control) helps prevent flea re-infestation(s)

Waterproof prevents flea re-infestation(s)

Waterproof flea re-infestation control

Kills fleas before they have a chance to lay eggs

New (Quick Drying) (Formula) (claim to be removed after 6 months)

Triple Active formula contains one adulticide and two insect growth regulators

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

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

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

X-pack

X-tubes

Value pack

X month supply

X monthly treatment(s)

Fragrance-free

Unscented

Fresh (scent) (fragrance)

Powder (scent) (fragrance)

Pleasant (scent) (fragrance)

Spring Fresh Scent

(Convenient)(easy to use) applicator

X Pro-cision Flo® Applicator(s)

X Pro-GlideTM Applicator(s)

(Pro-cision Flo®Applicator) (Now) (featuring the angled)

(Pro-GlideTM Applicator) easily gets through dog's fur, for gentle on-skin application

(Pro-cision Flo®Applicator) (Now) (featuring the angled)

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

(Pro-cision Flo®Applicator) (Now) (featuring the angled)

(Pro-GlideTM Applicator) easily penetrates dog's fur, for gentle on-skin application

(Pro-cision Flo®Applicator) (Now) (featuring the angled)

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

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

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-GlideTM Applicator features rounded edges for gentle on-skin application

September 29, 2011

Pro-Glide™ Applicator glides smoothly through the dog's fur			
Pro-Glide TM Applicator features an angled tip to help guide the application			
Easy to use Pro-Glide™ Applicator			
Direct to your dog's skin			
Easy (simple) to use (handle) (apply)			
(Featuring the) (with) EZC™ tube			
(Featuring the) (with) EZ2C™ tube			
(Featuring the) (with) EZView TM tube			
(Featuring the) (with) Clearview [™] tube			
(Clearview TM) (EZC TM) (EZ2C TM) (EZView TM) tube (visually) ensures all product has been dispensed			
(Clearview TM) (EZC TM) (EZ2C TM) (EZView TM) tubes give you the assurance all the product has been applied			
After application, the treated area may appear wet (or) (oily) for up to 24 hours You may bathe your dog 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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