

88082-1

1 1/22/2014

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 22, 2014

Mr. Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Media, Ohio 44256

Dear Mr. Kutcel:

Subject: Label amendment citation of Child Resistant Packaging
Smart Guard for Dogs
EPA Registration Number 88082-1
Your submission dated August 23, 2013 and January 17, 2014

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

A stamped label is enclosed for your records.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely yours,

A handwritten signature in black ink that reads "Richard Gebken".

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

Enclosure

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SMARTGUARD BOX INFORMATION

(Front Flap of Box)

Smart Guard For Dogs

Kills Fleas, Ticks, Chewing Lice
Treatment and control of fleas, ticks, chewing lice and aids in the control of Sarcoptic mange mites.

Fipronil 9.7%

3 Applicators

- (S) For Dogs Weighing Up to 11-22 lbs
- (M) For Dogs Weighing 23-44 lbs
- (L) For Dogs Weighing 45-88 lbs
- (XL) For Dogs Weighing 89-139 lbs

Contains the same active ingredient as Frontline® Top Spot
This product is not manufactured and distributed by Merial, the makers of Frontline Top Spot.

(PICTURE OF DOG)

ACCEPTED
JAN 22 2014
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg No. 88082-1

(Front Bottom of Box (Below Front Flap))

- **Fast-acting**
- **Long-lasting**
- **Waterproof**

DO NOT USE ON CATS. Keep dogs away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

(CAT PROHIBITION ICON)

Refer to inside for Precautionary Statements and Directions for Use on back of the box.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

For Dogs and Puppies 10 weeks and older

ACTIVE INGREDIENTS:

Fipronil	9.7%
OTHER INGREDIENTS.....	90.3%
TOTAL.....	100.0%

Net Weight 0.069fl oz; 0.135 fl oz; 0.273 fl oz; 0.408 fl oz;

Contains 3 -0.023 fl oz (0.67 ml) applicators

Contains 3 -0.045 fl oz (1.34 ml) applicators

Contains 3 -0.091 fl oz (2.68 ml) applicators

Contains 3 -0.136 fl oz (4.02 ml) applicators

(Sides of Box)

**Smart
Guard**

For Dogs

Fipronil 9.7%

3 Applicators

(S) For Dogs Weighing Up to 11-22 lbs

(M) For Dogs Weighing 23-44 lbs

(L) For Dogs Weighing 45-88 lbs

(XL) For Dogs Weighing 89-139 lbs

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(Inside Flap)

Smart Guard

For Dogs

Contains the same active ingredient as Frontline® Top Spot
This product is not manufactured and distributed by Merial, the makers of Frontline Top Spot.

Kills Fleas, Ticks, Chewing Lice

Smart Guard for Dogs contains the active ingredient fipronil that effectively targets fleas, ticks, chewing lice and mosquitoes. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

(Graphic) Fleas | (Graphic) Ticks | (Graphic) Lice | (Graphic) Mites | (Graphic) Mosquitoes)

- For Dogs Weighing Up to 11-22 lbs
- For Dogs Weighing 23-44 lbs
- For Dogs Weighing 45-88 lbs
- For Dogs Weighing 89-139 lbs

FLEAS

- Kills fleas
- Kills newly emerged adult fleas before they lay eggs
- Stops existing infestation and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

TICKS

- Kills all life stages of ticks (larva, nymph and adult), including deer
- ticks, brown dog ticks, American dog ticks, and lone star ticks.
- Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne disease.

LICE

- Rapidly eliminated chewing lice infestations.

MITES

- Aids in control of sarcoptic mange infestations.

MOSQUITOES

- Kills mosquitoes.

(Bottom of Box)

BARCODE

Lot No. xxxxxx

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(Back of Box)
(Left Back Side of Box)

**Smart
Guard**

For Dogs

- Kills Fleas
- Ticks
- Chewing Lice

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **READ THE ENTIRE LABEL AND ENCLOSED INSERT BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. KEEP OUT OF REACH OF CHILDREN. USE ONLY ON DOGS. DO NOT USE ON RABBITS OR OTHER ANIMALS.**

To kill fleas, ticks, chewing lice and mosquitoes apply Smart Guard as follows:

HOW TO APPLY

OPEN:

Hold applicator upright position and snap off applicator tip.

APPLY:

Apply product by parting the hair on the dog's back, between shoulder blades, until the skin is visible. Place the tip of the on the dog's skin and gently squeeze the entire contents of the tube directly on the skin. The entire contents should be applied to a single spot directly on to the skin. The product should be applied directly on to the skin and not on the hair coat itself. Try to avoid contact with treated area until dry. The dog should be standing for easy application.

FREQUENCY OF APPLICATION

Use Smart Guard for Dogs monthly for complete control of flea, tick, and chewing lice infestation. Smart Guard for Dogs is for monthly use and should not be reapplied for 30 days from last use.

- Smart Guard for Dogs kills adult fleas for up to 3 months. Apply monthly if there is a risk of high infestation, re-infestation or if the dog has flea allergy dermatitis (FAD).
- Smart Guard for Dogs kills ticks (ALL Life Stages: larva, nymph and adult) for at least 1 month. Apply monthly to control ticks.
- Smart Guard for Dogs kills chewing lice for at least 1 month. Apply monthly to control chewing lice.
- Smart Guard for Dogs kills mosquitoes for up to 7 days within 24 hours and 28 days within 48 hours with a monthly treatment.
- Smart Guard for Dogs aids in the control of mite infestations

(BEGINNING OF PACKAGING INSERT)



READ ENTIRE LABEL BEFORE EACH USE.

Only for use on dogs and puppies 10 weeks and older

Smart Guard For Dogs is a topical application for waterproof, fast acting, and lasting control of fleas, ticks, and chewing lice.

Frontline.....9.7%
 OTHER INGREDIENTS.....90.3%
 TOTAL.....100.0%

Compare to Frontline® Top Spot® same active ingredients*

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. READ THE ENTIRE LABEL AND ENCLOSED INSERT BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. KEEP OUT OF REACH OF CHILDREN. USE ONLY ON DOGS. DO NOT USE ON RABBITS OR OTHER ANIMALS.

HOW TO APPLY

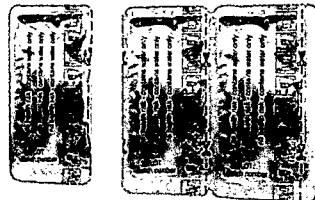
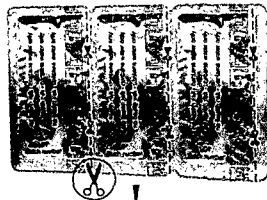
OPEN:

Hold applicator upright position and snap off applicator tip.

APPLY:

Apply product by parting the hair on the dog's back, between shoulder blades, until the skin is visible. Place the tip of the tube on the dog's skin and gently squeeze the entire contents of the tube directly on the skin. The entire contents should be applied to a single spot directly on to the skin. The product should be applied directly on to the skin and not on the hair coat itself. Try to avoid contact with treated area until dry. The dog should be standing for easy application.

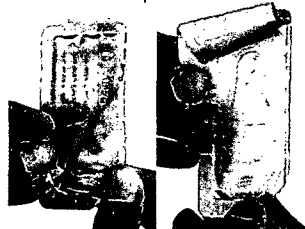
1 Cut along scissor cut line to separate unit



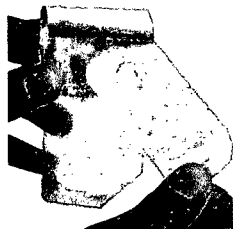
2 Turn unit over and cut corner at bulb end



3 From cut corner, peel backing completely off from bottom to top



4 Remove the applicator



FREQUENCY OF APPLICATION

Use Smart Guard For Dogs monthly for complete control of flea, tick, and chewing lice infestation. Smart Guard For Dogs is for monthly use and should not be reapplied for 30 days from last use.

- Smart Guard kills adult fleas for up to 3 months. Apply monthly if there is a risk of high infestation, re-infestation or if the dog has flea allergy dermatitis (FAD).
- Smart Guard for Dogs kills ticks (ALL Life Stages: larva, nymph and adult) for at least 1 month. Apply monthly to control ticks.
- Smart Guard kills chewing lice for at least 1 month. Apply monthly to control chewing lice.
- Smart Guard kills mosquitoes for up to 7 days within 24 hours and 28 days within 48 hours with a monthly treatment.
- Smart Guard aids in the control of mite infestations.

FIRST AID

Have the product container or label with you when calling poison control center or doctor or going for treatment.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

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.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

STORAGE:

Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL: 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.

CONTAINER DISPOSAL: If empty:

Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes 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.

HAZARDS TO DOMESTIC ANIMALS.

Do not use on dogs less than 10 weeks of age. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dog. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE: Keep away from heat and open flame.

WARRANTY

To the extent consistent with applicable law, sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

* This product is not manufactured or distributed by Merial, the makers of Frontline® Top Spot®.

Manufactured by: American Vet Sciences, LLC
 Largo, FL 33777

EPA Reg. No. 88082-1
 EPA Est No. xxxxx-xx-xxxx

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7/7

(END OF INSERT)
(Back of Box)
(Right Back Side of Box)

STORAGE AND DISPOSAL

See Insert for Storage and Disposal Instructions.

Smart Guard for Dogs is waterproof and remains effective following shampoo treatment, swimming or after exposure to rain or sunlight. Multiple monthly treatments are recommended if there is a risk of high infestation.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE: Keep away from heat and open flame.

SIDE EFFECTS:

Monitor your dog after application. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours. Some dogs may experience temporary startle effects when any product is applied. Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If signs persist or become more severe within a few days of application, consult a veterinarian immediately by calling 1-800-XXXXXX. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT. READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Do not use on rabbits or animals other than dogs. Do not allow your dog to ingest this product. Dogs exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. Do not use on kittens under 8 weeks of age. Use entire contents of tube vial on each dog. Do not split one tube between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and dogs for 24 hours after treatment has been applied.

WARRANTY

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DO NOT USE ON CATS. Keep dogs away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

(CAT PROHIBITION ICON)

Manufactured By:
American Vet Sciences LLC
6911 Bryan Dairy Road, Largo, FL 33777

EPA Reg. No. 88082-1
EPA Est. No. xxxxx-xx-xxx