

88082-3

10/8/2014

1/12



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 8, 2014

Mr. Kevin R. Kutcel
Agent for American Vet Sciences, LLC
c/o KRK Consulting, LLC
5807 Churchill Way
Medina, OH 44256

Subject: Label Amendment – Addition of Precautionary Language for Blister Packaging to Updated Master Label
Product Name: SMART GUARD for Cats & Kittens
EPA Reg No: 88082-3
Application Date: July 16 2014
Decision Number: 493543

Dear Mr. Kutcel:

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

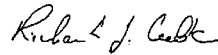
Should you wish to add/retain a reference to the company's website, smart phone/tablet app and/or a QR code reader on your product label, please be aware that the website, smart phone/tablet app and/or a QR code reader becomes labeling under FIFRA and is subject to review by the Agency. If the website, smart phone/tablet app, and/or a QR code reader 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, smart phone/tablet app, and/or a QR code reader is referenced on a product's label, claims made on the website, smart phone/tablet app, and/or a QR code reader 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, smart phone/tablet app, and/or a QR code reader contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website, smart phone/tablet app, and/or a QR code reader 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.

You must submit one (1) copy of the final printed master labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR §152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under section 2(gg) of FIFRA and its implementing regulation at 40 CFR §152.3. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA.

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A copy of your updated master label stamped "Accepted" is enclosed for your records. Please note that this letter does not supersede anything contained within the Notice of Registration dated July 10, 2014. If you have any questions, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Office of Pesticide Programs
Date: October 8, 2014

Enclosure: Updated Master Label Stamped "Accepted," dated October 8, 2014
088082-00003 D493543

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SMART GUARD For Cats & Kittens BOX INFORMATION

(Front Flap of Box)

Smart Guard For Cats & Kittens

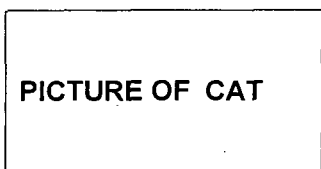
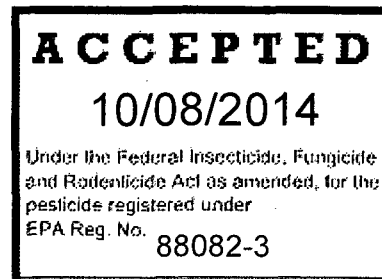
For use **ONLY** on cats or kittens 8 weeks of age and older.
For use **ONLY** on cats or kittens weighing 1.5 lbs. and over

Kills Fleas, Ticks, Chewing Lice and mosquitoes.
Treatment and control of fleas, ticks, mosquitoes and chewing lice.

Fipronil 9.7%

3 Applicators

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



(Front Bottom of Box (Below Front Flap))

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

For Cats and Kittens 8 weeks and older, weighing 1.5 lbs. and over.

ACTIVE INGREDIENTS:

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

Net Weight 0.051 fl oz
Contains 3 -0.017 fl oz (0.50 ml) applicators

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

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(Sides of Box)

Smart Guard For Cats & Kittens

Kills Fleas, Ticks, Chewing Lice & Mosquitoes

Fipronil 9.7%

3 Applicators

(Inside Flap)

Smart Guard For Cats & Kittens

Fipronil 9.7%

Kills Fleas, Ticks, Chewing Lice & Mosquitoes

Smart Guard for Cats & Kittens 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)

Smart Guard for Cats & Kittens provides convenient and effective flea, tick, chewing lice and mosquito control for cats and kittens 8 weeks and older, weighing 1.5 lbs and over.

- Fast-Acting and Long-Lasting
- Prevents Reinfestation
- Convenient to Use
- Kills Newly Emerged Adult Fleas Before they Lay Eggs.
- Controls Fleas Which may cause Flea Allergy Dermatitis.
- Kills All Stages of Brown Dog Ticks, American Dog Ticks, Lone Star Ticks.
- Kills Mosquitoes
- Rapidly Eliminates Infestations with Chewing Lice.
- Can Also be Used on Breeding, Pregnant and Lactating Queens.
- Waterproof

(Bottom of Box)

Lot No xxxxxx

BARCODE

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

Smart Guard For Cats & Kittens

- Kills Fleas
- Ticks
- Chewing Lice
- Mosquitoes

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 CATS AND KITTENS 8 WEEKS OR OLDER.

For topical application only. Apply **Smart Guard** for Cats & Kittens **ONLY** to cats and kittens aged 8 weeks or older and weighing greater than 1.5 lbs, including on breeding, pregnant, and lactating queens, as indicated below.

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 cat's back, between shoulder blades, until the skin is visible. Place the tip of the on the cat'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 cat should be standing for easy application.

FREQUENCY OF APPLICATION

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

- Smart Guard for Cats & Kittens kills adult fleas for up to 6 weeks. Apply monthly if there is a risk of high infestation, re-infestation or if the cat has flea allergy dermatitis (FAD).
- Smart Guard for Cats & Kittens kills ticks (ALL Life Stages: larva, nymph and adult) for at least 1 month. Apply monthly to control ticks.
- Smart Guard for Cats & Kittens kills chewing lice for at least 1 month. Apply monthly to control chewing lice.
- Smart Guard for Cats & Kittens kills mosquitoes for up to 7 days within 24 hours and 28 days within 48 hours with a monthly treatment.

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(BEGINNING OF PACKAGE INSERT)

READ ENTIRE LABEL BEFORE EACH USE.

Only for use on cats and kittens 8 weeks and older, weighing 1.5 lbs and over.

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

Fipronil	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 CATS AND KITTEN 8 WEEKS AND OLDER WEIGHING LESS THAN 1.5 LBS. DO NOT USE ON RABBITS OR OTHER ANIMALS.**

HOW TO APPLY

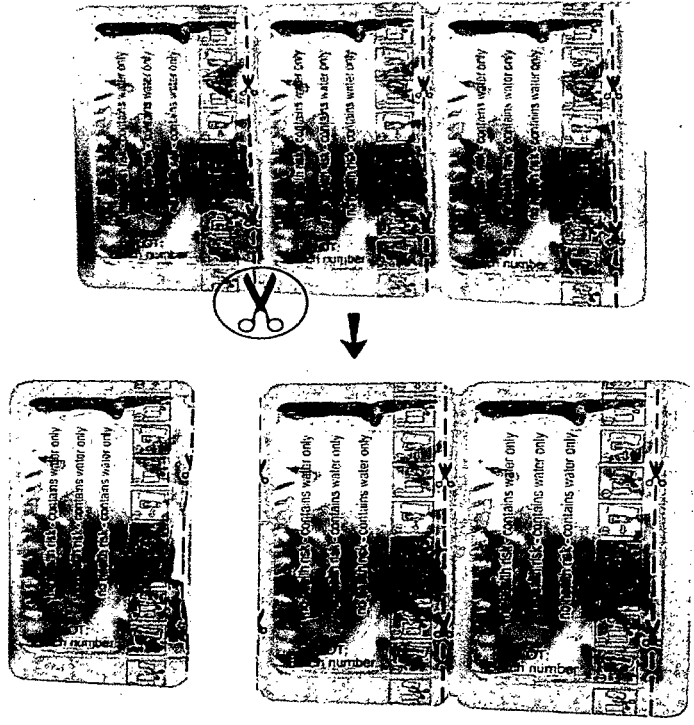
OPEN:

Hold applicator upright position and snap off applicator tip.

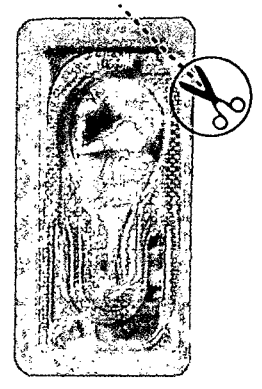
APPLY:

Apply product by parting the hair on the cat's back, between shoulder blades, until the skin is visible. Place the tip of the on the cat'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 cat should be standing for easy application.

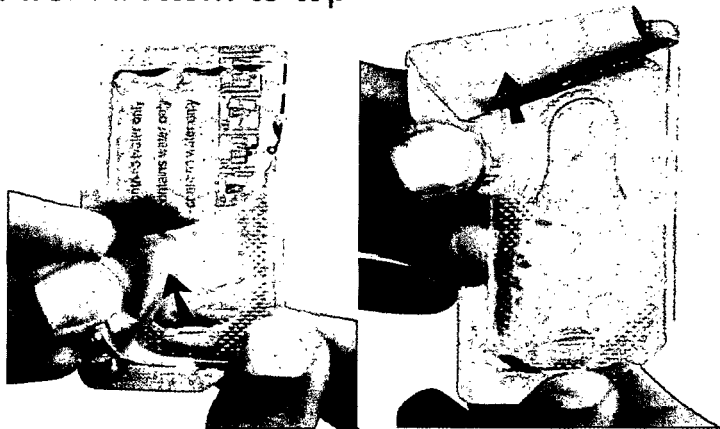
1 Cut along scissor cut line to separate unit



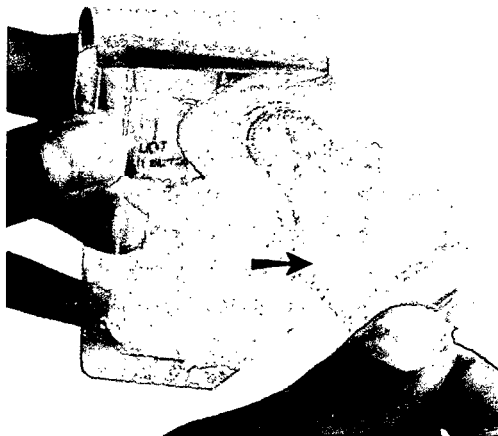
2 Turn unit over and cut corner at bulb end



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



④ Remove the applicator



FREQUENCY OF APPLICATION

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

- Smart Guard for Cats & Kittens kills adult fleas for up to 6 week. Apply monthly if there is a risk of high infestation, re-infestation or if the cat has flea allergy dermatitis (FAD).
- Smart Guard for Cats & Kittens kills ticks (ALL Life Stages: larva, nymph and adult) for at least 1 month. Apply monthly to control ticks.
- Smart Guard for Cats & Kittens kills chewing lice for at least 1 month. Apply monthly to control chewing lice.
- Smart Guard for Cats & Kittens kills mosquitoes for up to 7 days within 24 hours and 28 days within 48 hours with a monthly treatment.
- Smart Guard for Cats & Kittens aids in the control of mite infestations.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-xxx-xxx-xxxx, twenty-four (24) hours per day, seven (7) days per week.

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.

USER SAFETY RECOMMENDATIONS:

- Users should wash hands thoroughly with soap and water after handling, and before eating, drinking, chewing gum or using tobacco or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep this product in its original container when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to 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 moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling, and before eating, drinking, chewing gum or using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves."

HAZARDS TO DOMESTIC ANIMALS.

Do not use on kittens less than 8 weeks of age. Do not use on cats or kittens weighing less than 1.5 lbs. For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing cats. Consult a veterinarian before using on cats with known organ dysfunction. If your cat 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®.

For cat use only

(END OF INSERT)

11/12

(Back of Box)
(Right Back Side of Box)

STORAGE AND DISPOSAL

See Insert for Storage and Disposal Instructions.

Smart Guard for Cats & Kittens 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 cat after application. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours. Some cats may experience temporary startle effects when any product is applied. Cats 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 cat 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 cat 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 cats. Do not allow your cat to ingest this product. Cat's exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. Do not use on cats or kittens less than 8 weeks of age, weighing less than 1.5 lbs. Use entire contents of tube vial on each cat. Do not split one tube between cats. Do not use multiple tubes on one cat. Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

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.

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

EPA Reg. No. 88082-3
EPA Est. No. xxxxx-xx-xxx

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Applicator Tube Text

SMART GUARD for Cats & Kittens

**Only for Use on Cats or Kittens Over 1.5 lbs.
and Over 8 Weeks of Age.**

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Reg. No. 88082-3

**Contains fipronil (9.7%)
0.017 fl. oz. / 0.50 ml**

**READ DIRECTIONS FOR USE AND PRECAUTIONS
BEFORE USING THIS PRODUCT**

Blister package Text

SMART GUARD for Cats & Kittens

**Only for Use on Cats or Kittens Over 1.5 lbs.
and Over 8 Weeks of Age.**

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Reg. No. 88082-3

**Contains fipronil (9.7%)
0.017 fl. oz. / 0.50 ml**

**READ DIRECTIONS FOR USE AND PRECAUTIONS
BEFORE USING THIS PRODUCT**