


88082-3

7/10/2014

1/12

 <p>ENVIRONMENTAL PROTECTION AGENCY</p> <p>Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001</p>	EPA Registration No.	Date of Issuance:
	88082-3	JUL 10 2014
<p>NOTICE OF PESTICIDE:</p> <p><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p>(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	Term of Issuance:	Conditional
	Name of Pesticide Product:	Smart Guard for Cats & Kittens
<p>Name and Address of Registrant (include ZIP Code): American Vet Sciences, LLC 6911 Bryan Dairy Road Largo, FL 33777</p> <p><small>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.</small></p> <p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>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.</p> <p>This action is taken under the authority of section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p style="text-align: center;">Terms of Registration</p> <ol style="list-style-type: none"> EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment: <ol style="list-style-type: none"> Revise the EPA Registration Number to read: "EPA Registration No 88082-3" This registration is time-limited and expires two years (2) from the date this product is first released for shipment (July 10, 2016). 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. 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). Within twelve (12) 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). 		
Signature of Approving Official:	Date:	
Refer to Page #3	JUL 10 2014	
Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch		

- 5. You must submit the following data within the time-frame described below:
Within twelve (12) 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).
- 6. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on October 1, 2014. 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 (attn: Kaitlin Keller).

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

- 7. 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 cats 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 cats 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 s 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 cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dog for each clinical sign.

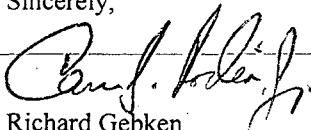
- j. Table showing number of incidents in dog for each organ system.
- k. Report aggregate incidents, but do not combine moderate and minor incidents.
- 8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
- 9. American Vet Sciences, LLC must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site:
<http://www.epa.gov/pesticides/health/spot-on-meetings.html>.
- 10. Enclosed is a copy of the data call-in (DCI) for fipronil.

You must submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA 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 along with hard copies of the acute toxicity, child-resistant packaging, companion animal safety study data, efficacy, and product chemistry reviews completed in support of the registration of this new product. If you have any questions concerning this letter, 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
Registration Division (7504P)

Enclosures: *Label Stamped "Accepted with Comments," dated July 10, 2014*
Acute Toxicity Review, dated March 19, 2014
Child-Resistant Packaging Review, dated November 22, 2013
Companion Animal Safety Study Data Review #1, dated April 25, 2014
Companion Animal Safety Study Data Review #2, dated May 14, 2014
Efficacy Review, dated July 10, 2014
Product Chemistry Review, dated March 26, 2014
Copy of DCI for Fipronil

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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.

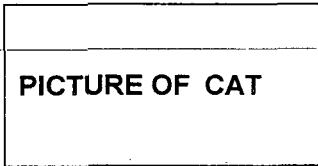
Treatment and control of fleas, ticks, mosquitoes and chewing lice.

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.



PICTURE OF CAT

(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.

ACCEPTED
 With COMMENTS
 In EPA Letter Dated:
July 10, 2014
 Under the Federal Insecticide, Fungicide
 and Rodenticide Act, As amended, for the
 pesticide Registered under EPA Reg. No:

88082-3

(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

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(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.

(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

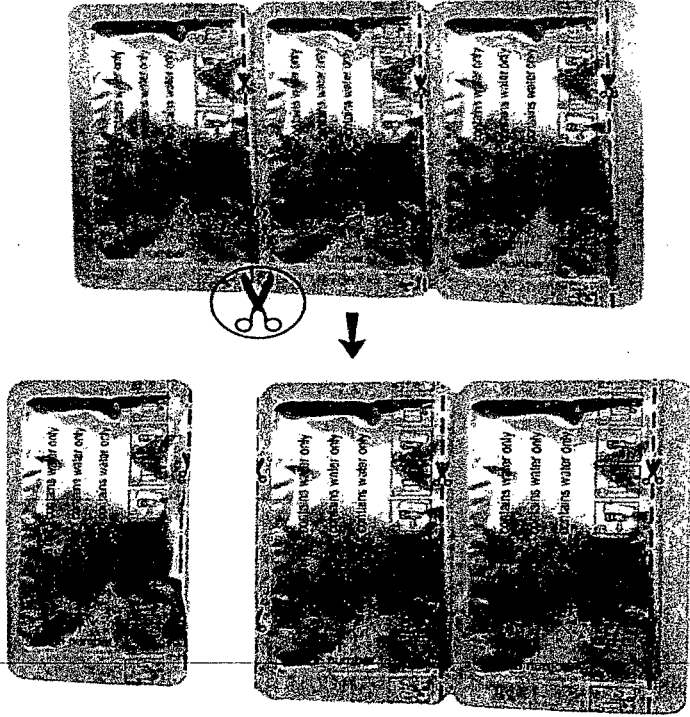
OPEN:

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.

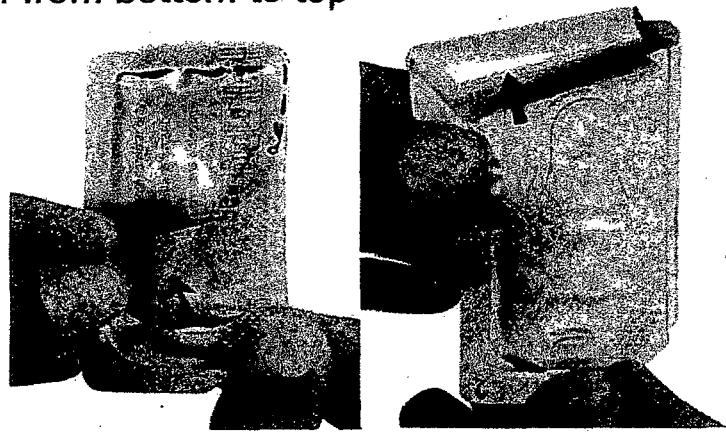
1 Cut along scissor cut line to separate unit



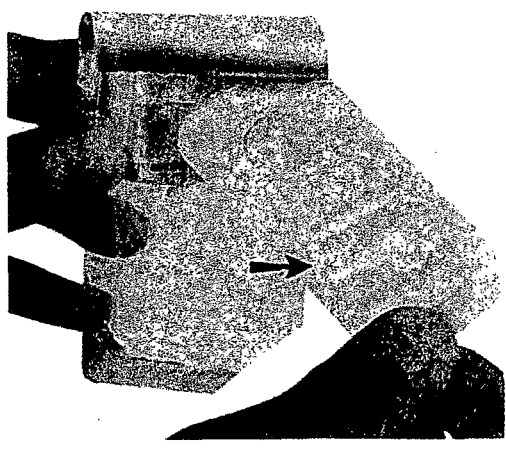
2 Turn unit over and cut corner at bulb end



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."

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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)

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(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-G
EPA Est. No. xxxxx-xx-xxx