



88082-5

EPA Reg. Number:

88082-5

Date of Issuance:

12/15/17

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 12/15/2019

Name of Pesticide Product:

SPOT AND CLEAR FOR CATS

Name and Address of Registrant (include ZIP Code):

Kevin Kutcel
KRR Consulting LLC
for American Vet Sciences LLC
5807 Churchill Way
Medina, OH 44256

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 conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

- 1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Elizabeth Fertich, Product Manager 04
Invertebrate Vertebrate Branch 1
Registration Division (7505P)

Date:

12/15/17

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 12/15/2019.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the initial registration notice dated 8/14/14.
4. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not 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 contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 08/15/2015

If you have any questions, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

Enclosure

1. Carton Text – Front Panel, 2. Carton Text – Back Panel, 3. Package Insert Text,
4. Carton Text – Side Panel, 5. Sachet (Pouch) Text, 6. Pipette Text

{NOTE TO REVIEWER: Optional Text is Placed in Brackets}

1. Carton Text – Front Panel

PICTURE OF A CAT OR KITTEN

{NOTE TO REVIEWER: A large clear picture of a cat in the weight range for the product as packaged will appear on the front label.}

Spot and Clear™ for CATS

[ABN: Fipronix™ for CATS]

{Note to Reviewer: The word “Cat” will be at least 75% the height of the largest letter in the product brand name.}

For use ONLY on CATS & KITTENS 8 weeks [of age] and older and [weighing] 1.5 lbs or over

ACTIVE INGREDIENT:

fipronil.....	9.7%
OTHER INGREDIENTS:.....	90.3%
TOTAL:.....	100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Package Insert for First Aid and Precautionary Statements.

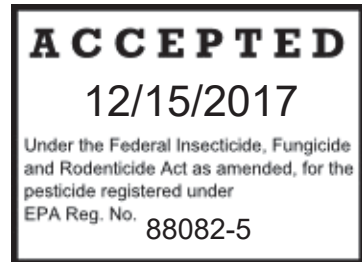
NET CONTENTS:

[0.017 fl. oz. (0.5 mL) (One applicator containing 0.017 fl. oz.)] (or)

[0.051 fl. oz. (1.5 mL) (Three applicators containing 0.017 fl. oz. each)] (or)

[0.102 fl. oz. (3 mL) (Six applicators containing 0.017 fl. oz. each)]

[FRONTLINE® and Top Spot® are registered trademarks of Merial.] [FIPAIRA™ is a trademark of Merial.]



2. Carton Text – Back Panel

[Long-lasting]

[1 Month Supply] [3 Month Supply] [6 Month Supply]

[1 Applicator] [3 Applicators] [6 Applicators] [1 Dose] [3 Doses] [6 Doses]

FOR USE ONLY ON CATS & KITTENS 8 WEEKS [OF AGE] AND OLDER AND WEIGHING 1.5 LBS OR OVER

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

Spot and Clear for Cats is approved for use on cats and kittens 8 weeks of age and older and weighing 1.5 lbs or over. Best if used year round. Spot and Clear for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain 24 hours after application.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply Spot and Clear for Cats when your cat is dry. Spot and Clear for Cats is applied at a single point on the surface of the skin above the cat's shoulder blades at the base of the neck and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands. Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes and chewing lice are killed. Allow treated area to dry thoroughly after application. Cats can be bathed 24 hours after treatment. Do not reapply for 30 days.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON CATS ONLY. .

Restrictions:

Do not allow children to apply product.

DO NOT USE ON RABBITS OR ON OTHER ANIMALS.

Avoid contact with the treated area until dry.

Do not allow your cat to ingest this product.

Do not bathe or allow your cat to swim for 24 hours.

Do not apply more than one applicator per treatment for one cat regardless of cat's weight.

{NOTE TO REVIEWER: A Side Effect box will appear on the back panel at the lower right-hand corner.}

Side Effects. After application, check your cat for side effects such as redness from skin irritation, scratching or other signs of discomfort. Vomiting or diarrhea may occur if the cat grooms itself after treatment. If you observe these signs in your treated cat, contact your veterinarian. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Call 1-866-591-5777 for customer service.

DIRECTIONS FOR APPLICATION: See enclosed package insert for directions for application.

FREQUENCY OF APPLICATION: Monthly application kills fleas, ticks, chewing lice and mosquitoes and controls flea, tick and chewing lice infestations. You can reapply Spot and Clear for Cats once every 30 days.

LIMITATION OF WARRANTY AND LIABILITY: Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the Conditions, Disclaimer of Warranties and Limitations of Liability herein.

Made in Ireland

[Distributed by] [Manufactured by] [Available exclusively from]:
Norbrook Laboratories Limited
Newry, BT35 6PU, Co. Down,
Northern Ireland

EPA Reg. No. 88082-5
EPA Establishment No. XXXX-XX-X

[Spot and Clear for Cats is not manufactured or distributed by Merial.]

Spot and Clear™ is a trademark of Norbrook Laboratories Limited.

[Optional Bar Code]

(NOTE TO REVIEWER: Lot number is stamped on back panel.)

3. Package Insert Text

Spot and Clear™ for CATS

[ABN: Fipronix™ for CATS]

{Note to Reviewer: The word “Cat” will be at least 75% the height of the largest letter in the product brand name.}

For use ONLY on CATS & KITTENS 8 weeks [of age] and older and weighing 1.5 lbs or over

ACTIVE INGREDIENT:

fipronil.....9.7%

OTHER INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[FRONTLINE® and Top Spot® are registered trademarks of Merial.] [FIPAIRA™ is a trademark of Merial.]

FIRST AID	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
If on skin or clothing:	Take off contaminated clothing. Wash skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor immediately for treatment advice.
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 to 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.
HOTLINE NUMBER	
For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide concerns), you may call 1-866-591-5777, twenty-four (24) hours per day, seven (7) days per week.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed or absorbed through skin. 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. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

CAUTION. FOR EXTERNAL USE ONLY ON CATS. Do not use on kittens under 8 weeks of age or less than 1.5 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide

product. Do not treat your cat with more than one pesticide product at a time. Some cats may experience temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats. This product is not a substitute for prescribed heartworm preventative.

Side Effects. After application, check your cat for side effects such as redness from skin irritation, scratching or other signs of discomfort. Vomiting or diarrhea may occur if the cat grooms itself after treatment. If you observe these signs in your treated cat, contact your veterinarian. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Call 1-866-591-5777 for customer service.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR CAT, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON CATS ONLY.

Restrictions:

Do not allow children to apply product.

DO NOT USE ON RABBITS OR ON OTHER ANIMALS.

Avoid contact with the treated area until dry.

Do not allow your cat to ingest this product.

Do not bathe or allow your cat to swim for 24 hours.

Do not apply more than one applicator per treatment for one cat regardless of cat's weight.

Spot and Clear for Cats is approved for use on cats and kittens 8 weeks of age and older and weighing 1.5 lbs or over. Best if used year round. Spot and Clear for Cats keeps on working even after cats are shampooed, rinsed with water, or if cats are outdoors and exposed to the sun or rain 24 hours after application.

A one-spot application is convenient and easy for effective treatment of fleas, ticks, chewing lice, and mosquitoes. Apply Spot and Clear for Cats when your cat is dry. Spot and Clear for Cats is applied at a single point on the surface of the skin above the cat's shoulder blades at the base of the neck and rapidly covers the entire cat by localizing in the hair, on the surface of the skin and in the sebaceous glands. Soon after coming into contact with a treated cat, fleas, ticks, mosquitoes and chewing lice are killed. Allow treated area to dry thoroughly after application. Cats can be bathed 24 hours after treatment. Do not reapply for 30 days.

FREQUENCY OF APPLICATION

Monthly application of Spot and Clear for Cats controls flea, tick and chewing lice infestations. You can reapply Spot and Clear for Cats once every 30 days.

Fleas: Spot and Clear for Cats kills adult fleas for up to six weeks. If your cat becomes reinfested with fleas, or if your cat is in situations where reinfestation may occur, you may apply Spot and Clear for Cats every 30 days.

Ticks: Spot and Clear for Cats kills ticks for up to one month. Apply Spot and Clear for Cats every 30 days to control all life stages of ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis and anaplasmosis.

Chewing Lice: Spot and Clear for Cats kills chewing lice for at least one month. Apply Spot and Clear for Cats every 30 days to control chewing lice.

Mosquitoes: Apply Spot and Clear for Cats every 30 days to kill mosquitoes. Mosquitoes are killed within 48 hours for up to 28 days.

DIRECTIONS FOR APPLICATION

Apply Spot and Clear for Cats as follows:

- **How to open:** Follow the instructions on the pouch to remove the applicator. Hold applicator upright away from face/body to allow product to drain from tip. Then cut with scissors or twist applicator to open it.
- **How to apply:** Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

[Optional drawings of application process]

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in original container in a cool, dry (preferably locked) place that is inaccessible to children and animals (pets). Do not remove applicator from the pack until ready to use. Protect from direct sunlight.

PESTICIDE DISPOSAL and CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container.

If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP (1-800-253-2687) for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all which are beyond the control of the manufacturer and sellers. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, the manufacturer and sellers make no warranty, expressed or implied, of merchantability or of fitness for a particular purpose, or otherwise concerning the use of this product other than as indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither the manufacturer nor the sellers shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

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

EPA Reg. No. 88082-5
EPA Establishment No. XXXX-XX-X

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Spot and Clear™ is a trademark of Norbrook Laboratories Limited.

4. Carton Text – Side Panel

[Spot and Clear™ for CATS]

[NET CONTENTS:]

[0.017 fl. oz. (0.5 mL) (One applicator containing 0.017 fl. oz.)] (*or*)

[0.051 fl. oz. (1.5 mL) (Three applicators containing 0.017 fl. oz. each)] (*or*)

[0.102 fl. oz. (3 mL) (Six applicators containing 0.017 fl. oz. each)]

5. Sachet (Pouch) Text

← Fold here →

then tear back

Or cut here (*picture of scissors*)

Spot and Clear™ for CATS & KITTENS 8 weeks [of age] and older
and [weighing] 1.5 lbs or over

Cats
0.5 ml
(0.017 fl. oz.)

CAUTION: Keep Out of Reach of Children.

Read entire label before each use. Do not open until ready to use.

Single dose
Fipronil 9.7%
0.5 mL (0.017 fl. oz.)

EPA Reg. No. 88082-5

(NOTE TO REVIEWER: Lot number is crimped into the sachet.)

(NOTE TO REVIEWER: Tradename and “Cats / ml / fl oz” circle is on both sides of the sachet.)

(NOTE TO REVIEWER: Company Name and logo are printed on one side of the sachet.)

6. Pipette Text

Spot and Clear™ Cats 1.5 lbs or over.

CAUTION

Fipronil 9.7%

0.017 fl oz

EPA Reg. No. 88082-5

[Optional Marketing Claims]:

[Long-lasting]

[Waterproof] [Does not wash off]

[For monthly control of fleas, ticks, chewing lice and mosquitoes.]

[Contains the same active ingredient as in FRONTLINE® Top Spot® for cats]

[Contains the same active ingredient as in FIPAIRA™ FOR CATS]

[Kills fleas] [Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Stops existing flea infestations and prevents establishment of new infestations on cats]

[Kills adult fleas which may cause flea allergy dermatitis]

[Kills ticks]

[Kills all life stages of ticks, including brown dog ticks [(*Rhipicephalus sanguineus*)], American dog ticks [(*Dermacentor variabilis*)], lone star ticks [(*Amblyomma americanum*)] and deer ticks [(*Ixodes scapularis*)]]

[Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis and anaplasmosis]

[Kills ticks including those that may transmit Lyme disease]

[Kills brown dog ticks, American dog ticks, lone star ticks and deer ticks for up to one month]

[Kills mosquitoes] [Kills adult mosquitoes]

[Kills chewing lice] [Eliminates chewing lice infestations on cats]

[Kills fleas, ticks, chewing lice and mosquitoes]

[1 Month Supply] [3 Month Supply] [6 Month Supply]

[1 Applicator] [3 Applicators] [6 Applicators]

[1 Dose] [3 Doses] [6 Doses]

[Optional picture of flea, tick, mosquito and/or chewing lice.]