



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 31, 2015

S. Lee Whaley
Norbrook, Inc.
9401 Indian Creek Parkway, Suite 680
Overland Park, KS 66210

Subject: Notification per PRN 98-10 – Minor Labeling Changes
Product Name: SPOT AND CLEAR FOR CATS
EPA Registration Number: 86223-2
Application Date: August 19, 2015
Decision Number: 508250

Dear Lee Whaley:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

If you have any questions, you may contact Maggie Rudick at (703) 347-0257 or via email at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Maggie Rudick for".

Kable Bo Davis, Product Manager 3
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

(~~14~~ 19 August 201~~5~~4)
Spot and Clear™ for CATS
[ABN: Fipronix™ for CATS]
Master Label

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

[NOTE TO REVIEWER: Optional Text is Placed in Brackets]

1. Package Insert Text

Spot and Clear™ for CATS
[ABN: Fipronix™ for CATS]

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:.....	<u>90.3%</u>
TOTAL:.....	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

[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]

[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]

[Kills fleas, ticks, chewing lice and mosquitoes]

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

(14 19 August 20154)
Spot and Clear™ for CATS
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Master Label

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 1.5 lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. 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.

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.

(14 19 August 20154)
Spot and Clear™ for CATS
[ABN: Fipronix™ for CATS]
Master Label

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. 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. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.

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.

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 at least 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 24 hours for up to 7 days, and 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]

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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 this is inaccessible to children and animals (pets).

CONTAINER DISPOSAL

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.

Made in Ireland

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

EPA Reg. No. 86223-2E
[EPA Establishment No. XXXXXXXX]

[Spot and Clear for Cats is not manufactured or distributed by Merial.]
Spot and Clear™ is a trademark of Norbrook Laboratories Limited.

(~~14~~ 19 August 2015~~4~~)
Spot and Clear™ for CATS
[ABN: Fipronix™ for CATS]
Master Label

2. Carton Text – Front Panel

PICTURE OF A CAT OR KITTEN

Spot and Clear™ for CATS
[ABN: Fipronix™ for CATS]

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.

[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]

[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]

[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.]

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)

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Master Label

3. Carton Text – Back Panel

[Long-lasting] [Waterproof]
[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 acts quickly, lasts up to 30 days, and controls fleas, ticks, chewing lice and mosquitoes. Best if used year round. Spot and Clear for Cats keeps on working even after shampooing and rinsing with water, and continues to work if cats are outdoors and exposed to the sun or rain.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. 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. DO NOT USE ON RABBITS OR ON OTHER ANIMALS.

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.

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[Optional Bar Code]

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

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Master Label

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)]

(14 19 August 20154)
Spot and Clear™ for CATS
[ABN: Fipronix™ for CATS]
Master Label

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

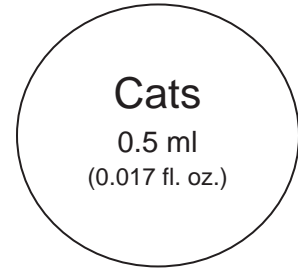
CAUTION: Keep Out of Reach of Children.

See full label for additional directions and precautions. Do not open until ready to use.

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

EPA Reg. No. 86223-2E
[EPA Establishment No. XXXXXXXX](#)

(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.)



(14 19 August 20154)
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Master Label

6. Pipette Text

Spot and Clear™ Cats 1.5 lbs or over.

CAUTION

Fipronil 9.7%

0.017 fl oz

EPA Reg. No. 86223-2E