



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 DOGS
EPA Registration Number: 86223-3
Application Date: August 19, 2015
Decision Number: 508251

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" with "for" written below it.

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

NOTIFICATION

86223-3

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

08/31/2015

(14 19 August 20154)

Spot and Clear™ for Dogs

[ABN: Fipronix™ for Dogs]

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 (except ABN) is Placed in Brackets]

1. Package Insert Text

Spot and Clear™ for DOGS **[ABN: Fipronix™ for DOGS]**

For use ONLY on Small DOGS & PUPPIES 8 weeks [of age] and older and 5 to 22 lbs. (or)

For use ONLY on Medium DOGS 23 to 44 lbs. (or)

For use ONLY on Large DOGS 45 to 88 lbs. (or)

For use ONLY on Extra-large DOGS 89 to 132 lbs.

ACTIVE INGREDIENT:

fipronil.....9.7%

OTHER INGREDIENTS:.....90.3%

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, mosquitoes and aids in the control of sarcoptic mange mites]

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

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

[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]

[Aids in control of sarcoptic mange mite infestations]

[Kills fleas, ticks, chewing lice and mosquitoes]

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

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Spot and Clear™ for Dogs
[ABN: Fipronix™ for Dogs]
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 ON DOGS ONLY. DO NOT USE ON CATS OR OTHER ANIMALS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Do not use on puppies under 8 weeks of age or [5 lbs. for small dogs] [23 lbs. for medium dogs] [45 lbs. for large dogs] [89 lbs. for extra-large dogs]. Individual sensitivities, while rare, may occur after using ANY pesticide product. Some dogs 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 dogs.

Side Effects. After application, check your dog for side effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea may occur. If you observe these signs in your treated dog, contact your veterinarian. If your dog 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 201~~5~~4)

Spot and Clear™ for Dogs
[ABN: Fipronix™ for Dogs]
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 DOG, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON CATS OR OTHER ANIMALS.

Spot and Clear for Dogs acts quickly, lasts up to 30 days and does not wash off treated dogs. Spot and Clear for Dogs controls fleas, ticks, chewing lice, mosquitoes and aids in the control of sarcoptic mange mites. For use on dogs and puppies 8 weeks of age or older (including small dogs and puppies weighing 5 to 22 lbs., medium dogs weighing 23-44 lbs., large dogs weighing 45-88 lbs., and extra-large dogs weighing 89-132 lbs.). **Use the appropriate product size based on the weight of your dog.** Best if used year round. Spot and Clear for Dogs keeps working even after shampooing and rinsing with water. Spot and Clear for Dogs continues to work if dogs are outdoors and exposed to the sun or rain, or even after swimming.

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

FREQUENCY OF APPLICATION

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

Fleas: Spot and Clear for Dogs kills adult fleas for up to three months unless the risk is high for reinfestation of fleas. If your dog becomes reinfested with fleas, or if your dog is in situations where reinfestation may occur, you may apply Spot and Clear for Dogs every 30 days.

Ticks: Spot and Clear for Dogs kills ticks for at least one month. Apply Spot and Clear for Dogs 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 Dogs kills chewing lice for at least one month. Apply Spot and Clear for Dogs every 30 days to control chewing lice.

Mosquitoes: Apply Spot and Clear for Dogs 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.

Sarcoptic Mange Mites: Spot and Clear for Dogs aids in the control of sarcoptic mange mite infestations. Apply Spot and Clear for Dogs every 30 days until mites are eliminated.

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Spot and Clear™ for Dogs
[ABN: Fipronix™ for Dogs]
Master Label

DIRECTIONS FOR APPLICATION

Apply Spot and Clear for Dogs 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 dog'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 dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

[Optional drawings of application process]

CAT PROHIBITION ICON
DO NOT USE ON CATS.

Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

(14 19 August 20154)

Spot and Clear™ for Dogs
[ABN: Fipronix™ for Dogs]
Master Label

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).

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. 86223-3G
[EPA Establishment No. XXXXXXXX]

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

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

2. Carton Text – Front Panel

PICTURE OF APPROPRIATE SIZED DOG
FOR RESPECTIVE PRODUCT WEIGHT RANGE

CAT PROHIBITION ICON
DO NOT USE ON CATS.
Keep cats away from treated
dogs for 24 hours. If applied
to or ingested by a cat, contact
your veterinarian.

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

For use ONLY on Small DOGS & PUPPIES 8 weeks [of age] and older and 5 to 22 lbs. (or)

For use ONLY on Medium DOGS 23 to 44 lbs. (or)

For use ONLY on Large DOGS 45 to 88 lbs. (or)

For use ONLY on Extra-large DOGS 89 to 132 lbs.

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, mosquitoes and aids in the control of sarcoptic mange mites]

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

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

[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]

[Aids in control of sarcoptic mange mite 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, chewing lice and/or sarcoptic mange mite.]

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

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

2. Carton Text – Front Panel (continued)

NET CONTENTS:

0.023 fl. oz. (0.67 mL) (One applicator containing 0.023 fl. oz.) (or)
0.069 fl. oz. (2.01 mL) (Three applicators containing 0.023 fl. oz. each) (or)
0.138 fl. oz. (4.02 mL) (Six applicators containing 0.023 fl. oz. each) (or)

0.045 fl. oz. (1.34 mL) (One applicator containing 0.045 fl. oz.) (or)
0.135 fl. oz. (4.02 mL) (Three applicators containing 0.045 fl. oz. each) (or)
0.270 fl. oz. (8.04 mL) (Six applicators containing 0.045 fl. oz. each) (or)

0.091 fl. oz. (2.68 mL) (One applicator containing 0.091 fl. oz.) (or)
0.273 fl. oz. (8.04 mL) (Three applicators containing 0.091 fl. oz. each) (or)
0.546 fl. oz. (16.08 mL) (Six applicators containing 0.091 fl. oz. each) (or)

0.136 fl. oz. (4.02 mL) (One applicator containing 0.136 fl. oz.) (or)
0.408 fl. oz. (12.06 mL) (Three applicators containing 0.136 fl. oz. each) (or)
0.816 fl. oz. (24.12 mL) (Six applicators containing 0.136 fl. oz. each)

(14 19 August 20154)

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

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]

CAT PROHIBITION ICON
DO NOT USE ON CATS.

Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

For Use Only on Small DOGS & PUPPIES 8 Weeks [of Age] and Older and 5 to 22 lbs. (or)

For Use Only on Medium DOGS 23 to 44 lbs. (or)

For Use Only on Large DOGS 45 to 88 lbs. (or)

For Use Only on Extra-large DOGS 89 to 132 lbs.

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

Spot and Clear for Dogs acts quickly, lasts up to 30 days and does not wash off treated dogs. Controls fleas, ticks, chewing lice, mosquitoes and sarcoptic mange mites.

Best if used year round. Spot and Clear for Dogs keeps working even after shampooing and rinsing with water, and continues to work if dogs are outdoors and exposed to the sun or rain, or even after swimming.

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 DOG, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON CATS OR OTHER ANIMALS.

Side Effects. After application, check your dog for side effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea may occur. If you observe these signs in your treated dog, contact your veterinarian. If your dog 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, chewing lice and sarcoptic mange mite infestations. You can reapply Spot and Clear for Dogs 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 ~~for~~ by] [Available exclusively from]:
Norbrook Laboratories Limited
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Northern Ireland

EPA Reg. No. 86223-3G
EPA Establishment No. XXXXXXXX

[Spot and Clear for Dogs 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.)

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

4. Carton Text – Side Panel

[Spot and Clear for DOGS]

[NET CONTENTS:]

[0.023 fl. oz. (0.67 mL) (One applicator containing 0.023 fl. oz.)] (or)
[0.069 fl. oz. (2.01 mL) (Three applicators containing 0.023 fl. oz. each)] (or)
[0.138 fl. oz. (4.02 mL) (Six applicators containing 0.023 fl. oz. each)] (or)

[0.045 fl. oz. (1.34 mL) (One applicator containing 0.045 fl. oz.)] (or)
[0.135 fl. oz. (4.02 mL) (Three applicators containing 0.045 fl. oz. each)] (or)
[0.270 fl. oz. (8.04 mL) (Six applicators containing 0.045 fl. oz. each)] (or)

[0.091 fl. oz. (2.68 mL) (One applicator containing 0.091 fl. oz.)] (or)
[0.273 fl. oz. (8.04 mL) (Three applicators containing 0.091 fl. oz. each)] (or)
[0.546 fl. oz. (16.08 mL) (Six applicators containing 0.091 fl. oz. each)] (or)

[0.136 fl. oz. (4.02 mL) (One applicator containing 0.136 fl. oz.)] (or)
[0.408 fl. oz. (12.06 mL) (Three applicators containing 0.136 fl. oz. each)] (or)
[0.816 fl. oz. (24.12 mL) (Six applicators containing 0.136 fl. oz. each)]

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

5. Sachet (Pouch) Text

← Fold here →

then tear back

Or cut here (*picture of scissors*)

Spot and Clear™ for DOGS & PUPPIES 8 weeks and over and 5 to 22 lbs (*or*)
Spot and Clear™ for DOGS 23 - 44 lbs (*or*)
Spot and Clear™ for DOGS 45 - 88 lbs (*or*)
Spot and Clear™ for DOGS 89 - 132 lbs

CAUTION: Keep Out of Reach of Children.

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

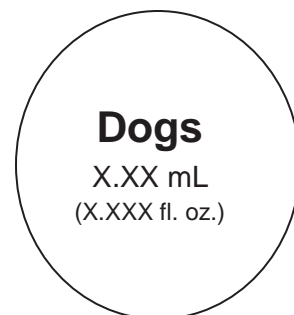
Single dose
Fipronil 9.7%
0.67 mL (0.023 fl. oz.) (*or*)
1.34 mL (0.045 fl. oz.) (*or*)
2.68 mL (0.091 fl. oz.) (*or*)
4.02 mL (0.136 fl. oz.)

EPA Reg. No. 86223-3~~G~~
EPA Establishment No. XXXXXXXX

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

(NOTE TO REVIEWER: Tradename and “Dogs / 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 201~~5~~4)
Spot and Clear™ for Dogs
[ABN: Fipronix™ for Dogs]
Master Label

6. Pipette Text

Spot and Clear Dogs 5 to 22 lbs. (*or*)
Spot and Clear Dogs 23 to 44 lbs. (*or*)
Spot and Clear Dogs 45 to 88 lbs. (*or*)
Spot and Clear Dogs 89 to 132 lbs.

CAUTION

Fipronil 9.7%

0.023 fl oz (*or*)
0.045 fl oz (*or*)
0.091 fl oz (*or*)
0.136 fl oz

EPA Reg. No. 86223-~~3~~6