

PM03

65331-3

11/30/98

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 30 1998

Louis S. Grosso, Ph.D.
Merial Limited
2100 Ronson Road
Iselin, NJ 08830-3077

Dear Dr. Grosso:

Subject: Frontline Top Spot for Dogs
EPA Reg. No. 65331-3
Your label amendments dated 9/29/98 and 11/30/98

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

Correct the net contents on pages 2 and 3 of the attached label.

As noted in the registration notice dated May 20, 1998, you must clarify that the directions for dogs weighing over 88 lbs is an exception to the directions to use only one pipette per treatment. Otherwise, the two sentences appear to be inconsistent with each other.

If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

for Marion J. Johnson, Jr.
Product Manager 3
Insecticide Branch
Registration Division (7505C)

CONCURRENCES							
SYMBOL	7505C						
SURNAME	A. Sibold						
DATE	11/30/98						

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U.S. DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection
Federal Animal Quarantine Service

11/30/98

Frontline Top Spot Insecticide,
Fipronil and (S)-methoprene act,
as a flea and tick repellent and
insecticide under EPA Reg. No.
65331-3

<p>FRONTLINE® TOP SPOT™ for Dogs</p> <p>(For Dogs and Puppies up to 22 lbs.) (For Dogs 23-44 lbs.) (For Dogs 45-88 lbs.)</p>	<p>Photo of Puppy / Dog</p>
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FRONTLINE® TOP SPOT™ FOR DOGS

(For dogs and puppies up to 22 lbs.)
(For dogs 23-44 lbs. / For dogs 45-88 lbs.)

Convenient, spot treatment for fast acting,
long lasting control of fleas and ticks.

Kills fleas up to 3 months.
Kills ticks for 1 month.

ACTIVE INGREDIENT

Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((1R,S)-(trifluoromethyl)sulfinyl)-1H-pyrazole-3-carbonitrile.....	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

- (Contains 3 / 0.023 fl oz (0.67 ml) pipettes)
- (Contains 3 / 0.045 fl oz (1.34 ml) pipettes)
- (Contains 3 / 0.091 fl oz (2.68 ml) pipettes)

FRONTLINE® TOP SPOT™ FOR DOGS and PUPPIES up to 22 lbs

For
DOGS &
PUPPIES
up to 22 lbs

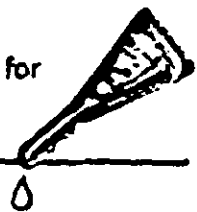
FRONTLINE

TOP SPOT



Kills fleas and ticks

Convenient, spot treatment for fast-acting, long-lasting control of fleas and ticks.



3 Easy to Use Pipettes

ACTIVE INGREDIENT	
Spinosad	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

CAUTION KEEP OUT OF REACH OF CHILDREN
Contains 3 - 0.023 fl oz (0.67 ml) pipettes



FRONTLINE TOP SPOT FOR DOGS For Dogs 23-44 lbs

For DOGS 23-44 lbs

FRONTLINE

TOP SPOT

Kills fleas and ticks

Convenient spot treatment for fast-acting, long-lasting control of fleas and ticks.



3 Easy to Use Pipettes

ACTIVE INGREDIENT	
Spinosad	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

CAUTION KEEP OUT OF REACH OF CHILDREN
Contains 3 - 0.017 fl oz (0.50 ml) pipettes



FRONTLINE® TOP SPOT FOR DOGS For Dogs 45-88 lbs

For
DOGS
45-88 lbs

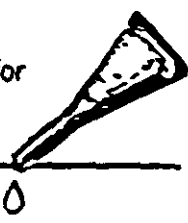
FRONTLINE

TOP SPOT



Kills fleas and ticks

Convenient spot treatment for fast-acting, long-lasting control of fleas and ticks.



3 Easy to Use Pipettes

ACTIVE INGREDIENT	
Spinosad	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

CAUTION KEEP OUT OF REACH OF CHILDREN
Contains 3 - 0.017 fl oz (0.50 ml) pipettes



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FRONTLINE® TOP SPOT™ FOR DOGS

Frontline® provides convenient and effective flea and tick control for dogs (weighing 23-44 lbs. / 45-88 lbs.) and puppies up to 22 lbs.

- *Fast acting*
- *Prevents reinfestation*
- *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, and deer ticks (the major carrier of human and canine Lyme disease)*
- *Long lasting - up to 3 months for fleas*
- *Convenient to use*

Frontline® contains the active ingredient fipronil which has a unique mode of action that effectively targets fleas and ticks. 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 residual activity.

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FIRST AID

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on puppies under 10 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product for pets. Pets may experience some 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 on medicated animals. Consult a veterinarian before using this product with other pesticides. This product may be harmful to debilitated, aged, pregnant or nursing animals; consult a veterinarian before using. Call 1-800-660-1842 for 24 hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Keep away from heat and open flame.

WARRANTY

Seller makes no warranty, expressed or implied, concerning the use of this product other than 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.

Merial Limited
2100 Ronson Road
Iselin, NJ 08830-3077, USA
Frontline® is a registered trademark of Merial Limited.

EPA Reg. No. 65331-3
EPA EST. Nos. 65331-FR-2; 65331-DEU-1; 65331-GA-1

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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 PET, READ ENTIRE LABEL AND ATTACHED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON OTHER ANIMALS.**

To kill fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (known to carry Lyme disease), apply to dogs or puppies (10 weeks or older) as follows: Wear household latex gloves and hold tube upright. Snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze tube, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one pipette per treatment is needed. (For dogs weighing over 88 lbs use the appropriate combination of Top Spot™ sizes.)

FREQUENCY OF APPLICATION

Research demonstrates that Frontline® kills fleas up to three months and ticks for at least one month. A once monthly use is recommended where there is a high risk of reinfestation, if the pet has fleas which may cause flea allergy dermatitis, or in situations where tick control is needed. When used monthly, Frontline® completely controls both flea and tick infestations.

In areas with less severe flea infestations or in areas where ticks are not a threat, Frontline® can be applied once every two to three months.

Frontline® remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply Frontline® for 30 days.

STORAGE & DISPOSAL

- Do not contaminate water, food, or feed by storage and disposal.
- STORAGE.** Store unused product in original container only, out of reach of children and animals.
- PESTICIDE DISPOSAL.** Waste resulting from use of this product may be disposed of on site or at an approved waste disposal facility.
- CONTAINER DISPOSAL.** Securely wrap original container in several layers of newspaper and discard in trash.

PIPETTE IDENTIFICATION
TOP SPOT FOR DOGS
 Up to 22 lbs. / 23-44 lbs. / 45-88 lbs.
 EPA Reg. No. 65331-3

