

PM 3

65331-3

5/20/98

1/7



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505C)  
401 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg. Number:

65331-3

Date of Issuance:

MAY 20 1998

Term of Issuance:

Unconditional

Name of Pesticide Product:

Frontline Top Spot for Dogs

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Louis S. Grosso, Ph.D.  
Director, Regulatory Affairs  
Merial Limited  
2100 Ronson Road, Bldg. D  
Iselin, NJ 08830

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/reregistered 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 unconditionally registered in accordance with FIFRA sec. 3(c) (5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c) (5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label change:

In the directions for use, 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. You may wish to consider including a table to clarify the appropriate combination of pipettes for dogs weighing over 88 lbs.

3. As set forth in your letter dated May 1, 1998, all product manufactured after January 1, 1999, shall be in child resistant packaging.

4. As stated in the review dated April 29, 1998, you must submit data on the rate of incidents per dose sold for Frontline Spray Treatment, Frontline Top Spot for Cats, and Top Spot for Dogs. This information must be submitted to EPA by December 31, 1998.

Signature of Approving Official:

Date: MAY 20 1998

CONCURRENCES

SYMBOL	7505C	75058					
SURNAME	[Signature]	[Signature]					
DATE	5/20/98	5/20/98					

5. You must continue to monitor misuse of Frontline products on rabbits or for treatment of ear mites. If such misuse continues, you must propose appropriate label amendments.

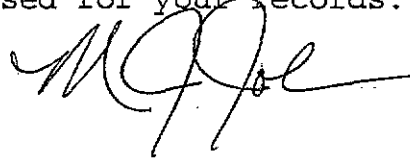
6. At your discretion, as set forth in PR Notice 98-6, you may list the active ingredient as "fipronil", and you do not need to include the chemical name.

7. You must submit individual incident reports on the breed Bichon Frisé, rather than including them with the summary reports which will be required under the final 6(a)(2) rule.

8. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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.

A handwritten signature in black ink, appearing to be 'M. G. J. P.', is written over the bottom right portion of the typed text.

3/7

<p><b>FRONTLINE® TOP SPOT™</b> for Dogs          (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>
---	---

**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,2S)-  
 (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)

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated:**

MAY 20 1998

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act,  
 as amended, for the pesticide  
 registered under EPA Reg. No.

65331-3

4/7

# 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.

5/7

**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. Persons applying this product must wear household latex gloves.

**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

6/7

### **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.

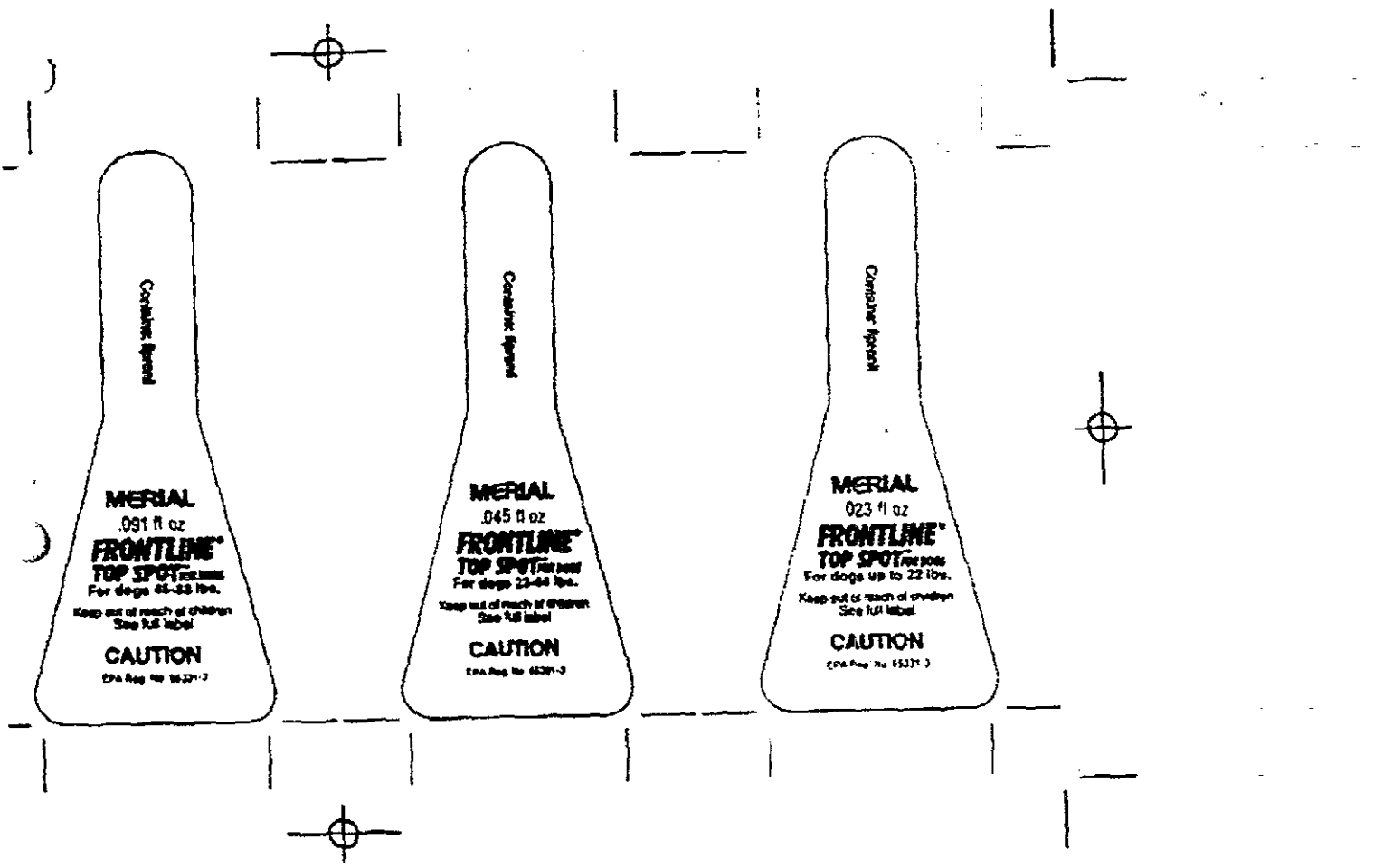
**STORAGE.** Store unused product in original container only, out of reach of children and animals.

**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.

7/7

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



Contains Spinal

**MERIAL**  
 .091 fl oz  
**FRONTLINE<sup>®</sup>**  
**TOP SPOT<sup>®</sup>** For dogs  
 For dogs up to 22 lbs.  
 Keep out of reach of children  
 See full label

**CAUTION**  
 EPA Reg. No. 65331-3

Contains Spinal

**MERIAL**  
 .045 fl oz  
**FRONTLINE<sup>®</sup>**  
**TOP SPOT<sup>®</sup>** For dogs  
 For dogs 23-44 lbs.  
 Keep out of reach of children  
 See full label

**CAUTION**  
 EPA Reg. No. 65331-3

Contains Spinal

**MERIAL**  
 .023 fl oz  
**FRONTLINE<sup>®</sup>**  
**TOP SPOT<sup>®</sup>** For dogs  
 For dogs up to 22 lbs.  
 Keep out of reach of children  
 See full label

**CAUTION**  
 EPA Reg. No. 65331-3