



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JAN 31 2001

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Zareen Ahmed, Ph.D.  
Merial  
2100 Ronson Road  
Iselin, NJ 08830-3077

Dear. Dr. Ahmed:

Subject: Frontline Spray  
EPA Reg. No. 65331-1  
Submission dated 1/16/01

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.

Change the first word of the container disposal statement to read "Securely."

Delete the following drug claim:

It quickly eliminates stress to pets from flea and tick annoyance, blood loss, biting and flea allergies.

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

Sincerely,

A handwritten signature in cursive script that reads "Ann Sibold".

Ann Sibold  
Acting Product Manager 10  
Insecticide Branch  
Registration Division (7505C)

## PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS: CAUTION.** Harmful if swallowed or absorbed through the skin. May cause severe eye irritation. Avoid breathing spray. 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. May cause severe eye irritation. Take care not to spray in the animal's eyes or facial area. Do not use on kittens and puppies under 8 weeks. Individual sensitivities, while rare, may occur after using any pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. Consult a veterinarian before using with other pesticides. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated animals. This product may be harmful to debilitated, aged, pregnant or nursing animals. Consult a veterinarian before using. Call 1-800-660-1842 for 24 hr. assistance.

**PHYSICAL OR CHEMICAL HAZARDS**  
**FLAMMABLE.** Keep away from heat and open flame.

### 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.** Security wrap original container in several layers of newspaper and discard in trash.

# FRONTLINE®

## SPRAY TREATMENT

8.5 fl oz (250 ml)  
17 fl oz (500 ml)

For Dogs, Puppies, Cats and Kittens  
Long Lasting Control  
of Fleas and Ticks

### ACTIVE INGREDIENT

fipronil:.....	0.29%
INERT INGREDIENTS .....	99.71%
TOTAL .....	100.00%

**CAUTION**  
**KEEP OUT OF REACH**  
**OF CHILDREN**

ACCEPTED  
WITH COMMENTS  
in EPA Letter Dated

JAN 31 2001

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

65331-1



## FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 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.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor 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 INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

## 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.

®FRONTLINE is a registered trademark of Merial.

EPA Reg. No. 65331-1  
EPA Est. 65331-FR-2

Made in France  
Merial Limited  
2100 Ronson Road  
Iselin, NJ 08830-3077, USA

FRONTLINE® SPRAY treatment for dogs, cats, puppies and kittens.

Frontline® provides effective flea and tick control for adult dogs and cats and for puppies and kittens 8 weeks of age or older.

- Fast-acting control
- Prevents reinfestation
- Kills adult fleas before they lay eggs
- Kills fleas and ticks for a minimum of 30 days

Frontline® is the only flea control product that contains fipronil, a patented GABA inhibitor.

Frontline® rapidly controls flea infestation by killing adult fleas. It quickly eliminates stress to pets from flea and tick annoyance, blood loss, biting and flea allergies.

Frontline® residual activity prevents reinfestation by killing fleas and ticks for at least 30 days. Studies have shown Frontline® may protect dogs against fleas for up to 90 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 PET, READ ENTIRE LABEL AND ATTACHED DIRECTIONS BEFORE EACH USE.**

Follow all directions and precautionary statements carefully. Use only on dogs and cats. Do not use on rabbits. Do not use on any other animals.

To kill fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease), apply to dogs, cats, puppies or kittens as follows:

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8.5 fl oz (250 ml)  
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Long Lasting Control  
of Fleas and Ticks

#### ACTIVE INGREDIENT

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TOTAL.....	100.00%

**CAUTION  
KEEP OUT OF REACH  
OF CHILDREN**



**How to unlock the trigger pump:** Press down on lock button located at the top of the trigger pump. At the same time, rotate the nozzle counterclockwise one full turn so that the tab on the lock button aligns with the notch in the nozzle. **To lock the trigger pump,** reverse the process. The trigger pump should be left in the locked position when not in use.

Wear household latex gloves. Hold bottle in upright position. Ruffle the animal's coat with one hand while applying spray mist to the animal's back, sides, abdomen, legs, shoulders and neck. For head and eye area, spray Frontline® on a gloved hand and rub gently into animal's hair. Do not get this product in you pet's eyes or mouth.

Apply spray mist until animal's hair is damp to thoroughly wet.

Approximately 1 to 2 pumps per pound of the animal's body weight will be required. Pets with long or dense coats will require the higher rate.

As with any flea control product, wash hands and exposed skin thoroughly with soap and water after use.

To prevent flea build-up or reinfestation, use Frontline® prior to the onset of flea season and monthly thereafter. Ticks do not need to receive spray directly upon their body for complete control. Do not reapply Frontline® for 30 days.

Product performance is unaffected by exposure to moderate rainfall or by bathing with most brands of pet shampoo.

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