

65331-1

8/6/2002

1/3



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

AUG - 6 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Timothy Dotson
Technical Director
Regulatory Affairs NA
Merial
3239 Satellite Blvd
Duluth, GA 30096

Dear Dr. Dotson:

Subject: Frontline Spray
EPA Reg. No. 65331-1
Submission dated 5-9-02

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.

You must delete the statement that says Frontline Spray is the only flea control product that contains fipronil. The other Frontline products also contain fipronil.

One copy of the finished labeling must be submitted prior to releasing the product for shipment. If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

Ann Sibold
for Joseph Tavano
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. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals. 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. Securely 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, Ticks and Chewing Lice

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:

AUG - 6 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA 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

3239 Satellite Blvd.

Duluth, GA 30096-4640, USA

3/2

FRONTLINE® Spray Treatment for dogs, cats, puppies and kittens.

FRONTLINE® Spray provides effective flea, tick and chewing lice 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 which may cause flea allergy dermatitis
- Kills fleas and ticks for a minimum of 30 days
- Rapidly eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations in dogs

FRONTLINE® Spray is the only flea control product that contains fipronil, a patented GABA inhibitor. FRONTLINE® Spray rapidly controls flea infestation by killing adult fleas. FRONTLINE® Spray residual activity prevents reinfestation by killing fleas, ticks and chewing lice for at least 30 days. Studies have shown FRONTLINE® Spray 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, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may transmit Lyme disease) and chewing lice, apply to dogs, cats, puppies or kittens as follows:

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, Ticks and Chewing Lice

ACTIVE INGREDIENT

fipronil.....	0.29%
INERT INGREDIENTS.....	99.71%
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® Spray 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® Spray 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® Spray for 30 days.

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

Made in France
Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096-4640, USA