

PM10

65331-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

EPA Reg. Number:  
65331-1

Date of Issuance:  
MAY 23 1996

Term of Issuance: Conditional

NOTICE OF PESTICIDE:  
  x   Registration  
      Reregistration

Name of Pesticide Product:  
Frontline Spray  
Treatment

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Rhone Merieux, Inc.  
115 Transtech Drive  
Athens, Georgia 30601

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 conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) with an expiration date of June 1, 1998 provided that you:

1. Submit and/or cite all data required for registration/reregistration 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 changes:
  - a. Revise the EPA Registration Number to read, "EPA Reg. No. 65331-1".
  - b. Delete the word "safe" from the marketing statements.
3. Submit a Confidential Statement of Formula revised so that the certified limits for the active ingredient bracket the nominal concentration of the active ingredient.

Signature of Approving Official:

*Susan Lewis*

Date:

MAY 23 1996

EPA Form 8570-6

CONCURRENCES

SYMBOL ▶	7505C PM10							
SURNAME ▶	Ann Sibold <i>AS</i>							
DATE ▶	5/23/96							

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

4. Report to the Agency the following data: dermal exposure of commercial pet groomers during application of fipronil pet spray as set forth in Pesticide Assessment Guideline No. 233. A protocol is required to be submitted within three months of the date of receipt of this registration notice. The final report is due within 18 months of the date of receipt of this registration notice. See attachment 1.

5. Report to the Agency inhalation exposure of commercial pet groomers during application of fipronil pet spray, as described in item 4 above and in accordance with Pesticide Assessment Guideline No. 234. A protocol is required to be submitted within three months of the date of receipt of this registration notice. The final report is due within 18 months of the date of receipt of this registration notice. See attachment 1.

6. Report to the Agency use and usage data for fipronil pet spray as set forth in Attachment 2 to this Registration Notice.

7. 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.

DERMAL AND INHALATION EXPOSURE FOR FIPRONIL PET SPRAY

The Agency is concerned about chronic risks from dermal and inhalation exposure of commercial applicators (pet groomers) using fipronil pet spray (Frontline Pet Spray). However, the Agency believes that limiting the registration to two years will adequately reduce these concerns during the period of registration. Data on exposure for this use are lacking, and, in order to refine risk estimates, the following studies are required:

Pesticide Assessment Guideline 233. A study of dermal exposure of commercial pet groomers during application of fipronil pet spray at the highest label rate and with the frequency typical of a pet groomer (that is, in terms of number of animals treated daily and duration of exposure). Justification and documentation must be provided to support the assumptions made about what is "typical."

Pesticide Assessment Guideline 234. Inhalation exposure must be included and measured in the study required to satisfy guideline 233:

USE AND USAGE DATA FOR FIPRONIL PET SPRAY

I. **What Data are Required.** The Agency is requiring submission of two types of data: usage data indicating volume and geographic area of use by pet groomers, and use data indicating the rate of use and methods of application used by pet groomers.

II. **Specific Data Requirements.**

A. **Usage Data.** Usage data must be submitted for fipronil pet spray. Whenever possible, data must be divided into product used primarily by professional pet groomers and product used by home users. All values may be given as ranges rather than single numbers. Provide the total pounds active ingredient sold, by U.S. Region (northeast, northwest, southeast, and southwest) per year for 1996 and 1997.

B. **Use Data.** The Agency is requiring information on how fipronil is typically used, not simply how it is registered for use. Typical use patterns are defined as those rates and application methods most commonly used on pets. In statistical terms, typical use is represented by the mode, not the mean or median. Specific data are required as follows:

1. For professional pet groomer use, provide numbers of animals treated per day and typical and maximum application rate.

2. For professional pet groomer use, describe typical application technique, including whether any protective clothing is worn during application. If protective clothing is used, describe it. Include the duration (in minutes or ranges of minutes) of a typical application. Provide justification and documentation for assumptions about what is "typical."

## FRONTLINE® SPRAY TREATMENT FOR DOGS, CATS, PUPPIES, AND KITTENS

Frontline® provides safe and 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®'s 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 any 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, cats, puppies or kittens as follows:

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, stomach, 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 your pet's eyes or mouth.

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

Approximately 3 to 6 pumps per pound (3.4 fl oz bottle)/ 1 to 2 pumps per pound (8.5 fl oz bottle) 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.



### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS: CAUTION.** Harmful if swallowed or absorbed through the skin. Causes eye injury. Avoid breathing spray mist. 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 ANIMALS:** For external use only. 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 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 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

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

### ACTIVE INGREDIENT

fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1H-pyrazole-3-carbonitrile..... 0.29%

**INERT INGREDIENTS**..... 99.71%

**TOTAL**..... 100.00%

**CAUTION  
KEEP OUT OF REACH  
OF CHILDREN**

3.4 fl oz (100ml)  
8.5 fl oz (250 ml)

### 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 INHALED:** Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

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

**IF ON SKIN:** Wash immediately with plenty of soap and water.

Get medical attention if irritation persists.

Phone Merieux, Inc.  
115 Transtech Drive • Athens, GA 30601 USA

EPA Reg. No. 65331-R  
EPA Est. No. 65331-FR-1, ->-2; 58996-MO-

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
registered under EPA Reg. No.  
65331-1

MAY 23 1996

ACCEPTED  
with COMMENTS  
In EPA Letter Dated

5/5