

PM10

65331-3

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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:

65331-3

Date of issuance:

JUN 1996

Term of Issuance:

Conditional

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):

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)(B) 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. 65331-3".
 - b. Comparisons between products are not acceptable on the label. Delete from the label wherever it appears the following phrases:
Nothing works like it
Nothing lasts like it
 - c. Modify the second sentence of the Precautionary statements to read as follows:
Causes eye injury.
 - d. Add to the directions for use, before the sentence which begins "Hold tube" the following: "Wear household latex gloves."

Signature of Approving Official:

OPK

Date:

CONCURRENCES

SYMBOL	PM10							
SURNAME	<i>A. D. ...</i>							
DATE	6/3/96							

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.

4. Report to the Agency the following data: dermal exposure of commercial pet groomers during application of fipronil spot treatment 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 use and usage data for fipronil spot treatment as set forth in Attachment 2 to this Registration Notice.

6. 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 EXPOSURE FOR FIPRONIL SPOT TREATMENT

The Agency is concerned about chronic risks from dermal exposure of commercial applicators (pet groomers) using fipronil spot treatment (Frontline Top Spot for Dogs). 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 spot treatment 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."

USE AND USAGE DATA FOR FIPRONIL SPOT TREATMENT

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 spot treatment. 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."

MAY 24 1996

DIRECTIONS FOR USE

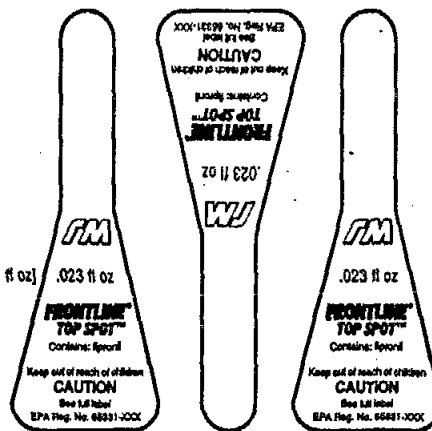
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ATTACHED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON 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: 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.

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.

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 is allergic to fleas, 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, for animals without Flea Allergy Dermatitis, and 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. Spotted areas may appear wet or oily up to 24 hours post treatment. Avoid contact with treated area until dry. Do not reapply Frontline® for 30 days.



FRONTLINE® TOP SPOT FOR DOGS
For dogs 23-44 lbs./For puppies up to 22 lbs.

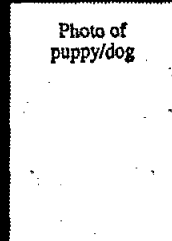


Photo of puppy/dog

Nothing works like it
Nothing lasts like it

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	
Spinosad	1.2%
(S)-Cyfluthrin	1.1%
Permethrin	1.1%
DEET	90.1%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION [0.045 fl oz (1.34 ml)/0.091 fl oz (2.68 ml) pipettes]
Contains 3 - 0.023 fl oz (0.67 ml) pipettes



ACCEPTED
with COMMENTS
in EPA Letter Dated

4 JUN 1996

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this product is registered under EPA Reg. No. 60831-XXXX

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MAY 24 1996

FRONTLINE® TOP SPOT™ FOR DOGS

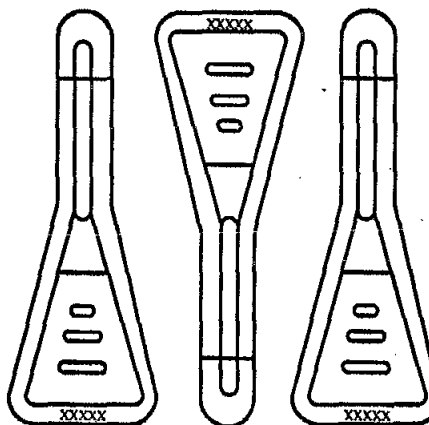
Frontline® provides convenient and effective flea and tick control for dogs and puppies up to 22 lbs. [from 23-44 lbs/for dogs weighing 45-88 lbs]

- Fast acting
- Long lasting - up to 3 months for fleas
- Prevents reinfestation
- Convenient to use
- Kills newly emerged adult fleas before they lay eggs
- Quickly eliminates the cause of 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)

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.



FRONTLINE® NOTHING WORKS LIKE IT • NOTHING LASTS LIKE IT



XXXXX = Lot No.

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. Pets may experience some temporary irritation at the site of product application. 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 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.

Rhone Merieux, Inc.
118 Transcend Drive
Athens, GA 30601 USA

Frontline is a registered trademark of Rhone Merieux, Inc.

EPA Reg. No. 66331-E
EPA Est. No. 66331-FR-2
66331-DEU-1; 66331-QA-1

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