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65331-1

5/20/98

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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 20 1998

NOTICE OF PESTICIDE:
[X] Registration
Reregistration

Term of Issuance: Unconditional

Name of Pesticide Product: Frontline Spray Treatment

(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

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

3. 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 is due December 31, 1998.

4. 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.

5. 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.

Signature of Approving Official:

[Handwritten Signature]

Date: MAY 20 1998

CONCURRENCES


Table with columns for SYMBOL, SURNAME, DATE, and multiple empty columns for CONCURRENCES. Includes handwritten entries for EPA Form 8570-6, 7505C, and dates 5/20/98.

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6. Submit two copies of the 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. J. ...', is written over the text 'A stamped copy of the label is enclosed for your records.'

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 ANIMALS: For external use only. May cause severe eye irritation. Take care not to spray in the animals eye 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 animals. Consult a veterinarian before using this product with other pesticides. This product may be harmful to debilitated, aged or 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.

FRONT-LINE 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-((1R,S)-(trifluoromethyl)sulfinyl)-1H-pyrazole-3-carbonitrile.....0.29%

INERT INGREDIENTS.....99.71%

TOTAL.....100.00%

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.
65331-1

CAUTION
KEEP OUT OF REACH
OF CHILDREN

8.5 fl oz (250ml)

3.4 fl oz (100 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.

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

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

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

Frontline® provides effective flea and tick control for adult dogs and cats for 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 which may result 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 PETS, 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.

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.

b/h