

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

Reregistration

NOTICE OF PESTICIDE:

<u>x</u> Registration

65331-2

Number:

Date of Issuance:

MAY 20 1998

Term of Issuance:

Unconditional

Name of Pesticide Product:

Frontline Top Spot for Cats

(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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must he 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 to EPA by 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.

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Signature of Approving Official:		Date:
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02 Form 0520-6		

CONCURRENCES										
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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.

FRONTLINE® TOP SPOTTM for Cats

For Cats and Kittens

Top Spot TM

For Cats

For Cats and Kittens

For Cats and Kittens

FRONTLINE® TOP SPOT™ FOR CATS

For cass and kittens.

Convenient, spot treatment for fast acting, long lasting control of fleas and ticks.

Kills fleas and ticks for at least 1 month.

KEEP OUT OF REACH OF CHILDREN CAUTION
Contains 3 / 0.017 fl oz (0.50 ml) pipettes

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAY 20 1998
Under the Federal Inserticide,
Fungicide, and Rodenticide Act,
no amended, for the persection
registered under EPA Rec. No.

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FRONTLINE® TOP SPOT™ FOR CATS

Frontline® provides convenient and effective flea and tick control for cats and kittens.

- Fast acting
- Long lasting at least 1 month
- Prevents reinfestation
- Convenient to use
- · Kills newly emerged adult fleas before they lay eggs
- Controls fleas which may cause 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.

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 kittens under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product for pets. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, 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.

Merial Limited
2100 Ronson Road
Iselin, NJ 08830-3077, USA
Frontline® is a registered trademark of Merial Limited.

EPA Reg. No. 65331-2 EPA EST. Nos. 65331-FR-2;65331-DEU-1; 65331-GA-1

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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 CATS 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 cats or kittens (12 weeks or older) as follows: Wear household latex gloves and 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. Only one pipette per treatment is needed.

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 has fleas which may cause flea allergy dermatitis, 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 or 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. Avoid contact with treated area until dry. Do not reapply Frontline® for 30 days.

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.

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PIPETTE IDENTIFICATION TOP SPOT FOR CATS EPA Reg. No. 65331-2

