

JUN 22 2001

Zareen Ahmed, Ph.D.
Merial
3239 Satellite Blvd.
Duluth, GA 30096-4640

Dear Dr. Ahmed:

Subject: Frontline Top Spot for Cats
EPA Reg. No. 65331-2
Letter dated 6/22/01

As discussed by phone on 6/22/01, the acute tox review dated 7/17/95 and revised 2/29/96 has been re-reviewed. The results of the skin irritation study show that this product is tox category IV for skin irritation. Therefore, if you chose to include an "If on Skin" first aid statement, you are strongly urged, but not required, to modify it to conform to PR Notice 2001-1 as follows:

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.

Alternately, since this product is now classified as tox category IV for dermal toxicity and irritation you may delete the "If on Skin" first aid statement. If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

for *Ann Sibold*
Marion J. Johnson, Jr.

Product Manager 3
Insecticide Branch
Registration Division (7505C)

ACCEPTED
with COMMENTS
to [unclear]

Master Label
Carton

JUN 22 2001

65331-2

FRONTLINE
Top Spot[®]
for cats

For Cats & Kittens

3 (6)
Applicators

FRONTLINE[®]

Kills fleas & ticks

Top Spot[®] for cats

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

For Cats & Kittens

ACTIVE INGREDIENTS	
fipronil	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

**KEEP OUT OF
REACH OF CHILDREN
CAUTION**

Contains 3 (6)-0.017 fl oz
(0.50 ml) applicators



Lift Here to Open



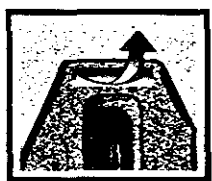
(PROTOTYPE GRAPHICS)

Printed at 110%
Actual Size

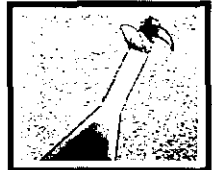
How to Apply

FRONTLINE®

Top Spot®
for cats



1. To Remove Applicator from Child-Resistant Package
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.



2. To Open Applicator
Hold upright and snap applicator tip away from face and body.



3. To Apply FRONTLINE
Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

INSERT COVER TAB HERE

Questions or Comments?
Call: 1-800-660-1842



FRONTLINE[®] For Cats & Kittens

Top Spot[®]

for cats

FRONTLINE provides convenient and effective flea and tick control for cats and kittens.

- **Fast-acting and long-lasting**
- **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 (which may carry 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-lasting activity.



Adult Flea



Brown Dog Tick



Lone Star Tick



Deer Tick



American Dog Tick

3 (6) Applicators
For Cats & Kittens

FRONTLINE[®]
Top Spot[®]
for cats



FRONTLINE[®]

Top Spot[®]
for cats



FRONTLINE provides convenient and effective flea and tick control for cats and kittens.

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 ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. 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 (which may carry Lyme disease), apply to cats or kittens (12 weeks or older) as follows:

Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

Frequency Of Application

When used monthly, FRONTLINE TOP SPOT FOR CATS completely controls both flea and tick infestations. Research demonstrates that FRONTLINE kills adult fleas for up to six weeks. FRONTLINE kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although FRONTLINE can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

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.

If you are not satisfied with FRONTLINE for any reason, the product will be replaced or the purchase price refunded. If you have any questions or comments, please call 1-800-660-1842

LOT NO:

Merial Limited
3239 Satellite Blvd
Duluth, GA 30096-4640, USA

MADE IN FRANCE

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EPA Reg. No. 65331-2
EPA Est. 65331-FR-2
(EPA Est.65331-DEU-1)



For animal use only

FRONTLINE®

Top Spot®
for cats

FOR CATS & KITTENS

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

ACTIVE INGREDIENT

fipronil	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE provides convenient and effective flea and tick control for cats and kittens.

- Fast-acting and long-lasting
- 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 (which may carry 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-lasting activity.

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 DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. 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 (which may carry Lyme disease), apply to cats or kittens (12 weeks or older) as follows:

Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE TOP SPOT FOR CATS completely controls both flea and tick infestations. Research demonstrates that FRONTLINE kills adult fleas for up to six weeks. FRONTLINE kills ticks for at least one month. A once monthly application is recommended where tick control is needed. Although FRONTLINE can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

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 AND 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.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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 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: 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.

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.

EPA Reg. No. 65331-2

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

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FRONTLINE[®]

"Flea and Tick Protection Card"

Top Spot[®]
for cats

Apply FRONTLINE[®] monthly, or as needed,
for continuous protection against fleas and ticks.

Pet's Name:

Date of first treatment:



Month 1



Month 2



Month 3



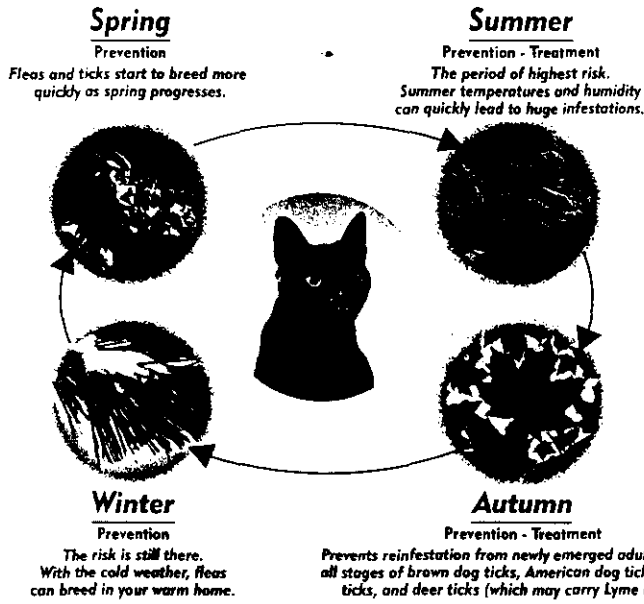
Place stickers on calendar as a reminder to apply FRONTLINE[®]
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xxx 2x [FFO] xxx

(Prototype Graphics)

Remove the adhesive backing and attach to your refrigerator door.

Fleas and ticks can be a year-round problem!



Flea and Tick Protection Card
Instructions for Use

The calendar stickers on the front of this card will help you remember to apply FRONTLINE.

- 1 - Write the date of your pet's first treatment in the box shown.
- 2 - After treating your pet, peel off the sticker corresponding to the current month.
- 3 - Place the remaining stickers on your calendar as a reminder to apply FRONTLINE monthly or as needed.



(Prototype Graphics)

FRONTLINE

"Flea and Tick Protection Card" **Top Spot**
for cats

Apply FRONTLINE® monthly, or as needed,
for continuous protection against fleas and ticks

Pet's Name:

Date of first treatment:



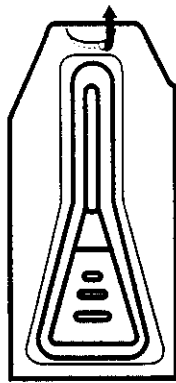
Month 1	Month 2	Month 3
Month 4	Month 5	Month 6

Place stickers on calendar as a reminder to apply FRONTLINE®
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(Prototype Graphics)

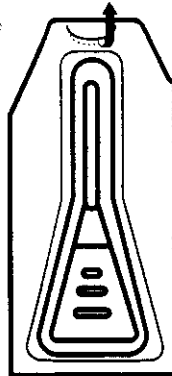
FRONTLINE®
Top Spot®



TO REMOVE APPLICATOR:
Use scissors. Or lift and remove
plastic tab to expose foil,
then peel down.

Cat
0.017 fl oz
Lot #

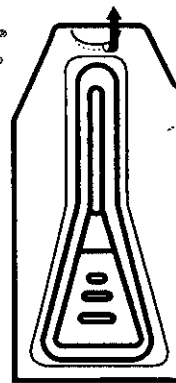
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Top Spot®



11/11

