



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 65331-2	2. EPA Product Manager Mr. Marion Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Frontline Top Spot for Cats	PM# 3	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd. Duluth, GA 30096 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION JAN 27 2003
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION Per PR-Notice 2001-6 (Disposal Statements) for changes to the Master Label. This notification is consistent with the guidance in PR Notice 2001-6 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula (CSF) of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the guidance of PR-Notice 2001-6 and the requirements of 40 CFR 156.10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 6 oz.	No. per container 3 and 6	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.017 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other Printed _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Timothy A. Dotson	Title Technical Director	Telephone No. (Include Area Code) 678-638-3713
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
Signature 	3. Title Technical Director	
4. Typed Name Timothy A. Dotson	5. Date 1/13/03	

2813



Timothy A. Dotson
Technical Director
Regulatory Affairs North America
Tel: 678-638-3713
Fax: 678-638-3715

3239 Satellite Blvd.
Duluth, GA 30096
Tel: 678 638 3000

January 13, 2003

Ms. Ann Sibold
Team 3, Insecticide Branch
Registration Division (H7505C)
Document Processing Desk (NOTIF)
Office of Pesticide Programs
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

SUBJECT: Frontline® Top Spot® for Cats, EPA Reg. No. 65331-2
Frontline® Top Spot® for Dogs, EPA Reg. No. 65331-3
Frontline® Plus for Cats, EPA Reg. No. 65331-4
Frontline® Plus for Dogs, EPA Reg. No. 65331-5
NOTIFICATION of Label Revisions Per PR-Notice 2001-6

Dear Ms. Sibold:

Please find enclosed a NOTIFICATION per PR-Notice 2001-6 for revision of pesticide disposal statements for the aforementioned Frontline® products. Since Merial chose to adopt the exact wording set forth in this notice, the Master labels are being submitted by NOTIFICATION only. Enclosed are copies of EPA Form 8570-1 along with a highlighted copy of the revised Master labels for the 3X/6X pipette presentations for cats/dogs including all four weight range presentations (dogs only). Please note the printed facsimile labels may not be actual size.

Thank you for your assistance. Please call me at 678-638-3713 (email at timothy.dotson@merial.com) if you have any questions regarding this submission.

Sincerely,

Timothy A. Dotson
Technical Director
Regulatory Affairs NA

www.merial.com



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3813



FRONTLINE
Top Spot[®]
for cats

For Cats & Kittens.

3(6)
Applicators

FRONTLINE

Top Spot[®]
for cats

Kills fleas & ticks

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

For Cats & Kittens.



Lift Here To Open

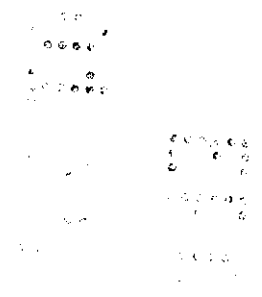
ACTIVE INGREDIENTS	
fipronil.....	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

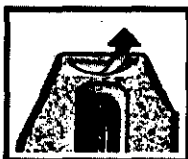
Contains 3(6)-0.017 fl oz
(0.50 ml) applicators

(Prototype Graphics)

NOTIFICATION
JAN 27 2003



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



Faint, illegible text at the bottom right of the page, possibly bleed-through from the reverse side.

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

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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.**

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.

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 and 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.

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

MADE IN FRANCE

EPA Reg. No. 65331-2
EPA Est. 65331-FR-2
(EPA Est. 74720-DEU-1)
(EPA Est. 74528-CHE-1)
(EPA Est. XXXXX-XXX-X)



LOT NO :

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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 and 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.



* 7 8 13 * * * * *

037 XXXXXX

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. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.

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®.

FRONTLINE and TOP SPOT are registered trademarks of Merck. ©2001 Merck. All rights reserved.

037 81270

Remove the adhesive backing and attach to your refrigerator door.

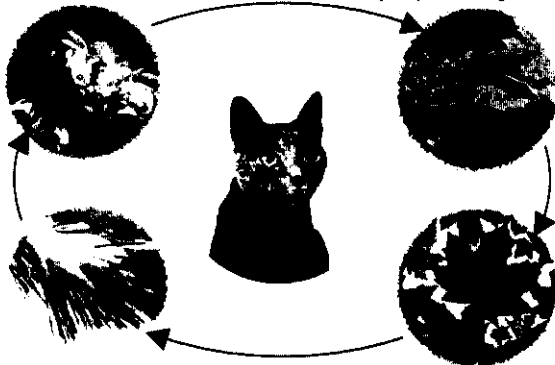
Fleas and ticks can be a year-round problem!

Spring

Prevention
Fleas and ticks start to breed more quickly as spring progresses.

Summer

Prevention - Treatment
The period of highest risk. Summer temperatures and humidity can quickly lead to huge infestations.



Winter

Prevention
The risk is still there. With the cold weather, fleas can breed in your warm home.

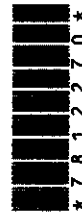
Autumn

Prevention - Treatment
Prevents reinfestation from newly emerged adult fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease).

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.



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®.

FRONTLINE and TOP SPOT are registered trademarks of Merial. ©2001 Merial. All rights reserved.

037 812372

Remove the adhesive backing and attach to your refrigerator door.

Fleas and ticks can be a year-round problem!

Spring

Prevention
Fleas and ticks start to breed more quickly as spring progresses.

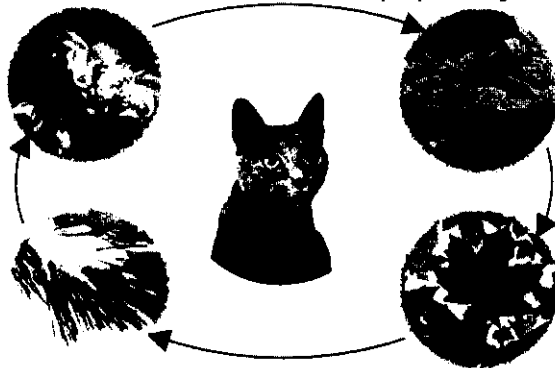
Summer

Prevention - Treatment
The period of highest risk. Summer temperatures and humidity can quickly lead to huge infestations.

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.



Winter

Prevention
The risk is still there. With the cold weather, fleas can breed in your warm home.

Autumn

Prevention - Treatment
Prevents reinfestation from newly emerged adult fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease).



