

65331-4

9/2/2014

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 2, 2014

Ms. Cassie Alexander  
Associate Manager, Regulatory Affairs  
Merial Limited  
3239 Satellite Boulevard, Building 500  
Duluth, GA 30096-4640

**Subject:** Label Notification per PRN 98-10 – Addition of Product Authentication Sticker  
Product Name: FRONTLINE® Plus For Cats  
EPA Registration Number: 65331-4  
Application Date: August 8, 2014  
Decision Number: 494213

Dear Ms. Alexander:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Richard J. Gebken".

Richard Gebken  
Product Manager 10  
Insecticide Branch  
Office of Pesticide Programs  
Date: September 2, 2014

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Merial Limited/65331-4	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Frontline Plus For Cats	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd., Bld. 500 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: <b>NOTIFICATION</b> EPA Reg. No. _____ Product Name <b>SEP 0 2 2014</b>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<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 of Facsimile Labeling including product authentication sticker. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula 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 terms of PR Notice 98-10 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.

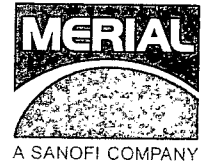
Section - III

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"/> Text <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 6 oz.	No. per container 1, 3 and 6	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
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 type="checkbox"/> On Label <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 checked="" type="checkbox"/> Other <u>Printed</u>	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Cassie Alexander	Title Associate Manager, RA N.America	Telephone No. (Include Area Code) 678-638-3753
<b>Certification</b> 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)
2. Signature <i>Cassie Alexander</i>	3. Title Associate Manager, RA N.America	
4. Typed Name Cassie Alexander	5. Date <i>August 8, 2014</i>	

Cassie Alexander  
Associate Manager  
Regulatory Affairs North America  
Tel: 678-638-3753  
Fax: 678-638-3707



August 8, 2014

Mr. Richard Gebken  
Project Manager, Registration Division  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room 5-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**NOTIFICATION**

SEP 02 2014

3239 Satellite Blvd  
Duluth, GA 30096  
Tel: 678.638.3000

**SUBJECT:** FRONTLINE® Plus for Cats, EPA Reg. No. 65331-4  
FRONTLINE® Plus for Dogs, EPA Reg. No. 65331-5

**RE: Submission of Labeling Notification for inclusion of a product authentication sticker**

Mr. Gebken:

Merial Limited (Merial) hereby provides a notification with facsimile labeling for the aforementioned Frontline products to provide for the inclusion of a product authentication sticker to the back panel of the product carton. Use of the sticker provides a noticeable marking that demonstrates authenticity of Merial product. No other labeling changes have been made.

Please find enclosed amended facsimile labeling in Attachments 1 and 2. Actual carton samples with the product authentication sticker attached is provided in Attachment 3 so that you can see the holographic nature of the sticker.

If you have any questions regarding this submission or require any additional information, please do not hesitate to contact me by phone at 678-638-3753 or by email at Cassie.Alexander@merial.com.

Sincerely,

Cassie Alexander  
Associate Manager  
Merial Limited  
Regulatory Affairs NA

- Enclosures: EPA Form 8570-1 for each product
- Attachment 1: One copy of facsimile labeling for Frontline Plus for Cats, EPA Reg. No. 65331-4
- Attachment 2: One copy of facsimile labeling for Frontline Plus for Dogs, EPA Reg. No. 65331-5
- Attachment 3: Two original cartons with original sticker  
Frontline Plus for Cats, EPA Reg. No. 65331-4  
Frontline Plus for Dogs, EPA Reg. No. 65331-5

www.merial.com

# NOTIFICATION

SEP 02 2014

Signature numérique de  
SERIE, No. de série 42476  
DIM = 176 x 112 - Pliée 88 x 112  
6 9 2342 192000 100 1 1  
MERCHEL, co-SENEC, Nympha  
41678  
Date: 2014 02 27 09 56 00  
01/00



## How to Apply **FRONTLINE<sup>®</sup> Plus** FOR CATS

### Step 1. OPEN Applicator

Hold upright with foil side toward you and snap applicator tip.

### Step 2. APPLY FRONTLINE Plus

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry. Do not apply to cats weighing less than 1.5 lbs or younger than 8 weeks of age. Do not allow your cat to ingest this product. Do not use more than one application per cat per month.

Questions or Comments?  
Call: **1-800-660-1842**,  
Monday-Friday, 8am-8pm EST or  
visit us at [www.FRONTLINE.com](http://www.FRONTLINE.com)



# FRONTLINE<sup>®</sup> Plus

Kills fleas, flea eggs & larvae,  
ticks & chewing lice

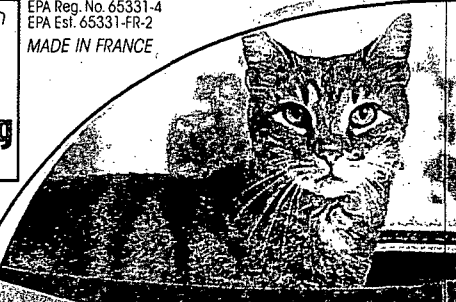
- Fast-acting
- Long-lasting
- Waterproof

ACTIVE INGREDIENTS:	
Fipronil	9.8%
(S)-methoprene	11.8%
INERT INGREDIENTS	78.4%
TOTAL	100%
NET CONTENTS: 1.0, 0.17 fl oz (0.50 mL) applicator	
1 monthly dose	

Kills ticks, including those that may transmit Lyme disease

For use **ONLY** on  
**CATS & KITTENS**  
**8 weeks**  
**and Older**  
**and Weighing**  
**Over 1.5 lbs.**

EPA Reg. No. 65331-4  
EPA Est. 65331-FR-2  
MADE IN FRANCE



053 906829



Technical area :  
No print except prod. barcode

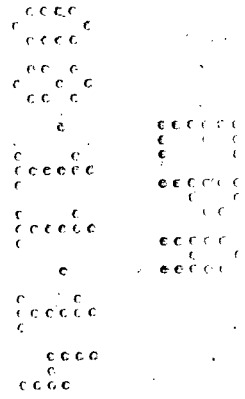
See inside panels  
for FIRST-AID and  
PRECAUTIONARY  
statements.  
KEEP OUT OF REACH OF CHILDREN  
**CAUTION**



### MERIAL GRAPHIC ARTWORK APPROVAL

Code: <b>053:906829</b>	VERSION:	COLORS:
PRODUCT: FRT PLUS NOTICE SINGLE CHATS RECTO	INITIALS: S3 AJ NSC	Black/Noir   Cyan
COUNTRY: United States of America (USA)	VERSION - DATE: A 17/07/13 17h20 B 22/07/13 13h57 C 05/08/13 COMPOSER ET 12h	Magenta
Dimensions: mm = 176 x 112 - Pliée 88 x 112 inches =	CANCEL AND REPLACE: 036 900999	Please use the official PANTONE® (P) matching system for an accurate color representation.

Marketing approval:	Regulatory approval:
COMPLETE NAME:	COMPLETE NAME:
DATE + SIGNATURE:	DATE + SIGNATURE:



# FRONTLINE<sup>®</sup> Plus FOR CATS

For use ONLY on CATS & KITTENS 8 weeks or older and weighing over 1.5 lbs.: Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, and chewing lice.

<b>ACTIVE INGREDIENTS</b>	
fluralaner.....	9.8%
(S)-methoprene.....	11.8%
<b>INERT INGREDIENTS</b> .....	78.4%
<b>TOTAL</b> .....	100.0%

**KEEP OUT OF REACH OF CHILDREN CAUTION**

### FRONTLINE<sup>®</sup> Plus for Cats:

#### Fleas

- Kills fleas, flea eggs and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Stops existing infestations and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

#### Ticks

- Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)
- Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

#### Lice

- Rapidly eliminates chewing lice infestations

**FRONTLINE Plus is approved for use on all cats, including:**

- Breeding, pregnant, and lactating queens
- Kittens as young as 8 weeks and weighing at least 1.5 lbs.

**One spot application is all that's needed:** FRONTLINE Plus spreads from the single point of application, rapidly covering the entire cat and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FRONTLINE Plus onto the skin and hair coat, so it keeps working even if the cat gets wet. Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treated cat. Fleas and ticks do not need to bite the cat in order to die.

#### 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, flea eggs & larvae, ticks, and chewing lice apply FRONTLINE Plus for Cats as follows:

- **OPEN** Applicator
- **APPLY** FRONTLINE Plus

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

Do not allow the cat to ingest the product. Do not apply to cats weighing less than 1.5-lbs. or younger than 8 weeks of age. Do not use more than one application per cat per month.

FRONTLINE Plus for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks. FRONTLINE Plus remains effective even after bathing, water immersion, or exposure to sunlight.

#### FREQUENCY OF APPLICATION

When used monthly, FRONTLINE Plus completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply FRONTLINE Plus for 30 days.

FRONTLINE Plus kills adult fleas, flea eggs, and flea larvae for up to six weeks. FRONTLINE Plus also prevents development of all flea stages for up to six weeks. FRONTLINE Plus can control fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FRONTLINE Plus kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE Plus kills all life stages of ticks (larva, nymph and adult). FRONTLINE Plus kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases. FRONTLINE Plus kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

#### 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: Nonrefillable container. Do not reuse or refill 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 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.

#### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

#### HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age or 1.5 lbs.

**SIDE EFFECTS:** Pets may experience some temporary irritation at the site of 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, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

#### PHYSICAL OR CHEMICAL HAZARDS

**COMBUSTIBLE:** Do not use or store near heat or open flame.

#### WARRANTY

To the extent consistent with applicable law, 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

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

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## MERIAL GRAPHIC ARTWORK APPROVAL

<b>Code:</b> 053:906829	<b>VERSION:</b>	<b>COLORS:</b>
PRODUCT: FRT PLUS NOTICE SINGLE CHATS VERSO	INITIALS: S1 AJ NSE	Black/Noir
COUNTRY: United States of America (USA)	VERSION - DATE: A 17/07/13 17h20 B 22/07/13 13h57 C 06/08/13 COMPOSER ET 12h	
Dimensions: mm = 176 x 112 - Pliee 88 x 112 inches =	CANCEL AND REPLACE: 036 900999	Please use the official PANTONE® (P) matching system for an accurate color representation.

<b>Marketing approval:</b>	<b>Regulatory approval:</b>
COMPLETE NAME:	COMPLETE NAME:
DATE + SIGNATURE:	DATE + SIGNATURE: