

65331-5

2/12/2013

1/22



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 12, 2013

Ms. Karen Mardis  
Senior Manager, Regulatory Affairs  
Merial Limited  
3239 Satellite Blvd. Building 500, Office 113  
Duluth, GA 30096-4640

Subject: Notification for Minor label Change  
EPA Registration Number: 65331-5  
Decision: 473828

Dear Ms. Mardis:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN) 98-10 dated December 20, 2012, for the abovementioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall 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 regarding this letter, please contact Driss Benmhend at (703) 308-9525.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken".

Richard J. Gebken  
Product Manager (10)  
Insecticide Branch  
Registration Division (7504P)

Enclosures: Copy of Label Stamped "Notification"

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 65331-5	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restrictive
4. Company/Product (Name) Frontline Plus For Dogs	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: 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 _____
<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.)

Addition of Alternate Brand Name per PR Notice 98-10

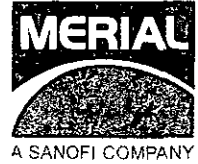
Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  If "Yes" Unit Packaging wgt. 6 oz.	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  If "Yes" Package wgt. 1, 3, or 6	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.023, 0.045, 0.091 and 0.136 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 Printed		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Karen Mardis	Title Senior Manager, Regulatory Affairs	Telephone No. (Include Area Code) 678-638-3706
<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 	3. Title Senior Manager, Regulatory Affairs	
4. Typed Name Karen Mardis	5. Date December 20, 2012	

3/22



**Karen Mardis**  
Senior Manager, Regulatory Affairs North America  
Tel: 678-638-3706  
Fax: 678-638-3707  
[karen.mardis@merial.com](mailto:karen.mardis@merial.com)

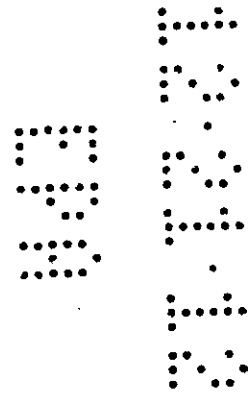
3239 Satellite Blvd  
Duluth, GA 30096  
Tel: 678.638.3000

December 20, 2012

Richard Gebken, Product Manager 10  
Registration Division  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**SUBJECT:** Addition of Alternate Brand Name

Frontline® Plus for Cats: EPA Reg. No. 65331-4  
Frontline Plus for Dogs: EPA Reg. No. 65331-5



Dear Mr. Gebken:

Merial hereby submits the following notification to add an alternate brand name to the above mentioned products. The alternate brand names will be Frontline Top Spot® for Cats (EPA Reg. No. 65331-4) and Frontline Top Spot for Dogs (EPA Reg. No. 65331-5). To that end please find attached:

- A completed application (EPA Form 8570-1) for each product
- 3 copies of labeling for each product

Please note that the labeling provided does not yet include all of the mitigation actions identified in the Agency's Pet Spot-On Mitigation Plan. Merial's submission of September 20, 2012 regarding specific points of the mitigation plan is still under review at the agency. Merial will update the labeling, as appropriate, once an agreement on these items has been reached.

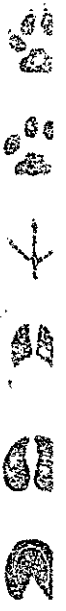
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false 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.

If you have any questions or require additional information, please contact me by telephone at 678-638-3138 or email at [Karen.Mardis@Merial.com](mailto:Karen.Mardis@Merial.com).

Sincerely,

Karen Mardis

www.merial.com



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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

**Master Label**  
**1x, 3x, and 6x presentations**

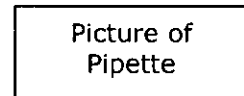
[Optional text appears in brackets-the final product label may include some or all of the optional text on the front, back or side panels.]

**FRONTLINE® Plus FOR DOGS**  
**[ABN] [FRONTLINE® Top Spot® FOR DOGS]**

(FRONT PANEL OF 3X and 6X CARTON)

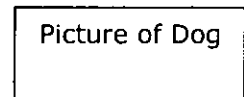
[Full brand name]

[3][6] doses



**Kills fleas, flea eggs & larvae, ticks, [&] chewing lice [& mosquitoes]**

- Fast-acting
- Long-lasting
- Waterproof



**Kills ticks, including those that may transmit Lyme disease**

[For use ONLY on DOGS & PUPPIES 8 Weeks or Older and up to **22lbs**]

[For use ONLY on DOGS **23 to 44lbs**]

[For use ONLY on DOGS **45 to 88lbs**]

[For use ONLY on DOGS **89 to 132lbs**]

**NOTIFICATION**  
**FEB 12 2013**

**ACTIVE INGREDIENTS:**

Fipronil.....9.8%

(S)-methoprene.....8.8%

**INERT INGREDIENTS.....81.4%**

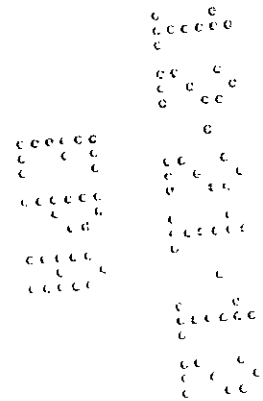
**TOTAL .....100%**

[Contains [3][6]-0.023 fl oz (0.67 ml) applicators]

[Contains [3][6]-0.045 fl oz (1.34 ml) applicators]

[Contains [3][6]-0.091 fl oz (2.68 ml) applicators]

[Contains [3][6]-0.136 fl oz (4.02 ml) applicators]



SEE INSERT FOR FIRST AID AND PRECAUTIONARY STATEMENTS

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(LEFT INNER PANEL OF 3X and 6X CARTON)

**[Full brand name]**

[Full or partial brand name] is:

- Fast-acting
- Long-lasting
- Waterproof

One spot application is all that's needed:

[Full or partial brand name] spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing [Full or partial brand name] onto the skin and hair coat, so it keeps working even if the dog gets wet.

Fleas, flea eggs & larvae, ticks and chewing lice are killed quickly after coming into contact with a treated dog. Fleas and ticks do not need to bite the dog in order to die.

[Full or partial brand name]:

**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 deer ticks (*Ixodes scapularis*), brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*) and lone star ticks (*Amblyomma americanum*)
- Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

**Lice**

- Rapidly eliminates chewing lice infestations

**[Mosquitoes]**

- [Kills mosquitoes]


**Mites**




- Aids in the control of sarcoptic mange infestations

[Full or partial brand name] is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks



-  Adult Fleas
-  Flea Eggs
-  Flea Larvae

-  Ticks
-  Chewing Lice
-  [Mosquitoes]

6/22

Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(RIGHT INNER PANEL OF 3X and 6X CARTON)

**How to Apply [Full or partial brand name]**



**Step 1. To REMOVE Applicator**

Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.



**Step 2. OPEN Applicator**

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



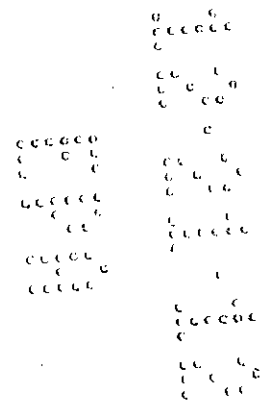
**Step 3. APPLY [Full or partial brand name]**

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

**Questions or Comments?**

**Call: 1-800-660-1842.**

**Monday-Friday, 8am-8pm EST or  
visit us at [www.FRONTLINE.com](http://www.FRONTLINE.com)**



Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

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(BACK PANEL OF 3X and 6X CARTON)

**[Full brand name]**

[Full or partial brand name] provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, [and] sarcoptic mites [and mosquitoes] for use ONLY on [dogs and puppies 8 weeks or older and up to 22 lbs.][dogs weighing 23-44 lbs.] [dogs weighing 45-88 lbs.][dogs weighing 89-132 lbs.].

**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 DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

To kill fleas, flea eggs & larvae, ticks, [and] chewing lice [and mosquitoes] apply [Full or partial brand name] as follows:

- To REMOVE Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.
- OPEN Applicator. Hold upright with foil side toward you and snap applicator tip.
- APPLY [Full or partial brand name]. Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the animal's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

[Full or partial brand name] is approved for use on breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.

[Full or partial brand name] remains effective even after bathing, water immersion, or exposure to sunlight.

**Frequency of Application**

When used monthly, [Full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply [Full or partial brand name] for 30 days.

[Full or partial brand name] kills adult fleas, flea eggs, and flea larvae for up to three months. [Full or partial brand name] also prevents development of all flea stages for up to three months. [Full or partial brand name] can control fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

[Full or partial brand name] kills ticks for at least one month. A once monthly application is recommended where tick control is needed. [Full or partial brand name] kills all life stages of ticks (larva, nymph and adult). [Full or partial brand name] kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

[Full or partial brand name] kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

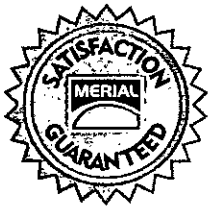
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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(BACK PANEL OF 3X and 6X CARTON – CONT.)

[Full or partial brand name] aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.  
[[Full or partial brand name] kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]

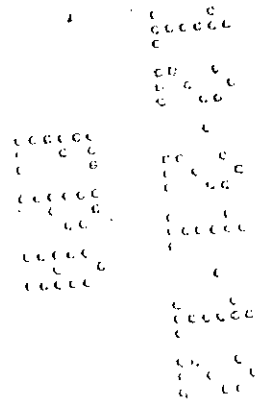


Please call our experts at **1-800-660-1842**, Monday-Friday, 8am-8pm EST, with any questions or comments about flea, tick, chewing lice, [or] sarcoptic mite [or mosquito] control or [Full or partial brand name]



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

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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

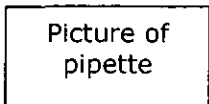
Notification

(TOP OUTER PANEL and LEFT SIDE OUTER PANEL OF 3X and 6X CARTON)

[Full brand name]

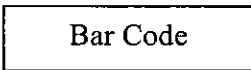
[For use ONLY on DOGS & PUPPIES 8 Weeks or Older and up to **22lbs**]  
[For use ONLY on DOGS **23 to 44lbs** ]  
[For use ONLY on DOGS **45 to 88lbs**]  
[For use ONLY on DOGS **89 to 132lbs**]

[3][6] doses



(BOTTOM OUTER PANEL OF 3X and 6X CARTON)

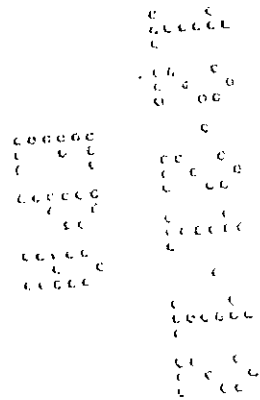
For dog use only



(RIGHT SIDE OUTER PANEL OF 3X and 6X CARTON)

EPA Reg. No 65331-5    LOT NO:

EPA Est.



10/22

Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(INSERT FOR 3X AND 6X)

[Full brand name]

For use ONLY on DOGS & PUPPIES 8 weeks or older:

Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, chewing lice, [and] sarcoptic mites [and mosquitoes].

**ACTIVE INGREDIENTS**

fipronil ..... 9.8%  
(S)-methoprene.....8.8%  
**INERT INGREDIENTS..... 81.4%**  
**TOTAL .....100.0%**

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

[Full or partial brand name]:

**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, Rocky Mountain spotted fever, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

**Lice**

- Rapidly eliminates chewing lice infestations

**Mites**

- Aids in the control of sarcoptic mange infestations

**[Mosquitoes]**

- [Kills mosquitoes]

[Full or partial brand name] is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks

**One spot application is all that's needed:**

[Full or partial brand name] spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing [Full or partial brand name] onto the skin and hair coat, so it keeps working even if the dog gets wet.

Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treated dog.

Fleas and ticks do not need to bite the dog 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 DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

11/22

Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(INSERT FOR 3X AND 6X – CONT.)

To kill fleas, flea eggs & larva, ticks, [and] chewing lice [and mosquitoes] apply [Full or partial brand name] as follows:

- To REMOVE Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.

- OPEN Applicator

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

- APPLY [Full or partial brand name]

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

[Full or partial brand name] is approved for use on all dogs, including breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.

[Full or partial brand name] remains effective even after bathing, water immersion, or exposure to sunlight.

**FREQUENCY OF APPLICATION**

When used monthly, [Full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply [Full or partial brand name] for 30 days.

[Full or partial brand name] kills adult fleas, flea eggs, and flea larvae for up to three months.

[Full or partial brand name] also prevents development of all flea stages for up to three months. [Full or partial brand name] can control fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

[Full or partial brand name] kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

[Full or partial brand name] kills all life stages of ticks (larva, nymph and adult). [Full or partial brand name] kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

[Full or partial brand name] kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

[Full or partial brand name] aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[[Full or partial brand name] kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container, 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.

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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(INSERT FOR 3X AND 6X – CONT.)

**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 or 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 puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. 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. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. 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.

**HOW SUPPLIED**

For easy and convenient treatment, [Full or partial brand name] is available in sizes for use ONLY on small dogs and puppies 8 weeks or older and up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra large dogs 89-132 lbs.

**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.

EPA Reg. No. 65331-5

**Merial Limited**

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

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Bar code

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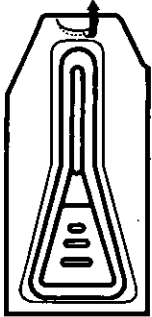
Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
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Notification

(3X and 6X BLISTER)

[Full or partial brand name]



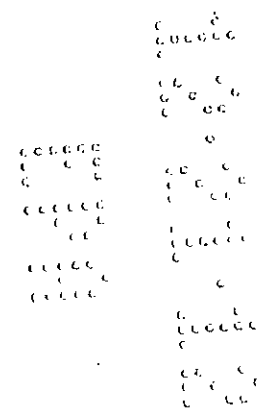
**TO REMOVE APPLICATOR:**

Lift and remove the plastic tab to expose foil backing;  
then peel away the foil. Or use scissors to open.

[0.023 fl oz][0.045 fl oz][0.091 fl oz][0.136 fl oz]

Lot #

**DOG [22][44][88][132]**



14/22

Reason to issue: Addition of Alternate Brand Name

Notification

EPA Reg. No. 65331-5

Information in [ ] is optional.

November 26, 2012

(1X, 3X, 6X PIPETTE)

**MERIAL**

Contains fipronil (9.8%)

(S)-methoprene (8.8%)



[0.023 fl oz][0.045 fl oz][0.091 fl oz][0.136 fl oz]

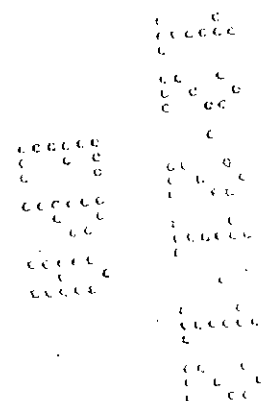
[Full or partial brand name]

Keep out of reach of children

See full label for additional directions

**CAUTION**

EPA Reg. No. 65331-5



15/22

Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(3X AND 6X COMPLIANCE CARD - FRONT)

**FRONTLINE®**

See other side for more...



**Fleas**



**Ticks**



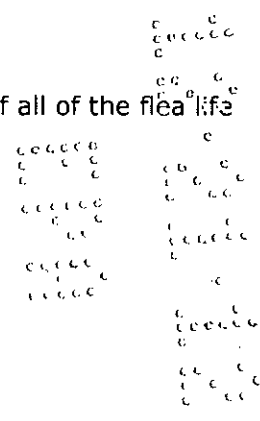
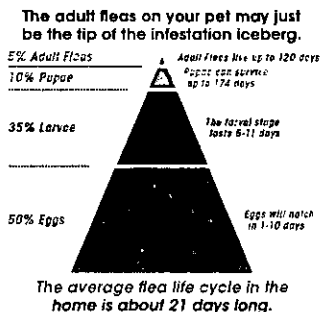
**Chewing Lice**

Some tips and other information

- To successfully control fleas and ticks, all dogs and cats must be treated with their own dose of FRONTLINE®.
- Apply according to label instructions, ensuring the product is applied to the skin, not on top of the fur and not near the collar. It may be helpful to remove the collar before application, so it doesn't absorb the product.
- Remember, your pet needs to be dry at the time FRONTLINE is applied and remain dry 24 hours after application.
- Verify pipette is empty after application (multiple squeezes may be necessary to apply the entire dose).
- Even indoor pets need flea and tick control because you or other pets in the household may bring fleas into the home. These fleas can lead to a flea infestation.

**FLEAS: What you need to know**

It can take up to 3 months to get rid of a serious flea infestation because of all of the flea life stages that existed BEFORE you started using FRONTLINE.



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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
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Notification

(3X AND 6X COMPLIANCE CARD - BACK)

Calendar Reminder Stickers

To ensure continued protection of your pets, use these stickers as a reminder to apply and re-purchase FRONTLINE.

After treating your pet for the first time, peel off the sticker and place on your calendar that day.

Place the remaining stickers on your calendar as a reminder to apply FRONTLINE monthly.

Don't forget to re-purchase!

**QUESTIONS?**

Contact your veterinarian or call our technical experts at **1-800-660-1842**.  
Monday-Friday, 8am-8pm. For more information, visit **www.FRONTLINE.com**.

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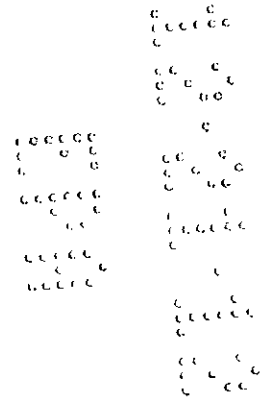
6 Months  
use all 6 stickers

3 stickers that read "Apply FRONTLINE®"  
with a picture of a pipette

3 Months

3 stickers that read "Apply FRONTLINE®"  
with a picture of a pipette

Bar code





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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

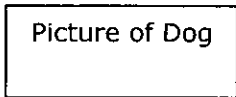
Notification

(FRONT PANEL OF 1X Insert)



[Full brand name]

EPA Reg. No. 65331-5  
EPA Est. No. 65331-FR-2  
MADE IN FRANCE



**Kills fleas, ticks, [&] chewing lice [& mosquitoes]**

- Fast-acting
- Long-lasting
- Waterproof

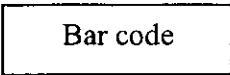
**ACTIVE INGREDIENTS:**

Fipronil.....	9.8%
(S)-methoprene.....	8.8%
INERT INGREDIENTS.....	81.4%
TOTAL .....	100%

- [Contains 1-0.023 fl oz (0.67 ml) applicator]
- [Contains 1-0.045 fl oz (1.34 ml) applicator]
- [Contains 1-0.091 fl oz (2.68 ml) applicator]
- [Contains 1-0.136 fl oz (4.02 ml) applicator]

**1 monthly dose**

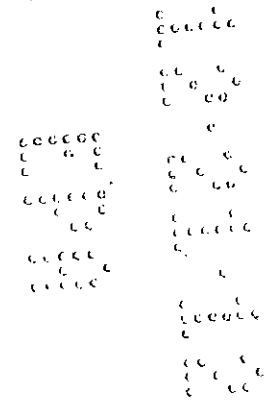
**Kills ticks, including those that may transmit Lyme disease**



- [For use ONLY on DOGS & PUPPIES 8 Weeks or Older and up to **22lbs**]
- [For use ONLY on DOGS **23 to 44lbs**]
- [For use ONLY on DOGS **45 to 88lbs**]
- [For use ONLY on DOGS **89 to 132lbs**]

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

**CAUTION**



Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

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(INNER PANELS FOR 1X INSERT)

[Full brand name]

**For use ONLY on DOGS & PUPPIES 8 weeks or older:  
Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, chewing lice, [and] sarcoptic mites [and mosquitoes].**

**ACTIVE INGREDIENTS**

fipronil .....	9.8%
(S)-methoprene.....	8.8%
<b>INERT INGREDIENTS.....</b>	<b>81.4%</b>
<b>TOTAL .....</b>	<b>100.0%</b>

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

[Full or partial brand name]:

**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, Rocky Mountain spotted fever, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis, and other tick-borne diseases

**Lice**

- Rapidly eliminates chewing lice infestations

**Mites**

- Aids in the control of sarcoptic mange infestations

**[Mosquitoes]**

- [Kills mosquitoes]

[Full or partial brand name] is approved for use on all dogs, including:

- Breeding, pregnant, and lactating bitches
- Puppies as young as 8 weeks

**One spot application is all that's needed:**

[Full or partial brand name] spreads from the single point of application, rapidly covering the entire dog and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing [Full or partial brand name] onto the skin and hair coat, so it keeps working even if the dog gets wet.

Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treated dog.

Fleas and ticks do not need to bite the dog 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 DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

19/22

(INNER PANELS FOR 1X INSERT - CONT.)

To kill fleas, flea eggs & larva, ticks, [and] chewing lice [and mosquitoes] apply [Full or partial brand name] as follows:

• **OPEN** Applicator

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

• **APPLY** [Full or partial brand name]

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

[Full or partial brand name] is approved for use on all dogs, including breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.

[Full or partial brand name] remains effective even after bathing, water immersion, or exposure to sunlight.

**FREQUENCY OF APPLICATION**

When used monthly, [Full or partial brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply [Full or partial brand name] for 30 days.

[Full or partial brand name] kills adult fleas, flea eggs, and flea larvae for up to three months.

[Full or partial brand name] also prevents development of all flea stages for up to three months. [Full or partial brand name] can control fleas for up to three months, however, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

[Full or partial brand name] kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

[Full or partial brand name] kills all life stages of ticks (larva, nymph and adult). [Full or partial brand name] kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

[Full or partial brand name] kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

[Full or partial brand name] aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

[[Full or partial brand name] kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.]

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

**STORAGE.** Store unused product in original container, 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.

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Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(INNER PANELS FOR 1X INSERT - CONT.)

**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 or 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 puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. 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. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. 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.

**HOW SUPPLIED**

For easy and convenient treatment, [Full or partial brand name] is available in sizes for use ONLY on small dogs and puppies 8 weeks or older and up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra large dogs 89-132 lbs.

**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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Reason to issue: Addition of Alternate Brand Name  
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November 26, 2012

Notification

(BACK PANEL OF 1X Insert)

**How to Apply [Full or partial brand name]**



**Step 1.**

**OPEN Applicator**

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



**Step 2.**

**APPLY [Full or partial brand name]**

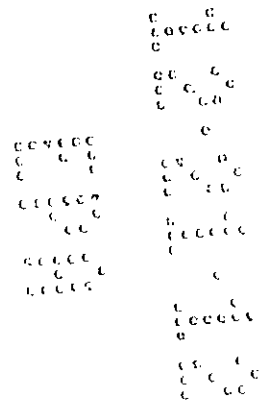
Part the dog's hair between the shoulder blades. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

**Questions or Comments?**

**Call: 1-800-660-1842.**

**Monday-Friday, 8am-8pm EST or  
visit us at [www. FRONTLINE.com](http://www.FRONTLINE.com)**

Bar code



22/22

Reason to issue: Addition of Alternate Brand Name  
EPA Reg. No. 65331-5  
Information in [ ] is optional.  
November 26, 2012

Notification

(1X BLISTER)

