65331-2.

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# 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: 65331-2 Decision: 473827

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.

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Sincerely,

I flache

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

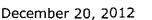
Enclosures: Copy of Label Stamped "Notification"

Image: Section Product Number     Image: Section Protection Agency Washington, Dc 20460     Amendment       Application for Pesticide - Section I     Amendment       I. Company/Product Number     2. EPA Product Manager     3. Proposed Classificat       Frontline Top Spot For Cats     Image: Section I     Image: Section I       S. Name and Address of Applicant <i>linclude 2IP Codel</i> 6. Expedited Reveiw. In accordance with FIFRA Section 2       Duluth, GA 30096     EPA Reg. No.       Image: Section - II     Section - II       Amendment - Explain below.     Fried printer linclude 2IP Codel       Merial Linited     Section - II       Amendment - Explain below.     Fried printer linclude in composition and is too       Besubmission in response to Agency latter drited     Fried printer linclude is information       Material This Product Will Be Packaged in:     Container       Change in primary Brand Name and deletion of website information per PR Notice 98-10     Section - III       Section - III     Section - III     Section of Line       I. Amendment Packaging     Interesting Packaged in:     Section of IM Packaging       Section - III     Section - III     Section of UM Packaging       Section - III     Section of Line     Section of Line       Section - III     Section of Line     Section of Line Diverse Section of Line       Section - III     Section of Line	Blassa cash instauctio	,	(	4				$\left( \right)$		2070.000	2 Print Form
1. Company/Product Number       2. EPA Product Manager       3. Proposed Cleasified         6331-2       Richard Gebken       Xone       R.         4. Company/Product (Nama)       PM4       Xone       R.         7 rontilled Top Spot For Cats       PM4       Xone       R.         5. Name and Address of Applicant (Include ZIP Code)       6. Expedited Reveiw. In accordance with FIFA Section 2         Merial Limited Top Spot For Cats       Check If this is a new address       Product Name         2.0 Duluth, GA 30096       EPA Reg. No.       Product Name         Section - II       Amendment - Explain below.       Final printed table in researses to for the composition and is top in primary Brand Name and delection of website information per PR Notice 98-10       Creation of the costage with the Studie Peckaging         Yee       Notification - Explain below.       Section - III       Creatification with the Reckaging         Indext Name       Water Soluble Peckaging       2. Type of Centainer       Creatification         Change in primary Brand Name and delection of website information per PR Notice 98-10       Creatification       Creatification of Label Directione for the costage with the soluble Peckaging       2. Type of Centainer         Soction - III       No       Yee       No. per container       Metai Perice Cite <t< th=""><th></th><th><u>u on r</u></th><th>L Environmenta <sub>Washi</sub></th><th>United States I <b>Protectic</b> ngton, DC 204</th><th>160</th><th>- -</th><th></th><th>×</th><th>Registra Amendi Other</th><th>ation</th><th>OPP Identifier Numbe</th></t<>		<u>u on r</u>	L Environmenta <sub>Washi</sub>	United States I <b>Protectic</b> ngton, DC 204	160	- -		×	Registra Amendi Other	ation	OPP Identifier Numbe
65331-2       Richard Gehken       Image: Section 1         4. Company/Product (Name)       PM#       10         5. Nome and Address of Applicant Unclude ZIP Code!       6. Expandited Reveiw. In accordance with FIFAA Section 1         6. Statistic Bivd, Bid, 500       Duluth, GA 30096       Final printed lebels in repsonse to intervent of the section 1         1. Amendment - Explain below.       Product Name       Product Name         Image: Section - 11       Section - 11         1. Amendment - Explain below.       Product Name         Image: Section - 11       The printed lebels in repsonse to intervent dated         Image: Section - 11       The product Name         Image: Section - 11       Section - 11         Image: Section - 11       Section - 11         Image: Section - 11       Section - 111         Image: Section - 111       Section - 111         Image: Section - 112       Section - 111				Applicatio	n for Pe	stic	ide - Sec	tion	1		
4. CompanyProduct (Mama) Frontiline Top Spot For Cats 5. Name and Address of Applicant <i>linclude 2IP Code/</i> Merial Linited 3.239 Statilite Bids, Bid, 500 Duluth, GA 30096  Check <i>if this is a new address</i> Product is similar or identical in composition and is to:  Check <i>if this is a new address</i> Product Name Section - II  Amendment - Explain balow.  Resubmission in response to Agency letter dated  Merial Linited  Charles <i>if this is a new address</i> Product Name  Explanation: Use additional page(a) if necessary. (For section 1 and Section 11.)  Charles <i>if this is a new address</i> Explanation: Use additional page(a) if necessary. (For section 1 and Section 11.)  Amendment - Explain balow.  Resubmission in response to Agency letter dated  Merial Linited  Charles <i>if this is a new address</i> Explanation: Use additional page(a) if necessary. (For section 1 and Section 11.)  Charles <i>if the Product Will Be Packaged bit</i> Charles <i>if the Product Bit Bit Bi</i>		lumber						neger		r	
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Child-Resistant Packaging       Unit Packaging       Water Soluble Packaging       2. Type of Container         X Yes       No       X Yes       Metal         No       If "Yes"       No. per       Plastic         be submitted       Goz.       1,3or6       Package wgt       No. per         2. Location of Net Contents Information       4. Size(s) Retail Container       S. Location of Label Directions       On Label Directions         Child-Resident in Which Label is Affixed to Product       Lithograph Package rigleed       X Other       Label insert         Section - IV       Section - IV       States directly below for identification of individual to be contacted, if necessary, to process this application.)         Name       Title       Senior Manager, Regulatory Affairs       6. Date Application.]         I certify that the statements I have made on this form and eli attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.       3. Title         Signature       S. Title       Senior Manager, Regulatory Affairs       6. Date Application (Stampet)         4. Typed Name       5. Date       State       Stampet)	•				Sectio	n - I	11			ç	C C
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Paper glued Stenciled         Section - IV         1. Contact Point (Complete items directly below for identification of individuel to be contacted, if necessary, to process this explication.)         Name Karen Mardis       Title Senior Manager, Regulatory Affairs         I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlinglty false or misleading statement may be punishable by fine or imprisonment or both under applicable law.       6. Date Application (Stamped Senior Manager, Regulatory Affairs)         2. Signature       3. Title Senior Manager, Regulatory Affairs       6. Date Application (Stamped Senior Manager, Regulatory Affairs)         4. Typed Name       5. Date       5. Date	Label	× c	ontainer		0.017 fl.	0Z.		x	On Labelii		paning product
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this explication.)         Name Karen Mardis       Title Senior Manager, Regulatory Affairs       Telephone No. (Include Area 678-638-3706         I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlinglty false or misleading statement may be punishable by fine or imprisonment or both under applicable law.       6. Date Application Received         2. Signature       3. Title Senior Manager, Regulatory Affairs       6. Date Application Received         4. Typed Name       5. Date       5. Date	6. Manner in Which Le	ibel is i	Affixed to Product	Lithogi Paper Stencil	raph glued ied		X Other	<u>La</u>	bel insert		
Name Karen Mardis       Title Senior Manager, Regulatory Affairs       Telephone No. (Include Area 678-638-3706         Certification I certify that the statements I have made on this form and ell attachments thereto are true, accurate and complete. I acknowledge that any knowlinglty false or misleading statement may be punishable by fine or imprisonment or both under applicable law.       6. Date Application Received (Stamped Senior Manager, Regulatory Affairs         2. Signature       3. Title Senior Manager, Regulatory Affairs       5. Date					Sectio	<u>n - I</u>	V				
Karen Mardis       Senior Manager, Regulatory Affairs       678-638-3706         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 knowlinglty 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       5. Date	1. Contact Point (Con	nplete i	items directly below f	or identification	n of individu	el to b	e contacted,	if nec	essary, to pr	ocess this	epplication.)
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Karen Mardis December 20, 2012	4. Typed Name				5. Date						
	Karen Mardis		· · · · ·		December	· 20, 2	012				

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

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Karen Mardis Senior Manager, Regulatory Affairs North America Tel: 678-638-3706 Fax: 678-638-3707 karen.mardis@merjal.com



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: Change in Primary Brand Name

Frontline<sup>®</sup> Top Spot<sup>®</sup> for Cats: EPA Reg. No. 65331-2 Frontline Top Spot for Dogs: EPA Reg. No. 65331-3 SANOFI COMPANY

3239 Satellite Blvd Duluth, GA 30096

Tel: 678.638.3000

### Dear Mr. Gebken:

Merial hereby submits the following notification to change the primary brand name of the above mentioned products to FIPAIRA<sup>TM</sup> for Cats (EPA Reg. No. 65331-2) and FIPAIRA for Dogs (EPA Reg. No. 65331-3). To that end please find attached:

- A completed application (EPA Form 8570-1) for each product
- \$ 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.

Additionally the following non-FIFRA information was deleted from the labeling: website information for <u>www.Frontline.com</u>.

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 is 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 <u>Karen.Mardis@Merial.com</u>.

Sincerely, Karen Mardis

### 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.]

## FIPAIRA<sup>™</sup> FOR CATS

(FRONT PANEL OF 3X and 6X CARTON)		
FIPAIRA <sup>TM</sup> FOR CATS	[3][6] doses	Picture of pipette
<ul> <li>Kills fleas, ticks, [&amp;] chewing lice [&amp; mosquitoes]</li> <li>Fast-acting</li> <li>Long-lasting</li> <li>Waterproof</li> </ul>	Picture of C	at
Kills ticks, including those that may transmit Lyme disease For use ONLY on CATS & KITTENS 8 Weeks and Older.		
ACTIVE INGREDIENT: Fipronil9.7% INERT INGREDIENTS90.3% TOTAL100%	NOTIFICATION FEB 1 2 2013	
Contains [3][6]-0.017 fl oz (0.50 ml) applicators	¢ ¢10¢	r _
SEE INSERT FOR FIRST AID AND PRECAUTIONARY STATEMENTS KEEP OUT OF REACH OF CHILDREN CAUTION		с с с с с с с с с с с с с с с с с с с

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

## FIPAIRA<sup>TM</sup> FOR CATS

## **FIPAIRA<sup>™</sup> for Cats** is:

- Fast-acting
- Long-lasting
- Waterproof

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

FIPAIRA 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 FIPAIRA 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.

## FIPAIRA for Cats:

#### Fleas

- Kills fleas
- · Kills newly emerged adult fleas before they lay eggs
- 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, haemobartonellosis and other tick-borne diseases

## Lice

Rapidly eliminates chewing lice infestations

### [Mosquitoes]

• [Kills mosquitoes]

### FIPAIRA is approved for use on all cats, including:

- Breeding, pregnant, and lactating queens
- Kittens as young as 8 weeks



Adult Fleas

	•	
P	Chewing	Lice

Ticks

[Mosquitoes]

2 of 19

Notification

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

## How to Apply FIPAIRA<sup>™</sup> FOR CATS







### 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 FIPAIRA

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the <u>skin</u> 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.

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Questions or Comments? Call: 1-800-660-1842. Monday-Friday, 8am-8pm EST

Bar code

(BACK PANEL OF 3X and 6X CARTON)

## FIPAIRA<sup>™</sup> FOR CATS

FIPAIRA for Cats provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, [and] chewing lice [and mosquitoes] for use ONLY on cats and kittens 8 weeks or older.

### **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, ticks, [and] chewing lice [and mosquitoes] apply FIPAIRA for Cats 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 FIPAIRA. 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.

FIPAIRA for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks.

FIPAIRA remains effective even after bathing, water immersion, or exposure to sunlight.

### **Frequency of Application**

When used monthly, FIPAIRA completely controls flea, tick and chewing lice infestations. Do not reapply FIPAIRA for 30 days.

FIPAIRA kills adult 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.

FIPAIRA kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FIPAIRA kills all life stages of ticks (larva, nymph and adult).

babesiosis, anaplasmosis, haemobartonellosis and other tick-borne diseases  $c_c^{eee}c_c$  FIPAIRA kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

[FIPAIRA kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days, with a monthly application.]

Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

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

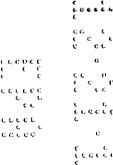


Please call our experts at **1-800-660-1842**, Monday-Friday, 8am-8pm EST, with any questions or comments about flea, tick, [or] chewing lice, [or mosquito] control or FIPAIRA.



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

<sup>TM</sup> FIPAIRA is a trademark of Merial.
 ©2012 Merial Limited, Duluth, GA.
 All rights reserved.



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Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

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

## FIPAIRA<sup>™</sup> FOR CATS

For use ONLY on CATS & KITTENS 8 Weeks and Older

[3][6] doses

Picture of pipette

## [BOTTOM OUTER PANEL OF 3X and 6X CARTON]

For cat use only

Bar Code

EPA Est.

10

Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

### (INSERT FOR 3X AND 6X)

## FIPAIRA<sup>™</sup> FOR CATS

For use ONLY on CATS & KITTENS 8 weeks or older: Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, [and] chewing lice [and mosquitoes].

ACTIVE INGREDIENT

fipronil	
TOTAL100%	
KEEP OUT OF REACH OF CHILDREN	
CAUTION	•
FIPAIRA <sup>™</sup> for Cats:	
Fleas	
Kills fleas	·
<ul> <li>Kills newly emerged adult fleas before they lay eggs</li> </ul>	
<ul> <li>Stops existing infestations and prevents establishment of new infestations</li> </ul>	
<ul> <li>Kilis fleas which may cause flea allergy dermatitis</li> </ul>	
Ticks	
• Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (Rhip	oicephalus
sanguineus), American dog ticks (Dermacentor variabilis), lone star ticks (Amblyom	ma
americanum) and deer ticks (Ixodes scapularis),	
• Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesic	osis,
anaplasmosis and other tick-borne diseases	
Lice	
<ul> <li>Rapidly eliminates chewing lice infestations</li> </ul>	e e coscit
[Mosquitoes]	c contito c
• [Kills mosquitoes]	сс с с с с
FIPAIRA is approved for use on all cats, including:	e ne
• Breeding, pregnant, and lactating queens	۲.
• Kittens as young as 8 weeks	
One spot application is all that's needed:	C (. i.
FIPAIRA spreads from the single point of application, rapidly covering the entire cat a	ndierere
localizing in the hair, on the surface of the skin and in the sebaceous glands. These g	lands,act
as a reservoir, continuously replenishing FIPAIRA onto the skin and hair coat, so it ke	eps ᢆ
working even if the cat gets wet.	elever e
Fleas, ticks, and chewing lice are killed quickly after coming into contact with a treate	ed cat. e
Fleas and ticks do not need to bite the cat in order to die.	ιεία ε
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.

### (INSERT FOR 3X AND 6X - CONT.)

To kill fleas, ticks, [and] chewing lice [and mosquitoes] apply FIPAIRA for Cats 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 FIPAIRA

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.

FIPAIRA for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks.

FIPAIRA remains effective even after bathing, water immersion, or exposure to sunlight. **FREQUENCY OF APPLICATION** 

When used monthly, FIPAIRA completely controls flea, tick and chewing lice infestations. Do not reapply FIPAIRA for 30 days.

FIPAIRA kills adult 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.

FIPAIRA kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

FIPAIRA kills all life stages of ticks (larva, nymph and adult). FIPAIRA kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

FIPAIRA kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed.

[FIPAIRA kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 23 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 only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-200-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.

#### Notification

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(INSERT FOR 3X AND 6X - CONT.)

**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 kittens 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. 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.

EPA Reg. No. 65331-2

### **Merial Limited**

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

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Bar Code

Notification

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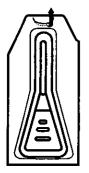
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Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

(3X and 6X Back of Blister)

**FIPAIRA<sup>™</sup>** 



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

0.017 fl oz Lot #

CAT

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Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

(1X, 3X, 6X PIPETTE)

MERIAL Contains fipronil (9.7%)



0.017 fl oz FIPAIRA™

Keep out of reach of children See full label for additional directions **CAUTION** EPA Reg. No. 65331-2

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(3X AND 6X COMPLIANCE CARD - FRONT)

**FIPAIRA**<sup>TM</sup>

See other side for more...







**Chewing Lice** 

Fleas

#### Ticks

Some tips and other information

- ☑ To successfully control fleas and ticks, all dogs and cats must be treated with their own dose of FIPAIRA<sup>™</sup>.
- 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 FIPAIRA is applied and remain dry 24 hours after application.
- $\square$  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 mayte 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 flife' stages that existed BEFORE you started using FIPAIRA.

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> > 66666

5% Adult Fiers	Aduit Fiens here op in 120 daes
10% Fupae	Pupok can survive up to 174 days
35% Larvae	The Jerval stage Jests 5-77 days
50% Eggs	Fggs with batch in 1-10 days

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Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

## (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 repurchase FIPAIRA.

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 FIPAIRA monthly.

Don't forget to re-purchase!

#### QUESTIONS?

6 Months

**3 Months** 

use all 6 stickers

Contact your veterinarian or call our technical experts at **1-800-660-1842**. Monday-Friday, 8am-8pm.

<sup>™</sup> FIPAIRA is a trademark of Merial. ©2012 Merial Limited, Duluth, GA. All rights reserved.

> 3 stickers that read "Apply FIPAIRA<sup>™</sup>" with a picture of a pipette

3 stickers that read "Apply FIPAIRA<sup>TM</sup>" with a picture of a pipette

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Bar Code

## (FRONT PANEL OF 1X Insert)

Notification

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Picture of Cat

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FIPAIRA<sup>™</sup> FOR CATS

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

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

- Fast-acting
- Long-lasting
- Waterproof

ACTIVE INGREDIENTS: Fipronil......9.7% INERT INGREDIENTS......90.3% TOTAL ......100%

Contains 1-0.017 fl oz (0.50 ml) applicator 1 monthly dose

Kills ticks, including those that may transmit Lyme disease

Bar code

For use ONLY on CATS & KITTENS 8 weeks and Older.

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

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Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

### (INNER PANELS FOR 1X INSERT)

## FIPAIRA<sup>™</sup> FOR CATS

For use ONLY on CATS & KITTENS 8 weeks or older: Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, [and] chewing lice [and mosquitoes].

## ACTIVE INGREDIENT

fipronil 9.7%	
INERT INGREDIENTS90.3%	
TOTAL100%	
KEEP OUT OF REACH OF CHILDREN	
CAUTION	
FIPAIRA <sup>™</sup> for Cats:	
Fleas	
Kills fleas	
Kills newly emerged adult fleas before they lay eggs	
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 ( <i>Rhip</i>	
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Rapidly eliminates chewing lice infestations	
[Mosquitoes]	ε ε εφοεφυ
• [Kills mosquitoes]	e
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Breeding, pregnant, and lactating queens	ç cc
Kittens as young as 8 weeks	0
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Reason to issue: Change Brand Name EPA Reg. No. 65331-2 Information in [] is optional. November 26, 2012

### (INNER PANELS FOR 1X INSERT - CONT.)

To kill fleas, ticks, [and] chewing lice [and mosquitoes] apply FIPAIRA for Cats as follows: • OPEN Applicator

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

APPLY FIPAIRA

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[FIPAIRA kills mosquitoes within 24 hours for up to 14 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 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.

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**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.

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**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.

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### PHYSICAL OR CHEMICAL HAZARDS

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

## WARKANIT

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### **Merial Limited**

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

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### Notification

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(BACK PANEL OF 1X Insert)

## How to Apply FIPAIRA<sup>™</sup> FOR CATS





# Step 1.

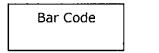
**OPEN** Applicator

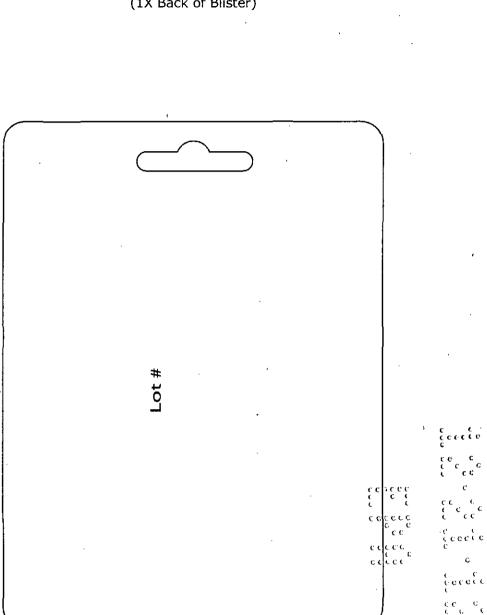
Hold upright with foil side toward you and snap applicator tip.

### Step 2. *APPLY* FIPAIRA

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the <u>skin</u> 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.

## Questions or Comments? Call: 1-800-660-1842. Monday-Friday, 8am-8pm EST





(1X Back of Blister)

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