



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 65331-5	2. EPA Product Manager Ms. Linda Arrington	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Frontline Plus for Dogs	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Merial Limited 3239 Satellite Blvd. Duluth, GA 30096 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION MAR 24 2004
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

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

NOTIFICATION per PR-Notice 98-10. This notification is consistent with the guidance in PR Notice 98-10 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula (CSF) of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the guidance of PR-Notice 98-10 and the requirements of 40 CFR 156.10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

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

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Timothy A. Dotson	Title Technical Director	Telephone No. (Include Area Code) 676-636-3713
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		h. Date Application Received (Stamped)
Signature 	3. Title Technical Director	
4. Typed Name Timothy A. Dotson	5. Date 3/11/04	



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

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

March 11, 2004

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

SUBJECT: Frontline® Top Spot® for Cats, EPA Reg. No. 65331-2
Frontline® Top Spot® for Dogs, EPA Reg. No. 65331-3
Frontline® Plus for Cats, EPA Reg. No. 65331-4
Frontline® Plus for Dogs, EPA Reg. No. 65331-5
NOTIFICATION of Label Revisions Per PR-Notice 98-10

Dear Ms. Sibold:

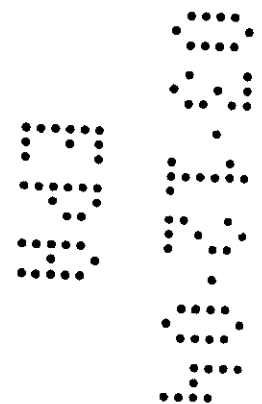
Please find enclosed a NOTIFICATION per PR-Notice 98-10 for revision of the consumer satisfaction guarantee statement located on the carton. Please note that this statement is a 'non-FIFRA' related agreement, if you will, between Merial and the consumer. A portion of this statement is being deleted. Merial's telephone access number will remain the same, providing the consumer with access to Merial's technical services as needed. This statement is similar to the warranty statement on the label, and therefore the Master labels are being submitted by NOTIFICATION only.

Enclosed are copies of EPA Form 8570-1 along with two copies of the revised Master labels for each of the 3X/6X pipette presentations for cats/dogs including all four weight range presentations (dogs only). One copy has been highlighted for ease of review.

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

Sincerely,


Timothy A. Dotson
Technical Director
Regulatory Affairs NA



www.merial.com



* Registered Trademark of Merial Ltd.

FRONTLINE®

3(6)
Applicators

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

- Fast-acting
- Kills ticks including those that may transmit Lyme disease
- Waterproof

Plus

for dogs

For Dogs & Puppies 8 weeks or older and up to 22 lbs.

For Dogs 23-44 lbs.

For Dogs 45-88 lbs.

For Dogs 89-132 lbs.

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

KEEP OUT OF REACH OF CHILDREN CAUTION

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



MERIAL

Lift Here To Open

FRONTLINE®

Plus

for dogs

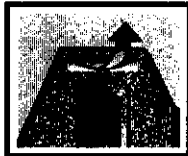
For Dogs & Puppies 8 weeks or older and up to 22 lbs.
For Dogs 23-44 lbs.
For Dogs 45-88 lbs.
For Dogs 89-132 lbs.

3(6)

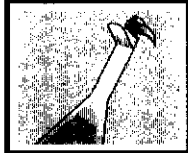
Applicators

(Prototype Graphics)

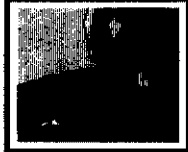
How to Apply **FRONTLINE®** *Plus* for dogs



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



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



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

INSERT COVER TAB HERE

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



3(6)
Applicators

LOT NO :

FRONTLINE[®] *Plus* for dogs

FRONTLINE PLUS FOR DOGS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for (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.)

- **Stops and prevents infestations**
- **Kills adult fleas, flea eggs & flea larvae**
- **Prevents all flea stages (eggs, larvae, pupae) from developing**
- **Kills fleas which may cause flea allergy dermatitis**
- **Kills all stages of deer ticks (which may carry Lyme disease), brown dog ticks, American dog ticks & lone star ticks**
- **Kills mosquitoes**
- **Prevents and controls reinfestations**
- **Rapidly eliminates infestations with chewing lice**
- **Aids in control of sarcoptic mange infestations**
- **Can also be used on breeding, pregnant and lactating bitches**
- **Fast-acting**
- **Long-lasting**
- **Waterproof**
- **Convenient to use**

FRONTLINE PLUS FOR DOGS contains fipronil and the insect growth regulator (IGR) (S)-methoprene. FRONTLINE PLUS effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.



Flea Adult



Flea Eggs



Flea Larvae



Flea Pupae



Brown Dog Tick



Lone Star Tick



Deer Tick



American Dog Tick



Chewing Lice



Mosquito

036 XXXXX

6/13

NOTIFICATION

MAR 24 2004

3(6) Applicators
For Dogs & Puppies 8 weeks or older and up to 22 lbs.
For Dogs 23-44 lbs.
For Dogs 45-88 lbs.
For Dogs 89-132 lbs.

FRONTLINE[®] Plus for dogs

3(6) Applicators

FRONTLINE[®] Plus for dogs

FRONTLINE PLUS FOR DOGS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for (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, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply to dogs or puppies (8 weeks or older) as follows. Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

FRONTLINE PLUS aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FRONTLINE PLUS FOR DOGS can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating bitches.

Frequency Of Application

When used monthly, FRONTLINE PLUS FOR DOGS completely breaks the flea life cycle and controls tick and chewing lice infestations.

Research demonstrates that FRONTLINE PLUS kills adult fleas, flea eggs, and flea larvae for up to three months. FRONTLINE PLUS also prevents development of all flea stages for up to three months. Although FRONTLINE PLUS can control fleas for up to three months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

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

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

With a monthly application, FRONTLINE PLUS kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

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

MADE IN FRANCE

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EPA Reg. No. 65331-5
EPA Est. 65331-FR-2
(EPA Est. 65331-DEU-1)
(EPA Est. 65331-GA-1)
(EPA Est. 74528-CHE-1)



Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, lice and mosquito control or FRONTLINE PLUS.



FRONTLINE[®] Plus for dogs

For Dogs & Puppies 8 weeks or older and up to 22 lbs.
For Dogs 23-44 lbs.
For Dogs 45-88 lbs.
For Dogs 89-132 lbs.

3(6) Applicators

LOT NO :

For animal use only

FRONTLINE® Plus for dogs

FOR DOGS & PUPPIES 8 weeks or older
Convenient spot treatment for fast-acting,
long-lasting control of fleas, ticks and chewing lice.
FRONTLINE® PLUS also kills mosquitoes.

ACTIVE INGREDIENTS

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

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® PLUS FOR DOGS provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes for dogs and puppies.

- Stops and prevents infestations
- Kills adult fleas, flea eggs, and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Kills fleas which may cause flea allergy dermatitis
- Kills all stages of deer ticks (which may carry Lyme disease), brown dog ticks, American dog ticks, and lone star ticks
- Kills mosquitoes
- Prevents and controls reinfestations
- Rapidly eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Can also be used on breeding, pregnant and lactating bitches
- Fast-acting
- Long-lasting
- Waterproof
- Convenient to use

FRONTLINE® PLUS FOR DOGS contains fipronil and the insect growth regulator (IGR) (S)-methoprene. *FRONTLINE® PLUS* effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

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.**

To kill fleas, all stages of **brown dog ticks, American dog ticks, lone star ticks, deer ticks** (which may carry Lyme disease), chewing lice and mosquitoes, apply to dogs or puppies (8 weeks or older) as follows:

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

FRONTLINE® PLUS aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

FRONTLINE® PLUS FOR DOGS can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating bitches.



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037 XXXXX

FREQUENCY OF APPLICATION

When used monthly, *FRONTLINE® PLUS FOR DOGS* completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that *FRONTLINE® PLUS* kills adult fleas, flea eggs, and flea larvae for up to three months. *FRONTLINE® PLUS* also prevents development of all flea stages for up to three months. Although *FRONTLINE® PLUS* can control fleas for up to three months, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. *FRONTLINE® PLUS* kills ticks for at least one month. A once monthly application is recommended where tick control is needed. *FRONTLINE® PLUS* kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed. With a monthly application, *FRONTLINE® PLUS* kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days. *FRONTLINE® PLUS FOR DOGS* remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply *FRONTLINE® PLUS* for 30 days.

STORAGE AND DISPOSAL

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

STORAGE. Store unused product in original container only, out of reach of children and animals.

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

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

FIRST AID

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

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Flush eyes with plenty of water. Call a doctor if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on 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 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

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

HOW SUPPLIED

For easy and convenient treatment, *FRONTLINE® PLUS FOR DOGS* is available in sizes for 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

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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DOGS compliance card x3 - Front

FRONTLINE[®] *Plus* for dogs




"Flea, Tick, Chewing Lice and Mosquito Protection Card"

Apply FRONTLINE PLUS FOR DOGS monthly, or as needed, for continuous protection against fleas, ticks and chewing lice.

Per's Name:

Date of first treatment:



- Month 1 
- Month 2 
- Month 3 

XXXXXX LEO

Place stickers on calendar as a reminder to apply FRONTLINE PLUS FOR DOGS.

(Prototype Graphics)

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DOGS compliance card x3 - Back

Remove the adhesive backing and attach to your refrigerator door

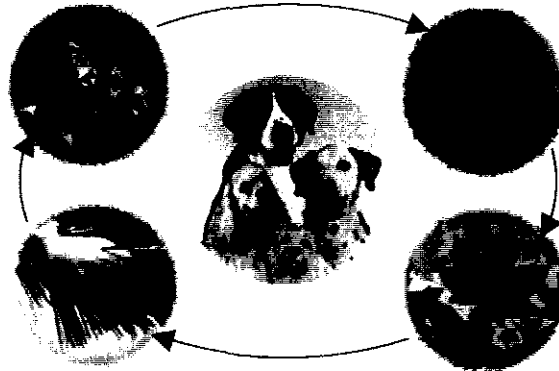
Fleas, Ticks, Chewing Lice and Mosquitoes can be a year-round problem!

Spring

Fleas and ticks breed more frequently as spring progresses.

Summer

The period of highest risk. Summer temperatures and humidity can quickly lead to flea and tick infestations.



Winter

Minimize the risk of any reinfestation.

Autumn

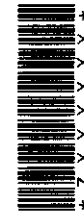
The risk continues. Fleas and ticks (brown dog ticks, American dog ticks, lone star ticks, and deer ticks which may carry Lyme disease) remain a threat.

Flea, Tick, Chewing Lice and Mosquito Protection Card

Instructions for Use

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

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



(Prototype Graphics)




DOGS compliance card x6 - Front



FRONTLINE® *Plus* for dogs
 "Flea, Tick, Chewing Lice and Mosquito Protection Card"

Apply FRONTLINE PLUS FOR DOGS monthly, or as needed, for continuous protection against fleas, ticks and chewing lice.

Pet's Name:

Date of first treatment:

Month 1  Month 2  Month 3 

Month 4  Month 5  Month 6 

FRONTLINE is a registered trademark of Merial. ©2003 Merial. All rights reserved.

Place stickers on calendar as a reminder to apply FRONTLINE PLUS FOR DOGS.

(Prototype Graphics)

FRONTLINE PLUS FOR DOGS

FRONTLINE PLUS FOR DOGS

DOGS compliance card x6 - Back

Remove the adhesive backing and attach to your refrigerator door

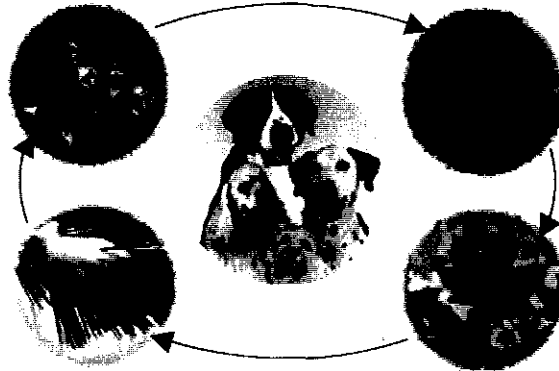
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(Prototype Graphics)

FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus}

MERIAL **MERIAL** **MERIAL** **MERIAL**

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

Dog 22
0.023 fl oz
Lot #

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

Dog 22
0.023 fl oz
Lot #

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

Dog 22
0.023 fl oz
Lot #

FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus}

MERIAL **MERIAL** **MERIAL** **MERIAL**

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

Dog 44
0.045 fl oz
Lot #

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

Dog 44
0.045 fl oz
Lot #

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

Dog 44
0.045 fl oz
Lot #

FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus}

MERIAL **MERIAL** **MERIAL** **MERIAL**

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

Dog 88
0.091 fl oz
Lot #

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

Dog 88
0.091 fl oz
Lot #

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

Dog 88
0.091 fl oz
Lot #

FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus} FRONTLINE^{Plus}

MERIAL **MERIAL** **MERIAL** **MERIAL**

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

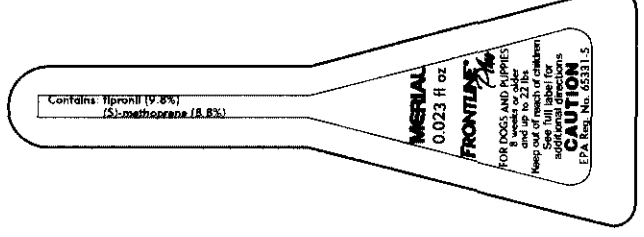
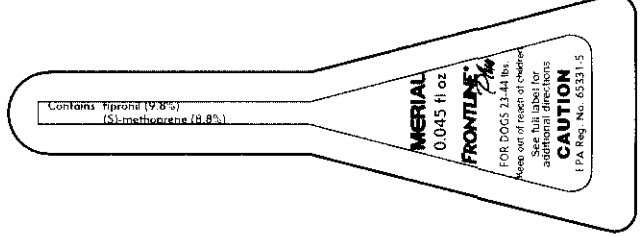
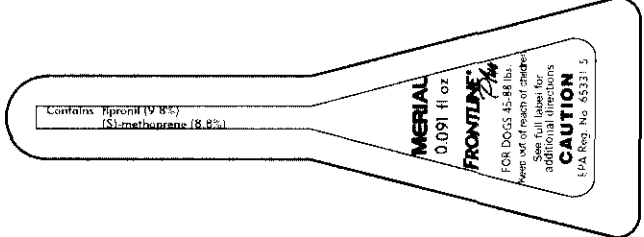
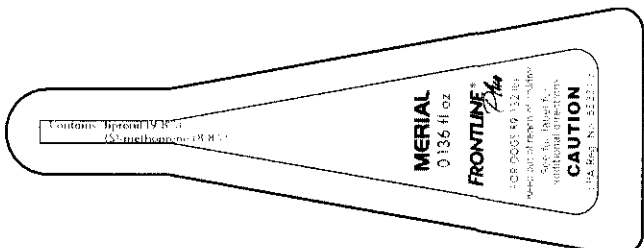
Dog 132
0.136 fl oz
Lot #

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

Dog 132
0.136 fl oz
Lot #

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

Dog 132
0.136 fl oz
Lot #



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