

65331-3

10-23-2003

1/12



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

OCT 23 2003

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Timothy A. Dotson
Merial
3239 Satellite Blvd.
Duluth, GA 30096

Dear Mr. Dotson:

Subject: Frontline Top Spot for Dogs
EPA Reg. No. 65331-3
Submission dated 7/23/03

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

Delete references to mosquito "infestations" on dogs. Mosquitoes do not infest dogs as do fleas, ticks, and chewing lice.

Delete the reference to "unique mode of action" as this is a comparative claim.

If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

A handwritten signature in cursive script that reads "Ann Sibold".

for

Linda Arrington
Acting Product Manager 10
Insecticide Branch
Registration Division (7505C)


2/12

ACCEPTED
with comments
OCT 23 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg. No. 65531-3

FRONTLINE
Top Spot[®]
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.



FRONTLINE

Kills fleas, ticks, chewing lice & mosquitoes

Top Spot

1076145


- Convenient spot treatment for fast-acting, long-lasting control of fleas, ticks and chewing lice
- Kills mosquitoes
- Waterproof

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.

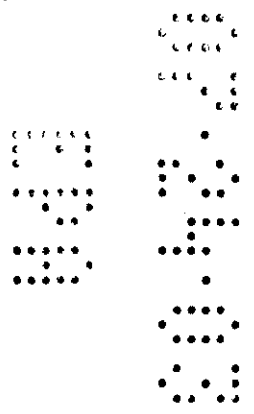
ACTIVE INGREDIENTS	
fluralaner.....	9.7%
INERT INGREDIENTS.....	90.3%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

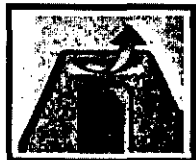
Contains 3(6)-0.023 fl oz (0.67 ml) applicators
 Contains 3(6)-0.045 fl oz (1.34 ml) applicators
 Contains 3(6)-0.091 fl oz (2.68 ml) applicators
 Contains 3(6)-0.136 fl oz (4.02 ml) applicators



(Prototype Graphics)



How to Apply **FRONTLINE[®]** *Top Spot[®]* for dogs



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



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

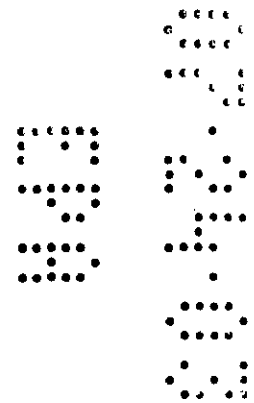


3. To Apply FRONTLINE[®]
Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

INSERT COVER TAB HERE

+

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



4/12

FRONTLINE®

Top Spot®

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.

FRONTLINE provides convenient and effective flea, tick, chewing lice and mosquito control 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.).

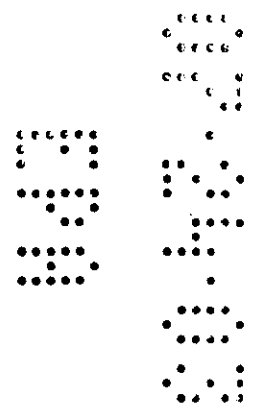
- **Fast-acting and long-lasting**
- **Prevents reinfestation**
- **Convenient to use**
- **Kills newly emerged adult fleas before they lay eggs**
- **Controls fleas which may cause flea allergy dermatitis**
- **Kills all stages of brown dog ticks, American dog ticks, lone star ticks and deer ticks (which may carry Lyme disease)**
- **Kills mosquitoes**
- **Rapidly eliminates infestations with chewing lice**
- **Aids in control of sarcoptic mange infestations**
- **Can also be used on breeding, pregnant and lactating bitches**
- **Waterproof**

FRONTLINE contains the active ingredient fipronil which has a unique mode of action that effectively targets fleas, ticks, chewing lice and mosquitoes. 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.



-  Flea Adult
-  Brown Dog Tick
-  Lone Star Tick
-  Deer Tick
-  American Dog Tick
-  Chewing Lice
-  Mosquito

036 XXXXXX



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FRONTLINE
Top Spot
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.
Applicators (3)



FRONTLINE[®]

Top Spot[®]
for dogs

FRONTLINE TOP SPOT FOR DOGS provides convenient and effective flea, tick, chewing lice and mosquito control 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 and puppies (8 weeks or older) as follows:

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

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

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

Frequency Of Application

When used monthly, FRONTLINE TOP SPOT FOR DOGS completely controls flea, tick and chewing lice infestations. Research demonstrates that FRONTLINE kills adult fleas for up to three months. Although FRONTLINE 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 kills ticks for at least one month. A once monthly application is recommended where tick control is needed.

FRONTLINE 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 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

EPA Reg. No. 65331-3
EPA Est. 65331-FR-2
(EPA Est. 65331-DEU-1)
(EPA Est. 65331-GA-1)
(EPA Est. XXXXX-XXX-X)

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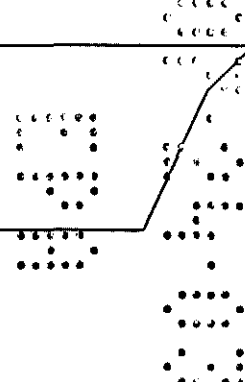
Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, lice and mosquito control or FRONTLINE TOP SPOT.

If you have purchased this product from a veterinary clinic and are not satisfied with its performance as per the label, Merial may provide replacement product or refund of the purchase price. Please call Merial for details.



LOT NO :

For animal use only



FRONT

BACK

6/12

FRONTLINE® Top Spot® 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® also kills mosquitoes.

ACTIVE INGREDIENT

fipronil	9.7%
INERT INGREDIENTS	90.3%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FRONTLINE® provides convenient and effective flea, tick, chewing lice and mosquito control for dogs and puppies.

- Fast-acting and long-lasting
- Prevents reinfestation
- Convenient to use
- Kills newly emerged adult fleas before they lay eggs
- Controls fleas which may cause flea allergy dermatitis
- Kills all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)
- Kills mosquitoes
- Rapidly eliminates infestations with chewing lice
- Aids in control of sarcoptic mange infestations
- Can also be used on breeding, pregnant and lactating bitches
- Waterproof

FRONTLINE® contains the active ingredient fipronil which has a unique mode of action that effectively targets fleas, ticks, chewing lice and mosquitoes. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON 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® aids in the control of sarcoptic mange infestations. Multiple monthly treatments are recommended for the elimination of mites.

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

037 XXXXXX



* 7 X X X X X X *

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE® TOP SPOT FOR DOGS completely controls flea, tick and chewing lice infestations. Research demonstrates that FRONTLINE® kills adult fleas for up to three months. Although FRONTLINE® 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® kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE® 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® kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days. FRONTLINE® remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE® for 30 days.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. **STORAGE.** Store unused product in original container only, out of reach of children and animals.

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

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

FIRST AID

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

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

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

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

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on 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

FLAMMABLE: Keep away from heat and open flame.

HOW SUPPLIED

For easy and convenient treatment, FRONTLINE® TOP SPOT 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. 65331-3

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



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7/12

DOGS compliance card x3 - Front

FRONTLINE

"Flea, Tick, Chewing Lice, Mosquito Protection Card" **Top Spot**

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

Pet's Name: _____

Date of first treatment: _____



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Month 1

Month 2

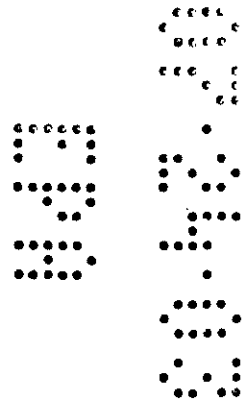
Month 3



Place stickers on calendar as a reminder to apply FRONTLINE®.

887 330003 887

(Prototype Graphics)



DOGS compliance card x3 - Back

Remove the adhesive backing and attach to your refrigerator door.

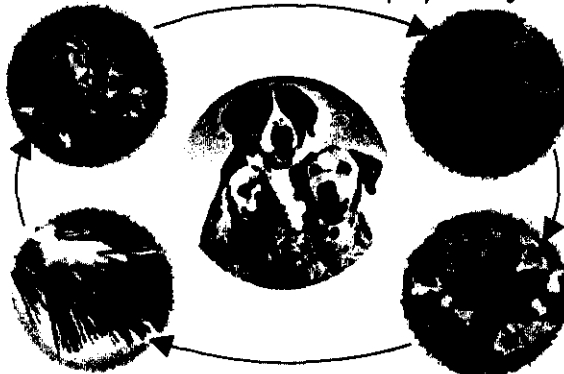
Fleas, Ticks, Chewing Lice and Mosquitoes can be a year round problem!

Spring

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

Summer

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



Winter

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

Autumn

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

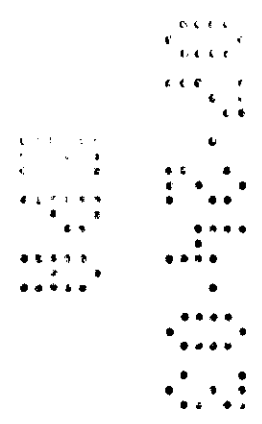
Flea, Tick, Chewing Lice and Mosquito Protection Card

Instructions for Use
The calendar stickers on the front of this card will help you remember to apply FRONTLINE®.

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



(Prototype Graphics)



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DOGS compliance card x6 - Front

FRONTLINE

"Flea, Tick, Chewing Lice and Mosquito Protection Card" **Top Spot**

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

Pet's Name: _____

Date of first treatment: _____



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Month 1

Month 2

Month 3



Month 4

Month 5

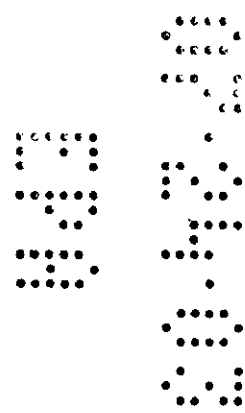
Month 6



Place stickers on calendar as a reminder to apply FRONTLINE®.

697 703030

(Prototype Graphics)



10/12

DOGS compliance card x6 - Back

Remove the adhesive backing and attach to your refrigerator door.

Fleas, Ticks, Chewing Lice and Mosquitoes can be a real pest problem!

Spring

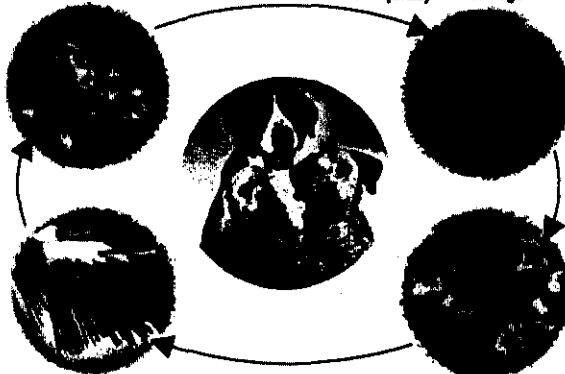
Prevention

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

Summer

Prevention - Treatment

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



Winter

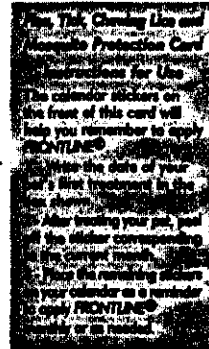
Prevention

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

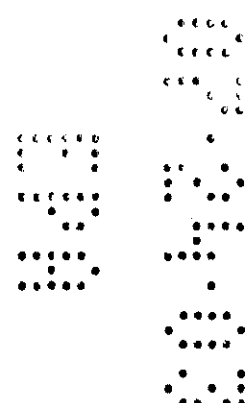
Autumn


Prevention - Treatment


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



(Prototype Graphics)




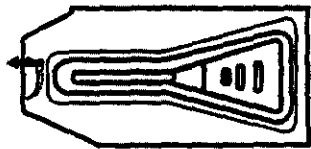
FRONTLINE[®] Top Spot[®] 



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


Dog 22
0.023 fl oz
Lot #

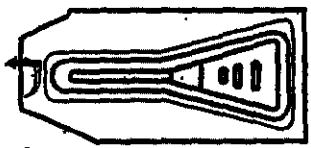
FRONTLINE[®] Top Spot[®] 



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


Dog 22
0.023 fl oz
Lot #

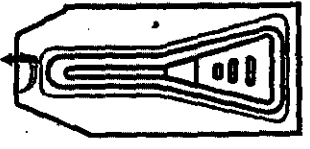
FRONTLINE[®] Top Spot[®] 



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


Dog 22
0.023 fl oz
Lot #

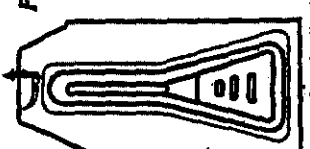
FRONTLINE[®] Top Spot[®] 



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


Dog 44
0.045 fl oz
Lot #

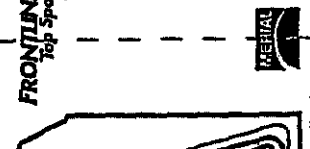
FRONTLINE[®] Top Spot[®] 



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


Dog 44
0.045 fl oz
Lot #

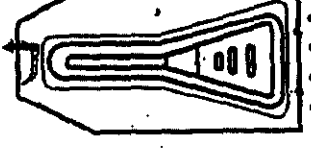
FRONTLINE[®] Top Spot[®] 



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[®] Top Spot[®] 



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


Dog 88
0.091 fl oz
Lot #

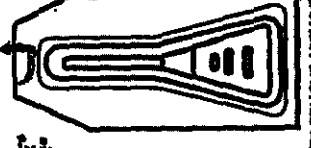
FRONTLINE[®] Top Spot[®] 



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


Dog 88
0.091 fl oz
Lot #

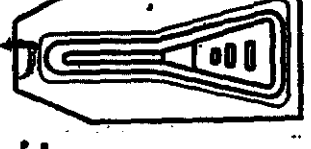
FRONTLINE[®] Top Spot[®] 



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


Dog 88
0.091 fl oz
Lot #

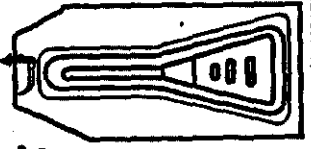
FRONTLINE[®] Top Spot[®] 



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


Dog 132
0.136 fl oz
Lot #

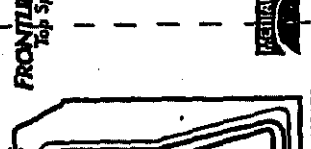
FRONTLINE[®] Top Spot[®] 



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

Dog 132
0.136 fl oz
Lot #

FRONTLINE[®] Top Spot[®] 



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

Dog 132
0.136 fl oz
Lot #

12/1/2

