65331-3



04-24-2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 24, 2012

Ms. Karen C. Cunningham, DVM, DABVP Head, Regulatory Affairs North America Merial Limited 3239 Satellite Boulevard, Building 500 Duluth, GA 30096-4640

Subject:

Amended Master Labeling; Removal of 2-Year Time-Limited Registration Restriction

FRONTLINE® Top Spot® For Dogs, EPA Reg. No. 65331-3

Your Submission Dated April 13, 2012

Dear Ms. Cunningham:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

In direct response to Merial Limited's submission (September 9, 2011) of enhanced reporting of adverse events for its FRONTLINE® products (EPA Reg. Nos. 65331-2, 65331-3, 65331-4, and 65331-5), the following changes are being made to the terms and conditions of the subject product registration as a result of EPA's recent review (copy enclosed) of this submission:

1. The 2-year time-limited registration restriction has been removed from the subject product registration.

2. Merial's reporting of enhanced incident data is now only required on an annual basis, rather than on a quarterly basis because 7 years of enhanced incident data reporting have been provided and these data did not demonstrate a concern.

Please note that this product is still subject to all other previously required conditions of registration, including the spot-on mitigation. A copy of your label stamped "Accepted" is enclosed for your records along with a hard copy of the HED review completed for the subject product. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Modia.Carmen@epa.gov.

Sincerely Yours,

Richard J. Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Com J. Mola. S.

Enclosures:

Label stamped "Accepted"

HED Memo: "Fipronil Spot-On Products: Conditional Registration and Enhanced Reporting," dated February 27, 2012

065331-00003 D463904



How to Apply FRONTLINE Top Spot® logs

Step 1.

OPEN Applicator

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

APPLY FRONTLINE TOP SPOT

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



RONTLINE Top Spot FOR DOGS

KEEP OUT OF REACH OF CHILDREN

CAUTION

Kills fleas, ticks, chewing lice & mosquitoes

Fast-acting
 Long-lasting
 Waterproof
 Wills ticks, including those that may transmit Lyme disease.

ACTIVE INGREDIENTS: 9.7%
INGREDIENTS: 9.3%
INGREDIENTS: 9.3

MADE IN FRANCE

may transmit Lyme disease 00000 00000

For use ONLY on DOGS 45_{to} 88_{lbs}

See inside panels for FIRST AID and MERIAL **PRECAUTIONARY** statements.

FRONTLINE® Top Spot® FOR DOGS

For use ONLY on DOGS & PUPPIES 8 weeks or older:
Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, sar:optic mites and mosquitoes.

ACTIVE INGREDIENT

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® TOP SPOT® for Dogs:

Technical area Na) print except prod, barcode

- Fleas

 kills fleas

 kills newly emerged adult fleas before they lay
- et gs
 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 arlulf), including brown dog ticks (hipicephalus sanguineus), American dog ticks (Dermacentor variabilis), lone star ticks (.tmblyomma americanum) and deer ticks

(Index scapularis)
kills ticks that may transmit Lyme disease,
Ricky Mountain Spotted Fever, ehrlichiosis,
by besiosis, anaplasmosis and other tick-borne diseases

- Lice
 Papidly eliminates chewing lice infestations Mittes

 • A ds in control of sarcoptic mange infestations
- Mosquitoes

Resquires

FRONTLINE TOP SPOT is approved for use on all dogs, including.

E-eading, pregnant, and lactating bitches

Frippies as young as 8 weeks

One spot application is all that's

One spot application is all mais needed:
FRONTLINE TOP SPOT spreads from the single point of application, rapidly covering the entitle 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 FRONTLINE TOP SPOT onto the skin and hair cool, so if keeps working even if the dog gets wet. Fleas, ticks and chewing lice are killed quickly after coming into contact with a treated dag. Fleas and ticks do not need to bite the dog in order to die.

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 labelling. 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, ticks, chewing lice and mosquitoes
apply FRONTLINE TOP SPOT for Dogs as
follows:

OPEN Applicator

tollows:

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

**APPLY FRONTLINE TOP SPOT

• "APPLY FRONTLINE TOP SPOT 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. FRONTLINE TOP SPOT for Dogs is approved for use on breeding, pregnant, and lacticiting bitches and puppies as young as 8 weeks. FRONTLINE TOP SPOT remains effective even after bathing, water immersion, or exposure to sunlight.

Sunignt.

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE FOP SPOT completely controls flee, tick and chewing lice infestations. Do not reapply FRONTLINE TOP SPOT for 30 days.

FRONTLINE TOP SPOT kills adult 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. FRONTLINE TOP SPOT kills ticks for at least one month. A once monthly application is recommended where fick control is needed. FRONTLINETOP SPOT kills all life stages of ficks (larva, nymph and adult). FRONTLINE TOP SPOT kills ficks that may transmit lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne disease.

diseases. FRONTLINE TOP SPOT kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is

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

or mires. FRONTUNE TOP SPOT 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

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

animals.

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

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if expilable. 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 IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS. CAUTION.

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

HAZARDS TO DOMESTIC ANIMALS.

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 ESI. PHYSICAL OR CHEMIC 11. HAZASTS

PHYSICAL OR CHEMICAL HAZAROS
COMBUSTIBLE: Do not use cretoral ear heat or open flame.

HOW SUPPLIED For easy and convenient treatment, FRONTUNE TOP SPOT for Dogs is available in sizes for use ONLY on small dags and pupples 8 weeks or older and up to 22 Uss., medium dags 23—44 lbs., large dags 45–88 lbs., and extra large dags ²⁹–132 lbs.

WARRANTY
To the extent consistent with applicable law, selle makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes or irsk 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 @FRONTLINE and TOP SPOT are registered trademarks of Merial. @2011 Merial Limited, Duluth. GA. All rights reserved.

INSIDE : PANELS

ACCEPTED

April 24, 2012 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

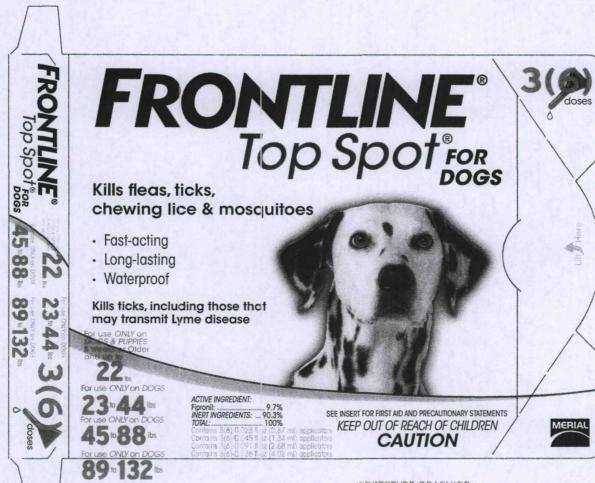
For use ONLY on DOGS & PUPPIES 8 Weeks or Older

For use ONLY on DOGS

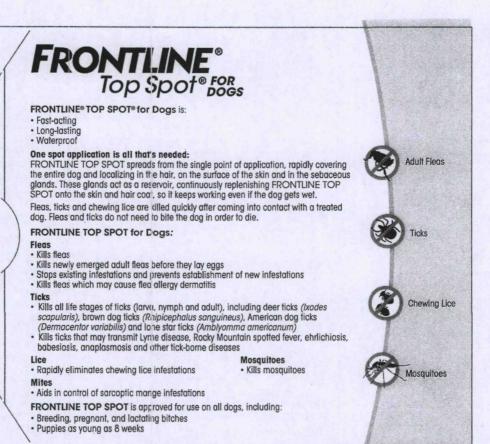
For use ONLY on DOGS

EPA. Reg. No: 65331-3

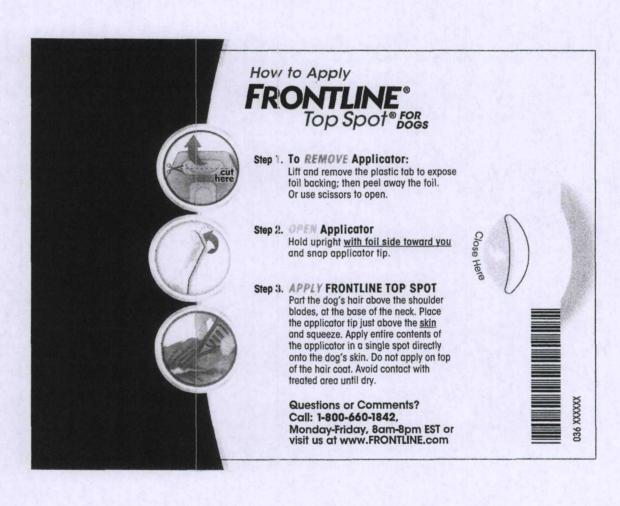
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PROTOTYPE GRAPHICS



PROTOTYPE GRAPHICS





45 88 ts 89 132 tb

Top Spot® for Boes **FROUTUNE**®

FRONTLINE®

FRONTLINE TOP SPOT for Dogs provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, sarcoptic mites and mosquifoes for use ONLY on (dogs and puppies 8 weeks or older and up to 22 lbs., dogs weighing 23-44 lbs., dogs weighing 45-86 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 ENTITIE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL, DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON RABEITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, ticks, chewing lice and mosquitoes apply FF-ONTLINE TOP SPOT for Dogs 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 FRONTLINE TOP SPOT. 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.

FRONTLINE TOP SPOT for Dogs is approved for use on breeding, pregnant, and lactating bitches and puppies as young as 8 weeks.

FRONTLINE TOP SPOT remains effective even after bothing, water immersion, or exposure to sunlight.

Frequency of Application

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

FRONTLINE TOP SPOT kills adult 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.

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

FRONTLINE TOP SPOT kills chewing lice for at least one month.

A once monthly application is recommended where chevring lice control is needed.

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

FRONTLINE TOP SPOT kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days, with a monthly application.

ATISFACTION

1-800-660-1842.

control or FRONTLINE TOP SPOT



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

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For dog use only

* Toulouse EPA Est. 65331-FR-2 Ivers Lee EPA Esl. 74528-CHE-1

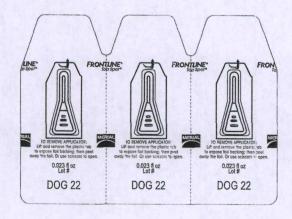
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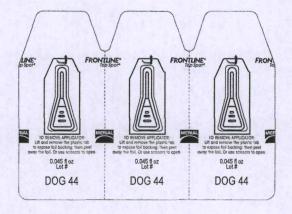
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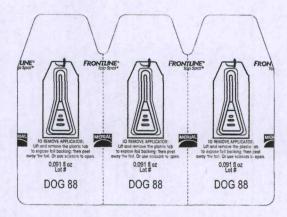
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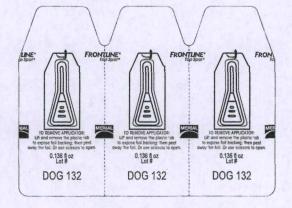
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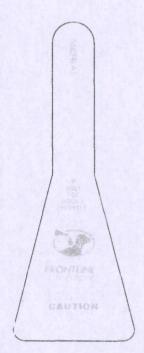
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FRONTLIN Top Spot FOR DOGS

For use ONLY on DOGS & PUPPIES 8 weeks or older: Fost-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice, sarcoptic mites and mosquitoes.

ACTIVE INGREDIENT
 fipronil
 9.7%

 INERT INGREDIENTS
 90.3%

 TOTAL
 100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® TOP SPOT® for Dogs:

Fleas

(ills fleas

Kills newly emerged adult fleas before they lay eggs Stops existing infestations and prevents establishment of new

Kills fleas which may cause flea allergy dermatitis

kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Ione star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)

kills ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, chriichiosis, babesiosis, anaplasmosis and other

ick-borne diseases

Lice

Rapidly eliminates chewing lice infestations

Mites

Aids in control of sarcoptic mange infestations

Mosquitoes

Kills mosquitoes
 FIRONTLINE TOP SPOT is approved for use on all

FRONTLINE TOP SPOT is approved for use on all dogs, including:

Breading, pregnant, and lactating bitches

Puppies as young as 8 weeks

Cne spot application is all that's needed:

FRONTLINE TOP SPOT 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 FRONTLINE TOP SPOT onto the skin and hair coat, so it keeps working even if the dag nets wet.

the dog gets wet.

Feas, 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.

To kill flens ticks chewing line and masquitage apply EPONTI INF To kill fleas, ticks, chewing lice and mosquitoes apply FRONTLINE TOP SPOT for Dogs 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

• OPENApplicator
Hold upright with foil side toward you and snap applicator tip.
• APPLY FRONTLINE TOP SPOT
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.
FIXONTLINE TOP SPOT for Dogs is approved for use on breeding pregnant, and lactating bitches and puppies as young as 8 weeks.



000000 037 FRONTLINE TOP SPOT remains effective even after bathing, water immersion, or exposure to sunlight.

FREQUENCY OF APPLICATION
When used monthly, FRONTLINE TOP SPOT completely controls flea, tick and chewing lice infestations. Do not reapply FRONTLINE TOP SPOT for 30 days

TOP SPOT for 30 days.
FRONTLINE TOP SPOT kills adult 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.
FRONTLINE TOP SPOT kills ticks for at least one month. A once monthly application is recommended where tick control is needed.
FRONTLINE TOP SPOT kills all life stages of ticks (larva, nymph and adult). FRONTLINE TOP SPOT kills ticks that may transmit tyme disease. Packy Mayntain Spotted Feyer, eprilichiasis. Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

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

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

FRONTLINE TOP SPOT 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 only, out of reach of children and animals.

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

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for any life or interest.

recycling if available.

FIRST AID

Have the product container or label with you when calling a poison

control center or doctor or going for treatment.

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

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

IF ON SKIN OR CLOTHING: Take off contaminated clothing.

Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment 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 ne sue or product application. It 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

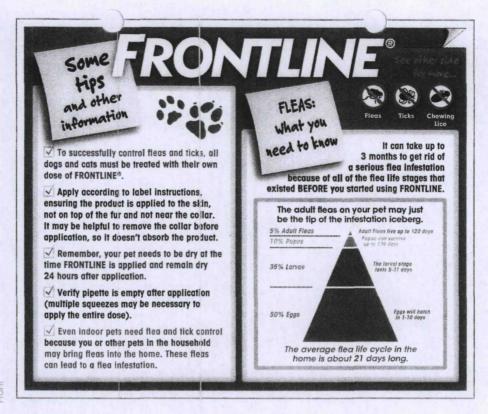
For easy and convenient treatment, FRONTLINE TOP SPOT for Dogs is available in sizes for use ONLY on small dags and puppies 8 weeks or older and up to 22 lbs., medium dags 23–44 lbs., large dags 45–88 lbs., and extra large dags 89–132 lbs.

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. 65331-3 Merial Limited Mertal Limited 3239 Sotellite Blvd. Duluth, GA 30096-4640, USA @FRONTLINE and TOP SPOT are registered trademarks of Merial. @2011 Merial Limited, Duluth, GA.





QUESTIONS? To ensure continued protection of your Calendar Contact your veterinarian or call our technical pets, use these stickers as a reminder Reminder to apply and re-purchase FRONTLINE. 1-800-660-1842, stickers Monday-Friday, 8am-8pm After treating your pet for the first time, For more information, visit peel off the sticker and place on your www.FRONTLINE.com calendar that day. MERIAL Place the remaining stickers on your Don't ®FRONTLINE is a calendar as a reminder to apply registered trademark forget to of Merial. FRONTLINE monthly. ©2011 Merial Limited, re-purchase! Duluth, GA. All rights reserved. 037 000000 6 Months use all 6 stickers 3 Months

3ack with stickers