

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 28, 2011

Karen C. Cunningham Head, Regulatory Affairs Merial Limited 3239 Satellite Blvd. Building 500, Office 113 Duluth, GA 30096-4640

Subject:

Application for Pesticide Amendment

Frontline Top Spot for Cats EPA Reg. No. 65331-2

Your Submission Dated May 24, 2011

Decision No: 449977

Dear Ms. Cunningham:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,

Richard Gebken

Product Manager 10, Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted"



How to Apply FRONTLINE® Top Spot® EARs

OPEN Applicator

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

Step 2.

APPLY FRONTLINE TOP SPOT

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.

Questions or Comments? Call: 1-800-660-1842, Monday-Friday, 8am-8pm EST or visit us at www.FRONTLINE.com

RONTLINE

kills fleas, ficks, chewing lice & mosquitoes

Kills fleas, ficks, Top Spo

· Fast-actina

Long-lasting

Waterproof

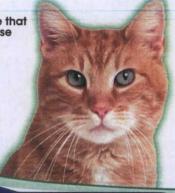
Kills ticks, including those that may transmit Lyme disease

INERT INGREDIENTS:

8 weeks and Older

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037



PIPETTE PLACEMENT SIMULATION

KEEP OUT OF REACH OF CHILDREN CAUTION

See inside panels for FIRST AID and PRECAUTIONARY

FRONT

BACK

FRONTLINE® Top Spot® FOR CATS

older: Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice and

ACTIVE INGREDIENT

INERT INGREDIENTS. 100%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® TOP SPOT® for Cats:

Kills fleas

· Kills newly emerged adult fleas before they lay

 Stops existing infestations and prevents establishment of new infestations · 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), lone star ticks (Amblyomma americanum) and deer ticks (Ixodes scapularis)

Kills ticks that may transmit Lyme disease,

haemobartonellosis, ehrlichiosis siosis, anaplasmosis and other tick-borne diseases

0222009 - 10h07 SJ LYON

1042009 - 12h29 SK DULUT

Rapidly eliminates chewing lice infestations

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

Breeding, pregnant, and lactating queens

Kithens as young as 8 weeks

One spot application is all that's needed: FRONTLINE TOP SPOT 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 FRONTLINE TOP SPOT 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.

DIRECTIONS FOR USE

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.
TO kill fleas, ticks, chewing lice and mosquitoes To kill fleas, ticks, chewing lice and mosquitoes apply FRONTLINE TOP SPOT for Cats as

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

APPLY FRONTLINE TOP SPOT

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. ted area until dry

FRONTLINE TOP SPOT for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8

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

FRONTLINE TOP SPOT 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.
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, haemobartonellosis, 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

FRONTLINE TOP SPOT 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

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

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 sortions. Place in tree to refill this

container. Place in trash or offer for recycling if

FIRST AID

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

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 gum, or using

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.

Meria Limited 3239 Satellite Blvd Duluth, GA 30096-4640, USA ®FRONTLIN'S and TOP SPOT are registered rademarks of Marial. ©2011 Merial Limited, Duluth, G/... All rights reserved.

ACCEPTED 11

INSIDE : PANELS

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

112009 - 10h21 SK DULUTH EPA. Reg. No:____

65331-2

Lot #

8 Weeks
and Older



FRONTLINE®
Top Spot® FOR CATS



Kills fleas, ticks, chewing lice & mosquitoes

- Fast-acting
- · Long-lasting
- Waterproof

Kills ticks, including those that may transmit Lyme disease

For use ONLY on CATS & KITTENS

8 Weeks and Older

ACTIVE INGREDIENT: SEE IN Fipronii: 9.7% K INERT INGREDIENTS: 90.3% K TOTAL: 100% Contains 3(6)-0.017 fl oz (0.50 mL) applicators

SEE INSERT FOR FIRST AID AND PRECAUTIONARY STATEMENTS. KEEP OUT OF REACH OF CHILDREN

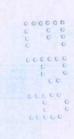
CAUTION



PROTOTYPE GRAPHICS

:8042008 - 14538 19122008 - SK 1/01/2008 TR 1/12/2008 - TR 13/12/2010 - TR





FRONTLINE® Top Spot® FOR CATS

FRONTLINE® TOP SPOT® for Cats is:

- · Fast-acting
- · Long-lasting
- Waterproof

One spot application is all that's needed:
FRONTLINE TOP SPOT 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 FRONTLINE TOP SPOT 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.

FRONTLINE TOP SPOT for Cats:

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

- 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

· Rapidly eliminates chewing lice infestations

Mosquitoes

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

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



Adult Fleas

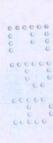


Ticks



Chewing Lice





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8 Weeks and Older

For use ONLY on CATS & KITTENS

FROUTLINE® Top Spot® FOR

FRONTLINE® Top Spot® FOR CATS

FRONTLINE TOP SPOT for Cats provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, 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, chewing lice and mosquitoes apply FRONTLINE TOP SPOT 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 FRONTLINE TOP SPOT. 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.

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

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

Frequency of Application

No.00000-0

Reg. N Est.

EPA R

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 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.

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

STISFACTION MERIAL PLANTED

Please call our experts at 1-800-660-1842.

Monday-Friday, 8am-8pm EST with any questions or comments about flea, tick, chewing lice, or mosquito control or FRONTLINE Top Spot.



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

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For cat use only

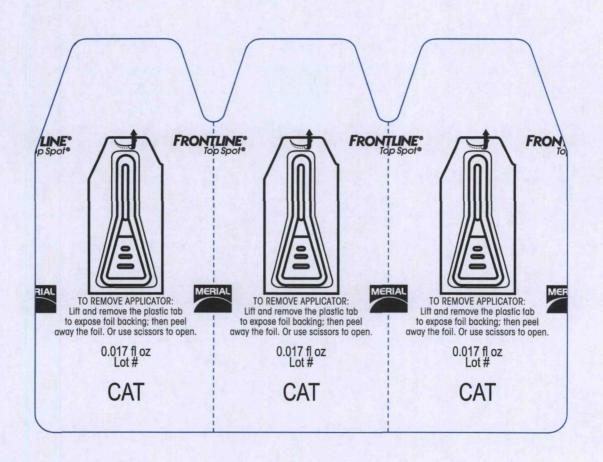
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A 96242008 - 14m00 8 07/74/2008 0 18/11/70/8

FRONTLINE® Top Spot®for CATS

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

ACTIVE INGREDIENT

fipronii 9.7% INERT INGREDIENTS 90.3%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® TOP SPOT® for Cats:

· Kills 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

Ticks

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

Kills ticks that may transmit Lyme disease,
haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis

and other tick-borne diseases

Lice
Rapidly eliminates chewing lice infestations

Mosquitoes

 Kills mosquitoes
 FRONTLINE TOP SPOT is approved for use on all cats, including:

· Breeding, pregnant, and lactating queens

Kittens as young as 8 weeks

One spot application is all that's needed:
FRONTLINE TOP SPOT 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 FRONTLINE TOP SPOT 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

DIRECTIONS FOR USE

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OPEN Applicator

 OPEN Applicator
Hold upright with foil side toward you and snap applicator tip.
 APPLY FRONTLINE TOP SPOT
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 day. treated area until dry.



000000 037 FRONTLINE TOP SPOT for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks.

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 FRÓNTLINE TOP SPOT for 30 days.

FRONTLINE TOP SPOT 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.
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, haemobartonellosis, 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 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.

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.

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.

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.

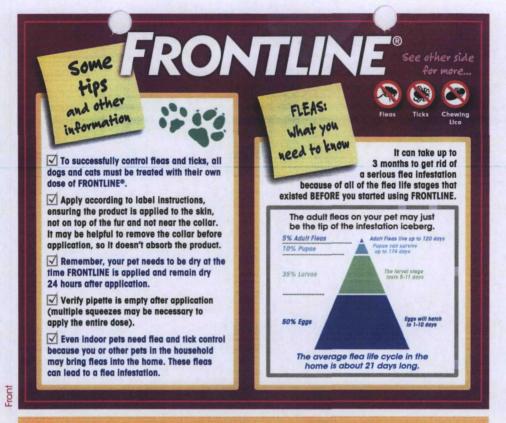
EPA Reg. No. 65331-2

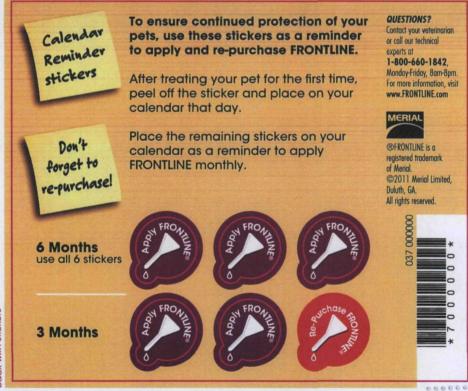
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