

65331-1

06-30-2011

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 30, 2011

Karen Mardis, Sr. Manager
Regulatory Affairs
Merial, Ltd.
3239 Satellite Blvd., Bld. 500
Duluth, GA 30096

Subject: Revised CR wording, and update labeling per Agency's request
Frontline Spray Treatment
EPA Reg. Nos. 65331-1
Application dated April 18, 2011

Dear Ms. Mardis:

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

Please note that we have approved the amended labeling for this product with the understanding that it is consistent with the Agency's previously stamped accepted labels; and other than the revisions stated in your application (dated April 18, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken,
Product Manager 10
Insecticide Branch
Registration Division (7505P)

Handwritten initials "EW" in black ink.

ACCEPTED

JUN 30 2011

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

EPA. Reg. No: 65331-1



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed or absorbed through the skin. May cause severe eye irritation. Avoid breathing spray. 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. Persons applying this product must wear household latex gloves.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. May cause severe eye irritation. Take care not to spray in the animal's eyes or facial area. Do not use on kittens and puppies under 8 weeks. Individual sensitivities, while rare, may occur after using any pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Keep away from heat and open flame.

STORAGE & 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.

FRONTLINE[®] Spray

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

For Dogs, Puppies,
Cats and Kittens

ACTIVE INGREDIENT: fipronil: 0.29%
INERT INGREDIENTS: 99.71%
TOTAL: 100%
8.5 fl oz (250ml)
17 fl oz (500ml)

KEEP OUT OF REACH OF CHILDREN
CAUTION



CONTACT. Please call our experts at 1-800-660-1842, Monday-Friday, 8am-8pm EST with any questions or comments about flea, tick, chewing lice and sarcoptic mange control or FRONTLINE[®] Spray.

WARRANTY: To the extent consistent with applicable law, the 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.

FIRST AID

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

IF IN EYES: Hold eye open and rinse slowly and gently with 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.

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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

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OPEN
HERE



Bottle label
("Bottom label")

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4-18-2011

FRONTLINE® Spray provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks and chewing lice for adult dogs and cats and for puppies and kittens 8 weeks of age or older.

Fleas

- Kills fleas
- Kills newly emerged adult fleas before they lay eggs
- Stops existing infestations and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

Lice

- Rapidly eliminates chewing lice infestations

Mites

- Aids in control of sarcoptic mange infestations in dogs

FRONTLINE® Spray

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

For Dogs, Puppies, Cats and Kittens

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TOTAL: 100%

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17 fl oz (500ml)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements



Ticks

- 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, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis, haemobartonellosis and other tick-borne diseases

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EPA Reg. No. 65331-1
EPA Est. 65331-FR-2.

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



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Booklet page 1
("Top label")
FIRST PAGE
SEEN BY USER.

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CRP Directions ✓

FRONTLINE® Spray

To kill fleas and all life stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may transmit Lyme disease) and chewing lice, apply FRONTLINE® Spray to dogs, cats, puppies and kittens as follows:

FRONTLINE Spray stops existing infestations and prevents establishment of new infestations by killing fleas, ticks, and chewing lice for at least 30 days.

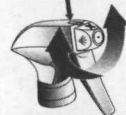
FRONTLINE Spray may protect dogs against fleas for up to 90 days.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ATTACHED DIRECTIONS BEFORE EACH USE.** Follow all directions and precautionary statements carefully. Use only on dogs and cats. Do not use on rabbits. Do not use on any other animals.



To Open: Push the button on top of the trigger and turn the nozzle to the **•••••** position.



To Close: Push the button on top of the spray and turn the nozzle to the **X** position.



1: Wear household latex gloves.



2: Hold bottle in upright position. Ruffle the animal's coat with one hand while applying spray mist to the animal's back, sides, abdomen, legs, shoulders and neck.



3: For head and eye area, spray **FRONTLINE** on a gloved hand and rub gently into animal's hair.

Do not get this product in your pet's eyes or mouth. Apply spray mist until animal's hair is damp to thoroughly wet. Approximately 1 to 2 pumps per pound of the animal's body weight will be required. Pets with long or dense coats will require the higher rate.

As with any flea control product, wash hands and exposed skin thoroughly with soap and water after use.

To prevent flea build-up or reinfestation, use **FRONTLINE** Spray prior to the onset of flea season and monthly thereafter. Ticks do not need to receive spray directly upon their body for complete control. Multiple monthly treatments are recommended for the elimination of mites. Do not reapply spray for 30 days.

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

4/5