

65331-1

9/16/2009

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 16, 2009

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

Subject: Change Graphics and Redesign Label Format
Frontline Spray Treatment
EPA Reg. Nos. 65331-1
Application dated July 14, 2009

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. 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)

Enclosure

ACCEPTED
SEP 16 2009

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

EPA. Reg. No: 65331-1

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

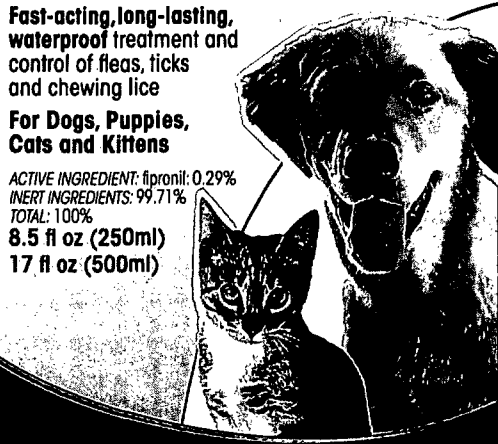
- Mites**
- Aids in control of sarcoptic mange infestations in dogs

FRONTLINE® Spray

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

For Dogs, Puppies, Cats and Kittens

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
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



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

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.

How to unlock the trigger pump: Press down on lock button located at the top of the trigger pump. At the same time, rotate the nozzle counterclockwise one full turn so that the tab on the lock button aligns with the notch in the nozzle. **To lock the trigger pump,** reverse the process. The trigger pump should be left in the locked position when not in use.



- 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.



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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 thoroughly with soap and water after handling. 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**

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**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: 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: Flush eyes with plenty of water. Call a doctor if irritation persists.

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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Bottle label
("Bottom label")

Lot No: