



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 28, 2016

Brandi Jones  
Associate Manager  
Regulatory Affairs  
Merial, Inc.  
3239 Satellite Boulevard  
Deluth, GA 30096

Subject: Notification per PRN 98-10 – Updating est. number and name on label  
Product Name: FRONTLINE SPRAY  
EPA Registration Number: 65331-1  
Application Date: 6/6/2016  
Decision Number: 518119

Dear Ms. Jones:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

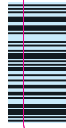
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at [hollis.angela@epa.gov](mailto:hollis.angela@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed in a hand-drawn oval.

Kable Bo Davis, Product Manager 3  
Invertebrate and Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs



Lot No:

EAN8 barcode made with last 7 digits of component code/EAN8 généré avec les 7 derniers chiffres du code article.

**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 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 animals' eyes or facial area. Do not use on kittens and puppies until they are 12 weeks old. Do not use on dogs until they are 6 weeks of age or until they have been spayed or neutered. Do not use on cats or other species unless otherwise indicated on the label. If symptoms occur after using any pesticide product for cats, if dogs 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.

**ENVIRONMENTAL OR CHEMICAL HAZARDS.**

**FLAMMABLE LIQUID.** Keep away from heat and open flame.

**STORAGE & DISPOSAL.**

Do not contaminate water, food, or feed by storage and disposal.

**KEEP OUT OF REACH OF CHILDREN**

Caution: Do not use on children and animals.

**PESTICIDE DISPOSAL.**

If empty, please refer to the label for disposal instructions.

**CONTAINER DISPOSAL.**

If empty, Non-refillable container. Do not reuse or refill this container. Place in trash or other for recycling if available.

# FRONTLINE<sup>®</sup> Spray

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

**For Dogs, Puppies, Cats and Kittens**



**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**



**CONTACT:**

Please call our experts at 1-800-640-1842, Monday-Friday, 8am-8pm EST with any questions or comments about flea, tick, chewing lice and sarcoptic mange treatments.

**WARNING:**

FRONTLINE<sup>®</sup> Spray should be used with application for the intended purpose. Do not use for any other purpose. The use of this product other than indicated on the label, may assume a 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 to treatment.

**IF IN EYES:**

Rinse thoroughly with clean water. Do not rub. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:**

Remove contaminated clothing. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:**

Call a poison control center or doctor for treatment advice. Do not induce vomiting unless instructed 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.

## NOTIFICATION

65331-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

06/28/2016

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**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 INGREDIENTS: fipronil: 0.29%  
OTHER INGREDIENTS: 99.71%  
**8.5 fl oz (250ml)**



**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. 453331-1  
EPA Est. 065331-FRA-002

**Merial Inc.** 3239 Scenic Blvd.  
Duluth, GA 30096-6640, USA  
Made in France



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Livret p. 1-Couv  
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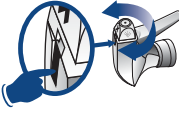
# FRONTLINE® Spray

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.

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:

**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.



EAN8 barcode made with last 7 digits of component code/EAN8 générée avec les 7 derniers chiffres du code article.



# 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%  
**17 fl oz (500ml)**



**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

### 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

Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

**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

Here 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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Lot No:

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**Fleas**

- Kills fleas
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**Lice**

- Rapidly eliminates chewing lice infestations

**Mites**

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# FRONTLINE® Spray

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

**For Dogs, Puppies, Cats and Kittens**

ACTIVE INGREDIENT: Ipronomil: 0.29%  
INERT INGREDIENTS: 99.71%  
TOTAL: 100%

**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*).
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# FRONTLINE® Spray

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

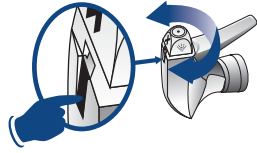
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**1:** Wear household latex gloves.

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