

65331-5

07/21/2000

1/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

65331-5

Date of Issuance:

JUL 21 2000

Term of Issuance:

Unconditional

Name of Pesticide Product:

Frontline Plus for Dogs

NOTICE OF PESTICIDE:

X Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Zareen Ahmed
Merial

2100 Ronson Road
Iselin, NJ 08830

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 65331-5."
b. The companion animal safety study review, a copy of which is attached, shows that the dose must be adjusted for smaller dogs (dogs weighing less than 11 lbs). Accordingly, the label for small dogs (0.67 ml) must be amended to read "For dogs 11 to 22 lbs." As specified in the review, the registrant may propose a smaller dose of 0.333 ml for dogs weighing between 5.5 and 11 lbs.

Signature of Approving Official:

[Handwritten Signature]

Date:

JUL 21 2000

Marion J. Johnson, Jr.

Product Manager 3
Insecticide Branch

CONCURRENCES

Table with columns for SYMBOL, SURNAME, and DATE, containing handwritten entries and stamps.

- c. All references to fleas and flea allergy dermatitis must be revised to clarify that fleas may cause flea allergy dermatitis.
- d. All references to deer ticks and lyme disease must be revised to clarify that deer ticks may carry lyme disease.
- e. In the Hazard to Domestic animals statement revise the second sentence to read as follows:
Individual sensitivities, while rare, may occur after using any pesticide product.
- f. Revise the Physical or Chemical Hazards statement to read as follows:
Combustible: Do not use or store near heat or open flame.
- g. The label review manual specifies that you may not include directions for use for more product than the package contains. Thus, you must limit stickers to the number of pipettes in the package, either 3 or 6 pipettes, as appropriate. You must delete or modify the directions to use the product year around, if it would require more doses than is contained in the package.
- h. The label must be revised to show the product name is Frontline Plus for Dogs, the name on the application for registration.
- i. You must limit claims for use on puppies to puppies 8 weeks of age or older.
- j. The marketing claim "new" may only be used for six months after the product is first released for shipment.
- k. You must clarify the directions for using the stickers so that users who need only flea control place the stickers at three month intervals, not one month intervals.

3. The Agency is reviewing the registrant's response to the requirement that a Rabbit Warning statement be included on the label of other Frontline products. Depending on the outcome of this review, the Agency may require a Rabbit Warning statement, a companion animal safety study with rabbits or continued annual incident analysis.

4. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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EPA Reg. No.65331-5

A stamped copy of the label is enclosed for your records.

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

JUL 21 2000
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
65331-5

**FRONTLINE[®]
PLUS**

NEW

For dogs & puppies up to 22 lbs.
For dogs 23-44 lbs.
For dogs 45-88 lbs.
For dogs 89-132 lbs.

3 (6)
Applicators

FRONTLINE[®] PLUS



For dogs & puppies up to 22 lbs.
For dogs 23-44 lbs.
For dogs 45-88 lbs.
For dogs 89-132 lbs.

*PHOTO AS PER
WEIGHT OF DOG*

ACTIVE INGREDIENTS
fipronil 9.8%
(S)-methoprene..... 8.8%
INERT INGREDIENTS... 81.4%
TOTAL 100.0%

**KEEP OUT OF
REACH OF CHILDREN
CAUTION**

- Stops And Prevents Infestations
- Kills Ticks Including Those That Transmit Lyme Disease
- Fast-Acting
- Waterproof

Contains 3 (6)-0.023 fl oz (0.67 ml) applicators
Contains 3 (6)-0.045 fl oz (1.34 ml) applicators
Contains 3 (6)-0.091 fl oz (2.68 ml) applicators
Contains 3 (6)-0.136 fl oz (4.02 ml) applicators



How to Apply

FRONTLINE[®]

PLUS



1. Remove Applicator from Child-Resistant Package
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.



2. Open Applicator
Hold upright and snap applicator tip away from face and body.



3. Apply FRONTLINE PLUS
Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin.

INSERT COVER TAB HERE

Questions or Comments?
Call: 1-800-660-1842



FRONTLINE[®] PLUS

FRONTLINE PLUS provides fast, effective and convenient treatment and control of fleas and ticks for dogs and puppies up to 22 lbs. (dogs weighing 23-44 lbs., dogs weighing 45-88 lbs., dogs weighing 89-132 lbs.)

- *Stops and prevents infestations*
- *Kills adult fleas, flea eggs & flea larvae*
- *Prevents all flea stages (eggs, larvae, pupae) from developing*
- *Kills fleas which cause flea allergy dermatitis*
- *Kills all stages of deer ticks (the major carrier of Lyme disease), brown dog ticks, American dog ticks & lone star ticks*
- *Prevents and controls reinfestations*
- *Fast-acting*
- *Long-lasting*
- *Waterproof*
- *Convenient to use*

FRONTLINE PLUS contains fipronil and the insect growth regulator (IGR) (S)-methoprene. FRONTLINE PLUS effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas and ticks.

MERIAL



Adult Flea



Flea Eggs



Flea Larvae



Flea Pupae



Brown Dog Tick



Lone Star Tick



Deer Tick



American Dog Tick

For dogs & puppies up to 22 lbs.
For dogs 23-44 lbs.
For dogs 45-88 lbs.
For dogs 89-132 lbs.



FRONTLINE[®]
PLUS



FRONTLINE[®]
PLUS

FRONTLINE PLUS provides fast, effective and convenient treatment and control of fleas and ticks for (dogs and puppies up to 22 lbs., dogs weighing 23-44 lbs., dogs weighing 45-88 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 ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON OTHER ANIMALS.**

To kill fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (the major carrier of Lyme disease), apply to dogs or puppies (8 weeks or older) as follows: Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.

Frequency Of Application

When used monthly, FRONTLINE PLUS completely breaks the flea life cycle and controls tick infestations. Research demonstrates that FRONTLINE PLUS kills adult fleas, flea eggs, and flea larvae for up to three months. FRONTLINE PLUS also prevents development of all flea stages for up to three months. FRONTLINE PLUS kills ticks for at least one month. A once monthly use is recommended where there is a high risk of reinfestation, if the pet has fleas which may cause flea allergy dermatitis, or where tick control is needed.

FRONTLINE PLUS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE PLUS for 30 days.

Merial Limited
2100 Ronson Road
Iselin, NJ 08830-3077, USA

MADE IN FRANCE

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EPA Reg. No. 65331-X
EPA Est. 65331-FR-2
(EPA Est. 65331-DEU-1)



If you are not satisfied with FRONTLINE PLUS for any reason, the product will be replaced or the purchase price refunded. The guarantee is limited to product replacement or refund of the purchase price, and applies only to purchases made at a veterinary clinic. If you have any questions or comments, please call 1-800-660-1842.

LOT NO:

For animal use only

FRONTLINE PLUS

FOR DOGS & PUPPIES

Convenient spot treatment for fast-acting, long-lasting control of fleas and ticks.

ACTIVE INGREDIENTS

fipronil:	9.8%
(S)-methoprene	8.8%
INERT INGREDIENTS	81.4%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE PLUS provides fast, effective and convenient treatment and control of fleas and ticks for dogs and puppies.

- Stops and prevents infestations
- Kills adult fleas, flea eggs, and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Kills fleas which cause flea allergy dermatitis
- Kills all stages of deer ticks (the major carrier of Lyme disease), brown dog ticks, American dog ticks, and lone star ticks
- Prevents and controls reinfestations
- Fast-acting
- Long-lasting
- Waterproof
- Convenient to use

FRONTLINE PLUS contains fipronil and the insect growth regulator (IGR) (S)-methoprene. FRONTLINE PLUS effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas and ticks.

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 OTHER ANIMALS.

To kill fleas and all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (the major carrier of Lyme disease), apply to dogs or puppies (8 weeks or older) as follows:

Remove applicator from child-resistant package. Hold applicator upright and snap applicator tip away from face and body. Place applicator tip through animal's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot to the animal's skin. Avoid superficial application to the animal's hair. Only one applicator per treatment is needed.



037 002704 - A 0004

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE PLUS completely breaks the flea life cycle and controls tick infestations. Research demonstrates that FRONTLINE PLUS kills adult fleas, flea eggs, and flea larvae for up to three months. FRONTLINE PLUS also prevents development of all flea stages for up to three months. FRONTLINE PLUS kills ticks for at least one month. A once monthly use is recommended where there is a high risk of reinfestation, if the pet has fleas which may cause flea allergy dermatitis, or where tick control is needed.

FRONTLINE PLUS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply FRONTLINE PLUS for 30 days.

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. Waste resulting from use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL. Securely wrap original container in several layers of newspaper and discard in trash.

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

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

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 topical parasiticide for pets. 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 topical parasiticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant, or nursing animals. Call 1-800-660-1842 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE. Keep away from heat and open flame.

HOW SUPPLIED

For easy and convenient treatment, FRONTLINE PLUS is available in sizes for small dogs and puppies up to 22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra large dogs 89-132 lbs.

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.

EPA Reg. No. 65331-x

Merial Limited
2100 Ronson Road
Iselin, NJ 08830-3077, USA



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Notice Frontline + USA - Chiens - EDIT-PUB - 09/06/2000 - S. CLION - Noir

For
DOGS

FRONTLINE PLUS

Flea and tick protection card

Apply FRONTLINE PLUS monthly for continuous protection against fleas and ticks

Pet's Name :

Date of first treatment :



Jan.	Feb.	Mar.	April	May	June
July	Aug.	Sept.	Oct.	Nov.	Dec.

Place calendar stickers on same date each month as a reminder to apply FRONTLINE PLUS

037 002706 - A 0004

EDIT-PUB - 18/05/2000 - Frontline Plus USA - Rappel Chiens
S. CLION - Quadrie + P872

Remove the adhesive backing and attach to your refrigerator door

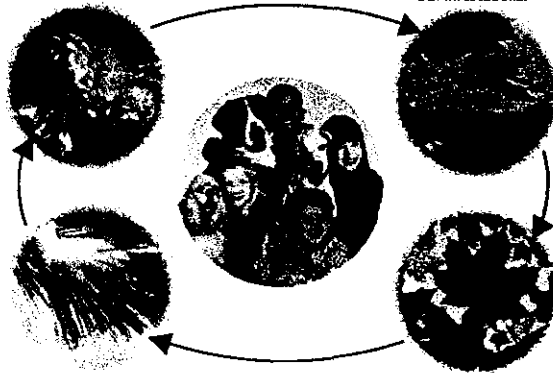
Fleas and ticks can be a year-round problem!

Spring

Fleas and ticks breed more frequently as spring progresses.

Summer

The period of highest risk. Summer temperatures and humidity can quickly lead to flea and tick infestations.



Winter

Minimize the risk of any reinfestation.

Autumn

The risk continues. Fleas and ticks (brown dog ticks, American dog ticks, lone star ticks, and deer ticks—the major carrier of Lyme disease) remain a threat.

Flea and Tick Protection Card Instructions for Use

- 1 - Peel the sticker out of the box of this card and use only one sticker to apply FRONTLINE PLUS monthly protection to your pet's hair treatment in the box shown.
- 2 - After treating your pet, peel off the sticker corresponding to the current month.
- 3 - Place the sticker on your calendar on the same day next month as a reminder to apply FRONTLINE PLUS.



The diagram shows three identical FRONTLINE PLUS applicators arranged horizontally. Each applicator is a teardrop-shaped container with a plastic tab at the top and a foil seal at the bottom. The applicators are connected by a wavy line at the top. The word "FRONTLINE PLUS" is printed on the top of each applicator, and "MERIAL" is printed on the bottom of each applicator. Below each applicator is a set of instructions and dosage information.

FRONTLINE PLUS

FRONTLINE PLUS

FRONTLINE PLUS

FRONTLINE PLUS

MERIAL

MERIAL

MERIAL

MERIAL

TO REMOVE APPLICATOR:
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

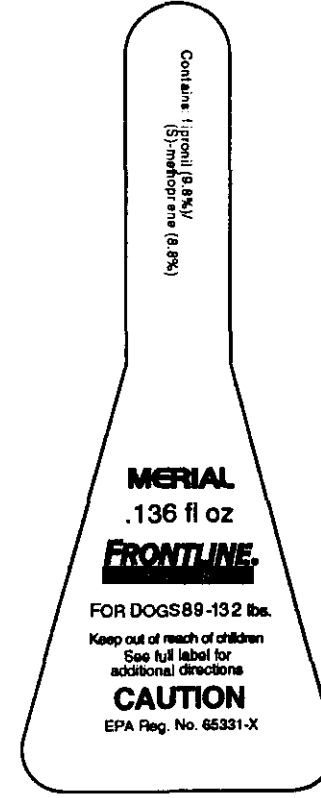
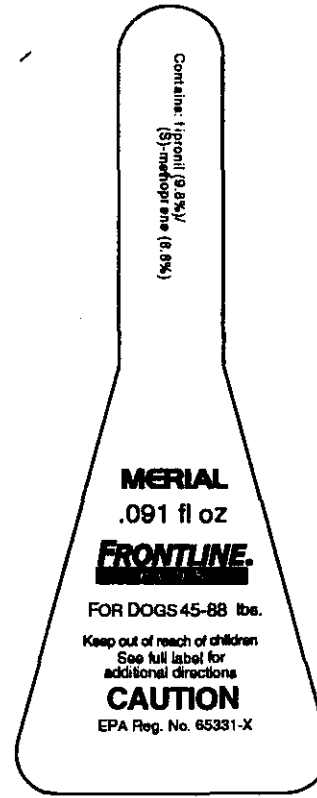
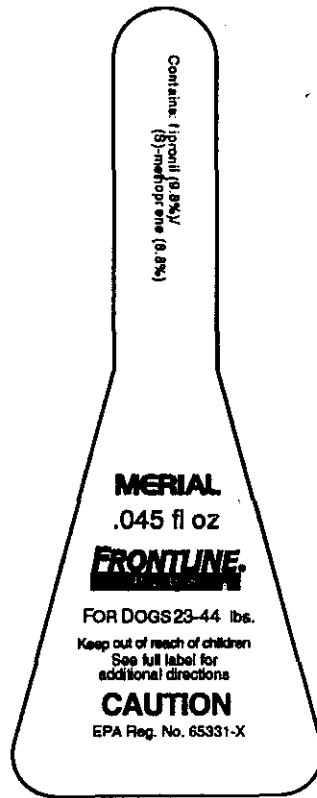
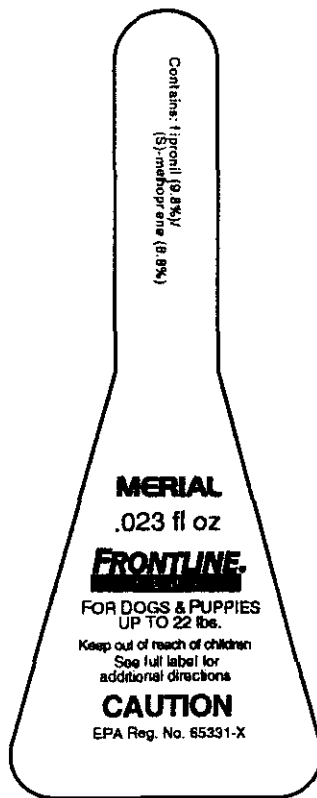
TO REMOVE APPLICATOR:
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

TO REMOVE APPLICATOR:
Use scissors. Or lift and remove plastic tab to expose foil, then peel down.

Dog (22, 44, 88, 132)
(0.67, 1.34, 2.68, 4.02 ml)
Lot #

Dog (22, 44, 88, 132)
(0.67, 1.34, 2.68, 4.02 ml)
Lot #

Dog (22, 44, 88, 132)
(0.67, 1.34, 2.68, 4.02 ml)
Lot #



SHOWN AT 125% OF ACTUAL SIZE

12/12