



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 11, 2019

Sandra O'Kelley  
Regulatory Affairs Manager  
Merial, Inc.  
3239 Satellite Blvd., Bldg 600, Office 6558-B  
Duluth, GA 30096

Subject: PRIA Label Amendment – Addition of speed of kill claim  
Product Name: Frontline Active for Dogs  
EPA Registration Number: 65331-9  
Application Date: 15-June-2018  
Decision Number: 542157

Dear Ms. O'Kelley,

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

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

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with FIFRA section 6. If you have any questions, please contact Dr. Breeden-Alemi by phone at 703.347.0511, or via email at [breeden-alemi.julie@epa.gov](mailto:breeden-alemi.julie@epa.gov).

Sincerely,



Catherine Aubee, Chief  
Invertebrate-Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

Text within braces { } denotes notes to reviewer.  
Text within brackets [ ] denotes optional language.

**Draft Master Label**

{The final label may include optional text on the front, back, or side panels of the carton, insert, or compliance card. Optional text will not obscure or contradict any mandatory text or label indications.}

**{Front Panel of 3, and 6 Applicator Carton}{Front panel of Single Applicator Package (visible)}**

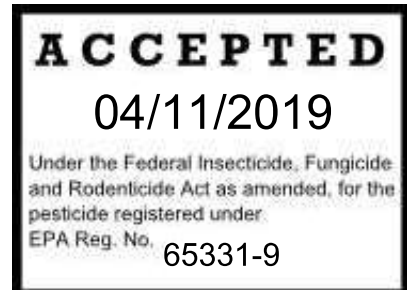
{The Master label includes label text for two different applicator sizes corresponding to two dog weight ranges, including a single for the 4.0 mL applicator, and a 3 and 6 applicator presentation for the 6.0 mL applicator. Due to space limitations the layout of the single applicator label differs from the 3 and 6 applicator labels since the single applicator label does not include a carton or compliance card. The single applicator package is a flat folded carton, where the front panel contents are consistent with the front panels of the other carton presentations (3 and 6 count). The single applicator can be seen on the front panel through a clear plastic casing that surrounds it. A large, clear picture of a dog in the appropriate weight range for the product as packaged will be placed on the front panel of all presentations. For optional marketing text, see pages 18-21}.

**FRONTLINE<sup>®</sup> SHIELD for Dogs**  
**[ABN] FRONTLINE<sup>®</sup> ACTIVE for Dogs**  
**[ABN] FRONTLINE<sup>®</sup> ULTRA for Dogs**  
**[ABN] FRONTLINE<sup>®</sup> EXTRA for dogs**  
**[From the maker of FRONTLINE<sup>®</sup>]**

[1][3][6]  
monthly  
dose(s)

{The "Dog" text size will be 75% of the height of the largest letter in the primary brand name}.

**Large Clear Picture of  
representative size dog  
will be included on the  
front panel**



**TICKS**

[Repels and Kills Ticks]

**FLEAS**

[Kills all life stages of fleas]

**[Plus]**

**MOSQUITOS**

[Repels Mosquitos]

[Long-lasting, monthly control of fleas, ticks, mosquitos, stable flies and lice]

[Repels Ticks, Mosquitoes and Stable Flies]

[Kills Fleas, Flea eggs, and Flea larvae, Ticks, Stable Flies, and Lice and aids in the control of Sarcoptes mites]

[Kills fleas in 6 hours, beginning 2 days after application]

[Prevents all flea stages [(eggs and larvae)] from developing]

For use ONLY on Dogs 9 weeks or older and weighing [41-80] [81-120] lbs.

{Text will be placed in a box prominently on the front panel.}

**READ THE ENTIRE LABEL BEFORE EACH USE.**

**ACTIVE INGREDIENTS**

Fipronil.....	6.01%
Permethrin*.....	44.88%
Pyriproxyfen .....	1.8%
<b>OTHER INGREDIENTS.....</b>	<b>47.31%</b>
<b>TOTAL.....</b>	<b>100.0%</b>

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

Net Contents:

{for 1 applicator package}

1 Applicator - 0.135 fl. oz. [(4.0 mL)]

{for 3 applicator carton}

0.405 oz [(12 mL)] Contains 3 – 0.135 fl. oz. [(4.0 mL)] applicators

0.609 fl oz [(18 mL)] Contains 3 - 0.203 fl oz. [(6.0 mL)] applicators

{for 6 applicator carton}

0.81 fl. oz [(24.0 mL)] Contains 6 - 0.135 fl. oz. [(4.0 mL)] applicators

1.218 fl oz. [(36.0 mL)] Contains 6 – 0.203 fl. oz. [(6.0 mL)] applicators

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

{Front Panel of 3 and 6 Applicator Carton}

For First Aid and additional Directions for Use refer to front inside panel.

For Precautionary Statements refer to back of carton.

{Front Panel of Single Applicator Package}

For First Aid, Precautionary Statements, and additional Directions for Use, refer to inner panels of package.



[1.5 x 1.5 cm]

*{Note to the Reviewer: This 1.5cm x 1.5cm cat prohibition icon in yellow with black images will be located inside a box at the lower right hand corner of the front panel of the carton for the 3x, and 6x, presentations, and on the lower right hand corner of the front panel for the 1x applicator package. }*

**{Front Inside Panel of 3 and 6 Applicator Carton}**

*{The front panel of the carton is printed on both sides and perforated on the right edge of the carton. To open the carton and view the carton inside front panel, pull up on the right side of the front panel breaking the perforations to open, and by using a right-to-left motion, invert the front panel to view the carton inside front panel.}*

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON DOGS ONLY.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

**RESTRICTIONS**

Do not allow children to apply product. Do not allow adults, children, or other pets to touch treated area until dry.

Do not use on cats or rabbits; or any animals other than dogs. Do not allow your dog to ingest this product. Do not use on dogs under 9 weeks of age or weighing less than [41][81] lbs. Do not apply more than once a month, or use more than one applicator per dog, regardless of the dog's weight. Do not split applicators between dogs. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness.

Do not bathe your dog within the first 24 hours after the product has been applied. Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product. .

For use ONLY on dogs 9 weeks or older and weighing [41-80][81-120] lbs to kill fleas and ticks and prevent fleas from developing; to repel and reduce blood-feeding by ticks, mosquitos and stable flies; to kill chewing lice and to aid in control of Sarcoptes mites. Apply the entire contents of the applicator at each treatment. It may be helpful to remove the collar before application, so it doesn't absorb the product.

<b>FIRST AID</b>	
<b>IF IN EYES:</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have a person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 for 24-hour assistance.</b>	

{Back Panel of 3 and 6 Applicator Carton}

## FRONTLINE® SHIELD for Dogs

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS and DOMESTIC ANIMALS

#### HAZARDS TO HUMANS

**WARNING.** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash clothing that may have come in contact with the product before reuse.

#### HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY. Do not use on animals other than dogs. Do not use on dogs under 9 weeks of age or weighing less than [41][81] lbs. Individual sensitivities may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your dog with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or dogs known to be sensitive to pesticide products. Consult a veterinarian for guidance on use against sarcoptes mites. This product is not a substitute for a prescribed heartworm preventative. Call 1-800-660-1842, Mon-Fri 8AM-8PM for assistance.

#### PHYSICAL OR CHEMICAL HAZARDS

Do not allow this product to come in contact with an oxidizing agent, as a hazardous chemical reaction may occur.

*{A box labeled "Side Effects" will be placed immediately above the cat warning box on the back panel of the 3 and 6 applicator carton and the single applicator package. The rest of the contents of the single applicator back panel is described on the next page.}*

**Side Effects:** Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. If these or other side effects occur, consult your veterinarian or call 1-800-660-1842.



*{Note to the Reviewer: A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be located in the lower right hand corner of the back panel in yellow with black images}*

{Back Panel of 3 and 6 Applicator Carton}

Satisfaction  
Guarantee  
Icon

For questions or comments, please call our experts at 1-800-660-1842, who can provide further details on our one time satisfaction guarantee which may include a refund or replacement of product. Conditions of use apply.

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

EPA Reg. No. 65331-9  
EPA Est. No.

{Inside Front Panel Flaps of 3 and 6 Applicator Carton and Back Panel of Single Applicator Package (visible)}

{To view the inside carton flaps, see the previous note on how to open the carton front panel. Once the carton front panel is opened, the two carton inside flaps will be visible as they are folded under the carton front panel. Replace Step 4 of the instructions below with the appropriate size dog. Step 4 will display the number of application sites relevant to the directions for the weight band of the product. The back panel of the single applicator package will only include Steps 2-4 since there is no need to separate blisters, and they will be renumbered as Steps 1-3.}

How to Apply **FRONTLINE® Shield for Dogs:**

**1** **TO REMOVE Applicator:**  
Prior to opening separate one blister by tearing along perforation.

**2** **TO OPEN,**  
use scissors to cut along dotted line of single blister, then pull apart foil and remove the applicator. **OR** fold on line at corner, tear and open at slit and remove the applicator.

**3** **HOLD Applicator Upright**  
away from you and your dog's face, cut applicator tip with scissors to open. Do not get product in your dog's eyes or mouth.

**4** **APPLY FRONTLINE® SHIELD**  
Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. Ensure that FRONTLINE® Shield for Dogs is not applied superficially on dog's hair.

[Questions or Comments?  
Call: 1-800-660-1842,  
Monday – Friday, 8am-8pm EST]

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**{Front of Insert included with 3 and 6 Applicator carton}**

*{The package insert for the 3 and 6 applicator presentations is a single page printed on both sides and placed inside the carton.}*

**FRONTLINE® Shield for Dogs**

For use ONLY on dogs 9 weeks or older and weighing [41-80][81-120] lbs.

**ACTIVE INGREDIENTS**

Fipronil.....6.01%  
Permethrin\*.....44.88%  
Pyriproxyfen .....1.8%

**OTHER INGREDIENTS**.....47.31%

**TOTAL**.....100.0%

\*cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans



**KEEP OUT OF REACH OF CHILDREN  
WARNING**

For additional Precautionary Statements, refer to carton back panel.

For additional Directions for Use and First Aid information, refer to carton inside panel.

**FRONTLINE® Shield for Dogs**

Convenient, [long-lasting] monthly topical for treatment of fleas, ticks, and chewing lice, and repellency of mosquitos and stable flies. Effectively controls existing infestations and prevents re-infestations of fleas, ticks and chewing lice.

**Ticks:**

- Repels and kills ticks for an entire month, including Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks
- Kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis

**Fleas:**

- Kills fleas, flea eggs and flea larvae for an entire month
- Prevents development of flea eggs and flea larvae, effectively breaking the flea life-cycle
- Kills fleas which may cause flea allergy dermatitis and that may transmit bartonellosis, tularemia and tapeworm

**Mosquitos and Flies:**

- Repels mosquitos that may transmit [heartworm disease][and][West Nile].
- Repels and reduces blood-feeding by stable flies and mosquitos for a month.

**Lice and Mites:**

- Kills chewing lice
- Aids in control of Sarcoptes mite infestations which may cause sarcoptic mange.



**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON DOGS ONLY.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

{The 3x and 6x insert may include text only without the illustrations. These illustrations are found on the Inside Front Panel Flaps of the carton, so the consumer will still have the illustrations available}

Apply **FRONTLINE Shield for Dogs** as follows:

**1** **TO REMOVE Applicator:**  
Prior to opening separate one blister by tearing along perforation.

**2** **TO OPEN,**  
use scissors to cut along dotted line of single blister, then pull apart foil and remove the applicator. **OR** fold on line at corner, **tear and open at slit** and remove the applicator.

**3** **HOLD Applicator Upright**  
away from you and your dog's face, cut applicator tip with scissors to open. Do not get product in your dog's eyes or mouth.

**4** **APPLY FRONTLINE® SHIELD**  
Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. Ensure that FRONTLINE® Shield for Dogs is not applied superficially on dog's hair.

**{Back of Insert for 3 and 6 Applicator Cartons}**

**FREQUENCY OF APPLICATION**

Apply [**FRONTLINE® Shield for Dogs**] monthly to control fleas, flea eggs, and flea larvae, ticks, and chewing lice infestations . Stable flies and mosquitos are repelled for one month by [a single application of] **FRONTLINE® Shield[for Dogs]**.

[Research demonstrates that ]**FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight 24 hours after application. A monthly application of **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing; kills all stages of ticks, chewing lice, and repels mosquitos and stable flies.

**RESTRICTIONS**

Do not allow children to apply product. Do not allow adults, children, or other pets to touch treated area until dry.

Do not use on cats or rabbits; or any animals other than dogs. Do not allow your dog to ingest this product. Do not use on dogs under 9 weeks of age or weighing less than [41] [81] lbs. Do not apply more than once a month, or use more than one applicator per dog, regardless of the dog's weight. Do not split applicators between dogs. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness.

Do not bathe your dog within the first 24 hours after the product has been applied. Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

For use ONLY on dogs 9 weeks or older and weighing [41-80][81-120] lbs. to kill fleas and ticks and prevent fleas from developing; to repel and reduce blood-feeding by ticks, mosquitos and stable flies; to kill chewing lice and to aid in control of Sarcoptes mites. Apply the entire contents of the applicator at each treatment. It may be helpful to remove the collar before application, so it doesn't absorb the product.

**PESTICIDE STORAGE AND DISPOSAL**

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

**STORAGE:** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL and CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available.

**If partly filled:** Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**Questions or Comments?**

**Call: 1-800-660-1842,**

**Monday – Friday, 8am-8pm EST**

EPA Reg. No. 65331-9

Merial, Inc.  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

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**{Inner Panels of Single Applicator Package}**

{The Single Applicator Package is a flat package with a front and back where the applicator is visible through a clear plastic casing surrounding it. This flat package opens along the right side of the front panel into a book style presentation. The interior panels of the package contain the package insert text reading from left to right across several columns.}

**FRONTLINE® Shield for Dogs**

For use ONLY on dogs 9 weeks or older and weighing [41-80][81-120] lbs

**KEEP OUT OF REACH OF CHILDREN  
WARNING**

**FRONTLINE® Shield for Dogs**

Convenient, [long-lasting] monthly topical for treatment of fleas, ticks, and chewing lice, and repellency of mosquitos and stable flies. Effectively controls existing infestations and prevents re-infestations of fleas, ticks and chewing lice.

**Ticks:**

- Repels and kills ticks for an entire month, including Dear ticks, Brown Dog ticks, American Dog ticks, and Lose Star ticks.
- Kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis

**Fleas:**

- Kills fleas, flea eggs and flea larvae for an entire month
- Prevents development of flea eggs and flea larvae, effectively breaking the flea life cycle
- Kills fleas which may cause flea allergy dermatitis and that may transmit bartonellosis, tularemia and tapeworm

**Mosquitos and Flies:**

- Repels mosquitos which may transmit heartworm disease and West Nile Virus
- Repels and reduces blood feeding by stable flies and mosquitos for a month

**Lice and Mites:**

- Kills chewing lice
- Aids in control of sarcoptes mite infestations which may cause sarcoptic mange

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. **FOR EXTERNAL USE ON DOGS ONLY.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

### How to Apply:

- (1) **TO OPEN, use scissors** to cut along dotted line of single blister, then pull apart foil and removed the applicator. **OR** fold on line at corner, tear open at slit and removed the applicator
- (2) **HOLD** applicator upright away from you and your dog's face, cut applicator tip with scissors to open. Do not get the product in your dog's eyes or mouth.
- (3) **APPLY FRONTLINE® Shield for Dogs:**  
Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. Place applicator tip directly against exposed skin. {For large-sized dogs ONLY weighing 41-80 lbs.} Apply the product evenly to three spots on the dog's back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. Ensure that **FRONTLINE® Shield for Dogs** is not applied superficially on dog's hair. {For extra-large dogs ONLY weighing 81-120 lbs.} Apply the product evenly to four spots on the dog's back, starting between the shoulder blades and continuing on to the second, third and fourth spots, squeezing the applicator until empty. Ensure that **FRONTLINE® Shield for Dogs** is not applied superficially on dog's hair.

### FREQUENCY OF APPLICATION

Apply [**FRONTLINE® Shield for Dogs**] monthly to control fleas, flea eggs, flea larvae, ticks, and chewing lice infestations. Stable flies and mosquitos are repelled for one month by [a single application of] **FRONTLINE® Shield [for Dogs]**.

[Research demonstrates that ]**FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing; kills all stages of ticks and chewing lice; and repels mosquitos and stable flies.

### RESTRICTIONS

Do not allow children to apply product. Do not allow adults, children, or other pets to touch treated area until dry.

Do not use on cats or rabbits; or animals other than dogs. Do not allow your dog to ingest this product. Do not use on dogs under 9 weeks of age or weighing less than [41][81] lbs. Do not apply more than once a month, or use more than one applicator per dog, regardless of the dog's weight. Do not split applicators between dogs. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Overdosing your dog can result in serious illness.

Do not bathe your dog within the first 24 hours after the product has been applied. Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

If your dog is exhibiting signs of and/or is being treated for skin problems, talk to your veterinarian before applying any topical flea and tick control product.

For use ONLY on dogs 9 weeks or older and weighing [41-80][81-120] lbs. to kill fleas and ticks and prevent fleas from developing; to repel and reduce blood-feeding by ticks, mosquitos and stable flies; to kill chewing lice and to aid in control of Sarcoptes mites. Apply the entire contents of the applicator at each treatment. It may be helpful to remove the collar before application, so it doesn't absorb the product.

<b>FIRST AID</b>	
<b>IF IN EYES:</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have a person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>Have product container or label with you when calling a poison control center or doctor, or going for treatment, or call 1-800-660-1842 Mon – Fri from 8AM-8PM for assistance.</b>	

**PESTICIDE STORAGE AND DISPOSAL**

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

**STORAGE:** Store unused product in original container only in a cool dry place, out of reach of children and animals.

**PESTICIDE DISPOSAL and CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available.

**If partly filled:** Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

**PRECAUTIONARY STATEMENTS**

**DO NOT USE ON CATS – MAY BE FATAL**

**HAZARDS TO HUMANS and DOMESTIC ANIMALS**

**HAZARDS TO HUMANS**

**WARNING:** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed or absorbed through the skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash clothing that may have come in contact with the product before reuse.

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**HAZARDS TO DOMESTIC ANIMALS**

For external use on dogs ONLY. Do not use on animals other than dogs.

Do not use on dogs under 9 weeks of age or weighing less than [41][81] lbs. Individual sensitivities may occur after using ANY pesticide product. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur, bathe your dog with mild soap or shampoo and rinse with large amounts of water. If signs of sensitivity occur and persist, contact a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs, or dogs known to be sensitive to pesticide products. Consult a veterinarian for guidance on use against sarcoptes mites. This product is not a substitute for a prescribed heartworm preventative. Call 1-800-660-1842 Mon-Fri from 8AM-8PM for assistance.

<p><b>Side Effects:</b> Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. If these or other side effects occur, consult your veterinarian or call 1-800-660-1842.</p>
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**PHYSICAL OR CHEMICAL HAZARDS**

Do not allow this product to come in contact with an oxidizing agent, as a hazardous chemical reaction may occur.

**WARRANTY**

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, buyer assumes all risk of use and handling of this material when such use and handling are contrary to the label instructions.

**[Questions or Comments?**

**Call: 1-800-660-1842**

**Monday-Friday, 8am-8pm EST]**

Merial, Inc.  
3239 Satellite Blvd.  
Duluth, GA 30096-4640, USA

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Questions or Comments? Call: 1-800-660-1842 Monday-Friday, 8am-8pm EST

**{Front of Calendar Reminder Stickers}**

See other side for more

**FRONTLINE® Shield for Dogs**

Some tips and other information:

**DO NOT USE ON CATS – MAY BE FATAL.**

To successfully treat fleas, ticks, and chewing lice, and repel mosquitos and stable flies, treat all dogs with the correct dose of **FRONTLINE® Shield for Dogs** for their weight range.

Read Entire Label before applying. Apply according to label instructions, ensuring the product is applied to the skin. Do not apply on top of the haircoat. It may be helpful to remove the collar before application, so it doesn't absorb the product.

Remember, your dog needs to be dry at the time **FRONTLINE® Shield for Dogs** is applied and remain dry 24 hours after application.

{PICTOGRAMS: icon with slash through}

- Adult Flea
- Flea eggs
- Flea larvae
- Adult Tick
- Chewing Lice
- Mosquitos
- Stable Flies

**{Back of Calendar Reminder Stickers}**



To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **FRONTLINE® Shield for Dogs**.

After treating your dog for the first time, peel off the sticker and place on your calendar that day. Place the remaining stickers on your calendar as a reminder to apply **FRONTLINE® Shield for Dogs** monthly. Don't forget to re-purchase!

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm.

6 months  
Use all 6 stickers

-----  
3 months  
Use all 3 stickers

5 stickers that read, "APPLY **FRONTLINE® Shield**", with the 6<sup>th</sup> sticker "Re-purchase **FRONTLINE® Shield**".

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**{Front Label of Individual Applicator}**

{Individual applicators are contained inside the child-resistant blister package.}

**FRONTLINE® Shield for Dogs**

For use ONLY on dogs 9 weeks or older and [41-80][81-120] lbs.

[0.135][0.203] fl. oz.



---

**{Back Label of Individual Applicator}**

**KEEP OUT OF REACH OF CHILDREN  
WARNING**

EPA Reg. No. 65331-9

6.01% Fipronil  
44.88% Permethrin  
1.8% Pyriproxyfen

Lot No.

**{Blister Package}**

**FRONTLINE® Shield for Dogs**

[0.035][0.203] fl. oz

**KEEP OUT OF REACH OF CHILDREN  
WARNING**

Read accompanying label before use  
For external use only

Lot No.

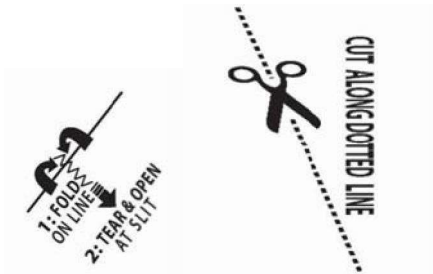


Illustration of dog with 3 or 4 arrows pointing to dog's back showing where to apply product

For use ONLY on dogs 9 weeks or older  
and [41-80][81-120] lbs.



**{Optional Marketing Text: Optional variations Appear in Brackets}**

{The final label may include some or all of the optional text for each claim}

**Multiple Infestations**

- Kills fleas and ticks [for an entire month] including **Deer ticks, Brown dog ticks, American Dog ticks, and Lone Star ticks**
- Repels [mosquitos][and][stable flies].
- Repels mosquitos for one month.
- Repels mosquitos and [kills][repels][stable flies]
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- [Kills][Controls] existing infestations and prevents re-infestations of fleas and ticks
- Long-lasting for 1 month against fleas and ticks
- Re-infestation of fleas, ticks, and chewing lice is prevented for [a][one]month.
- After application, **FRONTLINE® Shield** spreads over the dog's body to provide [full body][all over] protection against fleas, ticks, mosquitos, stable flies, and chewing lice
- **FRONTLINE® Shield[ for Dogs]** provides ongoing protection against fleas, ticks, mosquitos, stable flies, and chewing lice for one month.
- **FRONTLINE® Shield for Dogs** provides efficacy against [fleas][and][ticks]
- Effective monthly treatment of fleas and ticks.
- Fleas [and ticks] do not have to bite to die.
- Easy and effective control of fleas and ticks that lasts [1][one][a] month.
- Using the [patented][trademark] applicator, **FRONTLINE® Shield** is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation of [fleas][ticks] for one month
- Treat monthly for optimal control and prevention of fleas and ticks
- Proven treatment for the [control of flea infestations][control of ticks][repellency of ticks][repellency of mosquitos][control of stable flies][repellency of stable flies][control of chewing lice]
- **FRONTLINE® Shield** uses three [different] modes of action to [prevent fleas from developing][kill and repel ticks][kill fleas and chewing lice][kill and repel stable flies][repel mosquitos]
- For convenient, long-lasting one month control of fleas, ticks, and chewing lice.
- [When] Applied topically on a monthly basis, **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing; kills ticks and chewing lice, aids in control of Sarcoptes mites, and [repels][reduces blood feeding by] stable flies, and mosquitos.
- **FRONTLINE® Shield** contains the active ingredients fipronil, permethrin and pyriproxyfen, which control infestations caused by fleas, ticks and chewing lice; and repels [against] stable flies and mosquitos.
- To kill fleas and ticks and prevent fleas from developing
- Repels and reduces blood-feeding by ticks, mosquitos, and stable flies
- To kill chewing lice and to aid in control of Sarcoptes mites
- Kills fleas, ticks, chewing lice, and stable flies
- Repels [and reduces blood feeding by] stable flies and mosquitos for [a][one] month
- Kills [all stages] fleas and ticks
- Kills [all stages] of [ticks][and][chewing lice] and repels mosquitos and stable flies.
- Repels ticks, stable flies and mosquitos
- For the control and prevention of flea [and chewing lice] infestations
- Flea, tick, and chewing lice infestations can be controlled with monthly applications of **FRONTLINE® Shield for Dogs.**
- Stable flies and mosquitos are [also] repelled by **FRONTLINE® Shield for Dogs.**
- Monthly application against fleas and ticks

- Kills fleas and ticks for [one month][an entire month]
- Monthly application is recommended for control and prevention of fleas and ticks
- Monthly [Prevention of Fleas and Ticks][Protection against fleas and ticks].
- One month of long-lasting flea and tick control for your dog
- Long-lasting control of fleas, ticks, and lice, and repellency of mosquitos and stable flies for one month
- **FRONTLINE® Shield for Dogs** is indicated for the prevention and control of fleas, ticks, and chewing lice for use ONLY on [dogs 9 weeks or older and weighing 41-80lbs.][dogs 9 weeks or older and weighing 81-120 lbs.].
- **FRONTLINE® Shield for Dogs** kills and repels stable flies, and repels mosquitos
- Kills fleas, ticks, chewing lice, and aids in control of Sarcoptes mites
- Repels ticks and mosquitos
- Kills Fleas, Flea eggs, and Flea larvae, Ticks, Stable Flies, and Lice and aids in the control of Sarcoptes mites
- Controls existing infestations and prevents re-infestations of [fleas][ticks][chewing lice]
- [Fleas, flea eggs, flea larvae,][All flea life stages,] ticks, and chewing lice infestations can be controlled with monthly applications of **FRONTLINE® Shield for Dogs**.
- The active ingredients in **FRONTLINE® Shield** provide [long-lasting] control for one month of fleas, ticks, mosquitos, stable flies, and chewing lice on dogs.
- To [successfully] treat fleas, ticks, and chewing lice, and repel mosquitos and stable flies, all dogs must be treated with the correct dose of **FRONTLINE® Shield for Dogs** for their weight range.

[PICTOGRAMS: icon with slash through]

[Adult Flea]

[Flea eggs]

[Flea larvae]

[Adult Tick]

[Chewing Lice]

[Mosquitos]

[Stable Flies]

## Fleas

- Kills fleas within 6 hours, beginning 2 days after treatment with FRONTLINE® Shield.
- Prevents fleas on treated dogs from infesting your home
- Prevents fleas from developing
- Prevents fleas, flea eggs and flea larvae from developing
- Kills fleas on dogs and continues to prevent infestations for a month
- Kills fleas [before they lay eggs][that may transmit bartonellosis and tapeworm disease]
- Kills fleas which may cause flea allergy dermatitis
- The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with **FRONTLINE® Shield** kills fleas that may cause this condition.
- **FRONTLINE® Shield** kills existing fleas on dogs.
- Re-infesting fleas are killed quickly with protection against further flea infestation lasting a [full] month.
- Kills [newly emerged] fleas [before they lay eggs] for one month.
- **FRONTLINE® Shield for Dogs** kills adult fleas and lasts for one month. Apply monthly to kill fleas that may cause flea allergy dermatitis (FAD), and prevent reinfestations .
- Kills newly emerged adult fleas prior to egg laying.
- Kills fleas that may transmit bartonellosis, [and tularemia][and tapeworm][infections].
- Acts to kill fleas that may transmit bartonellosis and tularemia.
- Kills fleas that may serve as an intermediate host for tapeworms (*Dipylidium caninum*).

- Kills fleas that may serve as an intermediate host for cysticercoids of tapeworms.
- Kills fleas that may serve as hosts for life cycle intermediates of tapeworms.
- Kills (adult) fleas that may cause [Flea Allergy Dermatitis (FAD)][or][flea-bite anemia]
- **FRONTLINE® Shield for Dogs** kills fleas that may cause FAD (Flea Allergy Dermatitis).
- Kills [adult] fleas.
- Easy to apply, control [of][for] fleas that lasts [one month][a full month].
- **FRONTLINE® Shield for Dogs** kills fleas on your dog.
- Once a month topical flea control for use ONLY on [dogs 9 weeks or older and weighing 41-80 lbs][dogs 9 weeks or older and weighing 81-120 lbs].
- **FRONTLINE® Shield for Dogs** is indicated for the prevention and control of fleas, for use ONLY on dogs 9 weeks or older and weighing [41-80 lbs.][81-120 lbs.].
- One application prevents further flea infestations for one month.
- Monthly treatment [all year] is recommended for control and prevention of fleas.
- Provides [lasting][ongoing] protection against fleas for a month.
- Controls existing flea infestations by killing adult fleas [and preventing new fleas from developing].
- Kills fleas before they lay eggs.
- [Prevents] re-infestations by killing adult fleas [before they lay eggs].
- Treatment with **FRONTLINE® Shield** kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity.
- Use flea [prevention][protection] year-round.
- **FRONTLINE® Shield for Dogs** kills flea eggs and larvae for one month.
- **FRONTLINE® Shield for Dogs** breaks the flea life cycle when used [on a] monthly [basis][before they become biting adults].
- Prevents establishment of new flea infestations
- **FRONTLINE® Shield for Dogs** prevents flea eggs from hatching
- Kills flea eggs and flea larvae to help prevent future re-infestations
- [Prevents] flea eggs from developing into biting adults for one month.
- Prevents all flea stages [eggs][larvae][adult] from developing[ to help prevent re-infestation].
- Inhibits the development of immature flea stages [and prevents them from reaching the biting adult stage]
- Provides multi-stage flea control [effectively breaking the flea life-cycle] for lasting control of flea populations.
- Fleas do not have to bite to [die][be controlled][be killed][be inhibited from developing].
- Prevents development of [immature flea stages][flea eggs][flea larvae], breaking the flea life cycle.
- **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing.
- A monthly application of **FRONTLINE® Shield for Dogs** kills existing fleas and prevents new fleas from developing.

### Ticks

- [Kills][and][repels] all stages of ticks that infest dogs.
- [Kills][and][repels][ticks][which may cause][which may transmit][Lyme disease], [canine Ehrlichiosis][Anaplasmosis][Babesiosis][Tick Paralysis][Rocky Mountain Spotted Fever][Southern Tick Associated Rash Illness],[or cause tick paralysis].
- [Kills][and][repels] ticks for one month.
- **FRONTLINE® Shield for Dogs** [kills][repels] all stages of ticks, including Deer ticks, Brown dog ticks, American dog ticks and Lone Star ticks.
- Kills and repels ticks.
- [Kills][and][repels] the tick vectors that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis and anaplasmosis.

- **Ticks: FRONTLINE® Shield for Dogs** can [kill][repel] ticks for [one month][a month]. Apply monthly for tick control.
- [Kills][and][repels] Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks [that may transmit Lyme disease, Rocky Mountain Spotted Fever, babesiosis, ehrlichiosis and anaplasmosis].
- [Kills][and][repels] ticks including Deer ticks [that may transmit Lyme disease], American dog ticks [that may transmit Rocky Mountain Spotted Fever], Brown dog ticks and Lone Star ticks [that may transmit ehrlichiosis] for one month.
- [Kills][and][repels] Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.), and Lone Star ticks (*Amblyomma americanum*) for one month].
- [Kills][and][repels] *Amblyomma americanum* (Lone Star tick) for one month.
- Monthly application against ticks.

### **Mosquitos and stable flies**

- Repels mosquitos and stable flies.
- Repels and reduces blood-feeding by stable flies and mosquitos.
- **Stable flies and mosquitos:** When applied [monthly], **FRONTLINE® Shield for Dogs** [repels][and][reduces blood feeding by] stable flies and mosquitos for [one][a] month.
- **Stable flies: FRONTLINE® Shield for Dogs** kills stable flies for one month.
- Stable flies and mosquitos are repelled by **FRONTLINE® Shield for Dogs** for one month.
- Repels and reduces blood-feeding by stable flies and mosquitos for a month.
- Repels mosquitos for one month.
- Reduces blood-feeding by [and repels] mosquitos.
- Repels mosquitos that may carry vector borne diseases such as [heartworm disease][and][West Nile].
- Reduces blood-feeding by stable flies.
- Kills stable flies.
- Repels and reduces blood-feeding by stable flies for [a][one] month..
- Repels stable flies.
- Repels [annoying][bothersome][nuisance]stable flies for a month.
- Repels mosquitos which may be a vector of heartworm (*Dirofilaria immitis*) for one month.

### **Chewing lice and Sarcoptes mites**

- [For treatment of][Treats and controls][Provides effective control of][For treatment of infestations with][Kills][Stops existing] chewing lice [infestations].
- Kills chewing lice for one month.
- **[Chewing] Lice: FRONTLINE® Shield for Dogs** can kill chewing lice for one month. Apply monthly where lice control is consistently needed.
- **Sarcoptes mites: FRONTLINE® Shield for Dogs** aids in the control of sarcoptes mites that may cause sarcoptic mange.
- **FRONTLINE® Shield for Dogs** aids in [the] control of sarcoptes mite infestations [that may cause sarcoptic mange].
- [Apply,] **FRONTLINE® Shield for Dogs** [monthly to] aid[s] in the control of sarcoptes mites that may cause sarcoptic mange.
- Aids in the control of sarcoptes mite [infestations].
- [Also] Kills chewing lice and aids in the control of sarcoptes mites [that may cause sarcoptic mange].
- Controls existing chewing lice infestations.
- For control and prevention of chewing lice [infestations].

- Prevents and controls chewing lice [infestations].
- Provides control of chewing lice [infestations].
- Kills chewing lice and prevents further infestations.
- For control and prevention of [infestations with] chewing lice.
- **Sarcoptes Mites: FRONTLINE® Shield for Dogs** aids in the control of sarcoptes mite infestations [that may lead to sarcoptic mange].

### Miscellaneous

- **FRONTLINE® Shield for Dogs** [is waterproof and] remains effective following bathing, shampooing, swimming [water immersion] or after exposure to rain or sunlight beginning 24 hours after application.
- Convenient topical treatment for dogs that enjoy the outdoors.
- [Easy and convenient][Convenient][to use][Easy to apply][topical] application(s).
- Persistent [sustained] efficacy through [one][an entire] month.
- Protects for [one][a full] month.
- Convenient [easy to apply] topical treatment [with patented applicator][that allows application down to the skin][for dogs].
- [Patented] applicator [trademark] for easy application directly to the skin.
- Quick-drying.
- For easy and convenient application, **FRONTLINE® Shield for Dogs** is available in sizes for use ONLY on large dogs 9 weeks or older and weighing 41-80 lbs. [0.135 fl. oz.][4.0 ml], and ONLY on extra-large dogs 9 weeks or older and weighing 81-120 lbs. [0.203 fl. oz.][6.0 ml].
- Easy [topical] application.
- Non-greasy.
- [Formulated] for dogs that [enjoy][love] the outdoors.
- Waterproof.
- [For use][Can be used] ONLY on dogs 9 weeks or older and weighing[41-80][81-120] lbs.
- Convenient to use.
- [1][3][6] applicator(s).
- [1][3][6] monthly dose(s) [application(s)].
- This product is for use ONLY on dogs 9 weeks or older and weighing [41-80 lbs.][81-120 lbs.]
- Controls existing infestations and prevents establishment of new infestations.
- Prevents (re-)infestation for [one][an entire] month.
- Once monthly application.
- **FRONTLINE® Shield for Dogs** is brought to you by the makers of **FRONTLINE®**.
- Quick drying, non-greasy.
- No noticeable odors.
- Easy to use applicator makes treatment simple [trouble free, smooth] and comfortable for you and your dog.
- [In] child-resistant packaging.
- Convenient [to use], easy to apply [topical solution].
- Water-proof [remains effective after bathing and swimming] for [a][one] month.
- Remains effective after exposure to sunlight for 24 hours after application.
- **FRONTLINE® Shield for Dogs** remains effective even after bathing, water immersion, or exposure to [rain][or][sunlight] that occurs at least 24 hours after application.
- Remains effective after exposure to rain and/or sunlight beginning 24 hours after application.
- Still works after bathing, swimming or exposure to sunlight starting 24 hours after application.
- Maintains residual efficacy after bathing and swimming beginning 24 hours after application.



- Remains effective after bathing [and swimming][for a month][for one month] beginning 24 hours after application.
- For indoor and outdoor dogs.
- Convenient topical treatment for dogs that enjoy the outdoors.
- Illustration of flea life cycle {without pupae stage}.
- Illustration of tick life cycle.
- Illustration of mosquito life cycle.
- Illustration of stable fly life cycle.
- Illustration of *sarcoptes scabiei* mite life cycle.
- Illustration of chewing lice life cycle.
- Illustration of flea.
- Illustration of flea eggs and/or larvae
- Illustration of tick.
- Illustration of mosquito.
- Illustration of *sarcoptes scabiei* mite.
- Illustration of chewing lice.
- Illustration of stable fly.
- Picture or illustration of a dog.
- Picture or illustration of the Merial logo.
- Picture or illustration of the primary package [applicators].