

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

February 05, 2025

SENT BY EMAIL

Peter Stevenson
peter.stevenson@tsgconsulting.com
BOEHRINGER INGELHEIM ANIMAL HEALTH USA INC.

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 - Add two alternate brand

names, update trademarks, and correct typographical errors

Product Name: FRONTLINE SHIELD FOR DOGS

Admin Number: 65331-9 EPA Receipt Date: 01/22/2025 Action Case Number: 00642393

Dear Peter Stevenson:

The U.S. Environmental Protection Agency is in receipt of your application for notification under Pesticide Registration Notice 98-10 for the above referenced product. The EPA 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 labeling submitted with this application has been stamped "Notification" and will be placed in our records.

The alternate brand names: FRONTLINE PLATINUM for Dogs, FRONTLINE TRIPLE SHIELD for Dogs have been added to the registration. Our records have been updated accordingly.

Should you wish to add/retain a reference to your 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 EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

If you have questions, please contact Kaitlin Saunders via email at saunders.kaitlin@epa.gov. Sincerely,

Kaillin Saunders (far)
Hester Dingle, Acting PM 4

IVB1, RD

Office of Pesticide Programs

NOTIFICATION

65331-9

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:

02/05/2025

[1][3][6]

monthly

dose(s)

Reason to Issue: Update alternate trade names, typographical errors

Date: <u>0</u>10/2204/20245
EPA Reg. No.: 65331-9

Date: <u>0</u>10/2204/20223

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

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 five different applicator sizes corresponding to five dog weight ranges, including a single, 3 and 6 applicator presentations for each dog weight range. 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 18-23}.

FRONTLINE® SHIELD for Dogs

[ABN] FRONTLINE® ACTIVE for Dogs [ABN] FRONTLINE® ULTRA for Dogs

[ABN] FRONTLINE® EXTRA for Dog [ABN] FRONTLINE® EXTRA for

dogsDogs

[ABN] FRONTLINE® PLATINUM for Dogs

[ABN] FRONTLINE® TRIPLE SHIELD for Dogs

[From the maker of FRONTLINE®]

{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

Extra Strength [triple action for] monthly protection

[TICKS]

[Starts killing ticks in 1 hour, starting 2 days after treatment]

[Repels ticks]

[FLEAS]

[Kills all life stages of fleas]

[Starts killing fleas in 5 minutes, starting 2 days after treatment]

[Plus]

[MOSQUITOES][STABLE FLIES]

[Repels Mosquitoes [and stable flies]]

XS, S, M, L, XL

For use ONLY on Dogs/Puppies 9 weeks or older and weighing [5-10][11-20][21-40][41-80][81-120] lbs.

Page 1 of 23

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Commented [G(GRBUJ1]: Capitalize "D" to read Dogs

Commented [G(GRBUJ2]: Addition of two alternate brand names

Reason to Issue: Update alternate trade names, typographical errors EPA Reg. No.: 65331-9

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

Date: 010/2204/20245 Supersedes: 09/08/2023

READ THE ENTIRE LABEL BEFORE EACH USE.

ACTIVE INGREDIENTS Fipronil 6.01% Pyriproxyfen......1.8% **OTHER INGREDIENTS**<u>47.31%</u> TOTAL100.0% *cis-trans ratio: max. 55% (+/-) cis and min. 45% (+/-) trans

Net Contents:

{for 1 applicator package} 1 Applicator - 0.017 fl. oz. [(0.5 mL)]{Extra small dog} 1 Applicator - 0.034 fl. oz. [(1.0 mL)]{Small dog} 1 Applicator – 0.068 fl. oz. [(2.0 mL)]{Medium dog} 1 Applicator - 0.135 fl. oz. [(4.0 mL)]{Large dog} 1 Applicator - 0.203 fl. oz. [(6.0 mL)]{Extra large dog}

{for 3 applicator carton}

0.051 fl. oz. [(1.5 mL)] Contains 3 - 0.017 fl. oz. [(0.5 mL)] applicators {Extra small dog} 0.102 fl. oz. [(3 mL)] Contains 3 – 0.034 fl. oz. [(1.0 mL)] applicators {Small dog} 0.204 fl. oz. [(6 mL)] Contains 3 – 0.068 fl. oz. [(2.0 mL)] applicators {Medium dog} 0.405 fl. oz. [(12 mL)] Contains 3 - 0.135 fl. oz. [(4.0 mL)] applicators {Large dog} 0.609 fl. oz. [(18 mL)] Contains 3 - 0.203 fl. oz. [(6.0 mL)] applicators {Extra large dog}

{for 6 applicator carton} 0.102 fl. oz. [(3.0 mL)] Contains 6 - 0.017 fl. oz. [(0.5 mL)] applicators {Extra small dog} 0.204 fl. oz. [(6.0 mL)] Contains 6 – 0.034 fl. oz. [(1.0 mL)] applicators {Small dog} 0.408 fl. oz. [(12.0 mL)] Contains 6 – 0.068 fl. oz. [(2.0 mL)] applicators {Medium dog} 0.81 fl. oz. [(24.0 mL)] Contains 6 - 0.135 fl. oz. [(4.0 mL)] applicators {Large dog} 1.218 fl. oz. [(36.0 mL)] Contains 6 - 0.203 fl. oz. [(6.0 mL)] applicators {Extra large dog}

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 cm 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.}

Commented [G(GRBUJ3]: Insert colon to read "WARNING:

{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. Application of product on pets must only be done indoors.

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/puppies under 9 weeks of age or weighing less than [5][11][21] [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-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/puppies 9 weeks or older and weighing [5-10][11-20][21-40][41-80] [81-120] lbs. to kill fleas and ticks and prevent fleas from developing; to repel and reduce blood-feeding by ticks, mosquitoes 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.

Commented [G(GRBUJ4]: Throughout document capitalize SHIELD when used after FRONTLINE

Reason to Issue: Update alternate trade names, typographical errors EPA Reg. No.: 65331-9

FIRST AID	
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for 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 SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have a 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 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.

Date: <u>0</u>10/<u>22</u>04/202<u>45</u> Supersedes: 09/08/2023

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222. For general information on this product, call 1-888-637-4251, or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at http://npic.orst.edu.

Reason to Issue: Update alternate trade names, typographical errors

Date: 010/2204/20245

EPA Rea. No.: 65331-9

Supersodes: 09/08/2023

EPA Reg. No.: 65331-9 Supersedes: 09/08/2023

{Back Panel of 3 and 6 Applicator Carton}

FRONTLINE® SHIELD for Dogs

Illustration of [adult fleas][flea eggs][flea larvae][adult ticks][chewing lice] [mosquitoes][and][stable flies] {See page 22 for representative illustrations}

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 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.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs ONLY. Do not use on animals other than dogs. Do not use on dogs/ puppies under 9 weeks of age or weighing less than [5][11][21][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- 888-637-4251, 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 1-888-637-4251.



May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in trem ors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided, likepy cats away from treated dogs

{Note to the Reviewer: A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be

Reason to Issue: Update alternate trade names, typographical errors

Supersedes: 09/08/2023 EPA Reg. No.: 65331-9

located in the lower right hand corner of the back panel in yellow with black images}

Boehringer Ingelheim Animal Health USA Inc. 3239 Satellite Blvd.,

Duluth, GA 30096 MADE IN FRANCE

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

Satisfaction Guarantee: For product-related (non-emergency) questions or comments, please call our experts at 1-888-637-4251, who can provide further details on our one time satisfaction guarantee which may include a refund or replacement of product. Conditions of use

Date: <u>0</u>10/<u>22</u>04/202<u>45</u>

{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. Step 4 of the instructions below will depict the appropriate size dog and the number of application sites relevant to 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-SHIELD for Dogs:

DIRECTIONS TO USE ICONS FOR x3 and x6 CARTONS



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



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.

FOR X-SMALL and SMALL size:



AFFLI FROWILLE SHELLD
Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
Apply the entire contents by squeezing the entire applicator contents onto dog's skin, at a single site between the shoulder blades. Ensure that FRONTLINE® Shield for Dogs is not applied superficially on dog's hair.

FOR MEDIUM and LARGE size:



APPLY FRONTLINE® SHIELD APPLT PROMILIES* SHELD gainst exposed skin. Apply the product evenly to three spots against exposed skin. Apply the product evenly to three spots on the day is back, starting between the shoulder blades and continuing on to the second and third spots, squeezing the applicator until empty. Ensure that FRONLING® Sheld for Dogs is not applied superficially on dog's hair.

FOR X-LARGE size:



APPLY FRONTLINE® SHIELD APPLI FRONTLINE — SHIELD part dog is hair until skin is wishie. Place applicator tip directly against exposed skin. 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 susperficially on dog's hair.

[Product-Related (Non-Emergency) Questions or Comments? Call: 1-888-637-4251]

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Page 6 of 23

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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 SHIELD for Dogs

For use ONLY on Dogs/Puppies 9 weeks or older and weighing [5-10][11-20][21-40][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-SHIELD for Dogs

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

Ticks:

- [Starts killing ticks in 1 hour, starting 2 days after treatment]
- Repels and kills ticks for an entire month, including Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Starticks
- Kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis

Fleas:

- [Starts killing fleas in 5 minutes, starting 2 days after treatment]
- 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

Mosquitoes and Flies:

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

Lice and Mites:

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

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Reason to Issue: Update alternate trade names, typographical errors

EPA Reg. No.: 65331-9 Supersedes:09/08/2023

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-SHIELD for Dogs as follows:

DIRECTIONS TO USE ICONS FOR x3 and x6 CARTONS



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.



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.

FOR X-SMALL and SMALL size:



APPLY FRONTLINE® SHIELD
Part dog's hair until skin is visible.
Place applicator tip directly against exposed skin.
Apply the entire contents by squeezing the entire applicator
contents onto dog's skin, at a single site, between the
shoulder blades. Ensure that FRONTLINE® Shield for Dogs
is not applied superficially on dog's hair.

FOR MEDIUM and LARGE size:



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.

FOR X-LARGE size:



Date: 010/2204/20245

APPLY FRONTLINE® SHIELD
Part dog's hair until skin is visible. Place applicator tip directly
against exposed skin. 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.

[Product-Related (Non-Emergency) Questions or Comments? Call: 1-888-637-4251]

FRONTLINE® is a registered trademark and FRONTLINE_SHIELD SHEELD SHEELD is a trademark of Boehringer Ingelheim Animal Health France, used under license.

Health France, used under license. ©2024 2023 Boehringer Ingelheim Animal Health USA Inc. All rights reserved. $\begin{tabular}{ll} \textbf{Commented [G(GRBUJ12]:} Correct the spelling of "SHIELD" \end{tabular}$

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{Back of Insert for 3 and 6 Applicator Cartons}

FREQUENCY OF APPLICATION

Apply **[FRONTLINE® Shield-SHIELD for Dogs]** monthly to start killing ticks in 1 hour and fleas in just 5 minutes beginning 2 days after treatment. **FRONTLINE® Shield-SHIELD for Dogs** controls fleas, flea eggs, and flea larvae, ticks, and chewing lice infestations. Ticks, stable flies and mosquitoes are repelled for one month by [a single application of] **FRONTLINE® Shield-SHIELD [for Dogs]**.

[Research demonstrates that] **FRONTLINE®** <u>Shield-SHIELD</u> for **Dogs** remains effective even after bathing, water immersion, or exposure to sunlight 24 hours after application. A monthly application of **FRONTLINE®** <u>Shield-SHIELD</u> for **Dogs** kills existing fleas and prevents new fleas from developing; kills all stages of ticks, chewing lice, and repels mosquitoes 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. Application of product on pets must only be done indoors.

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/puppies under 9 weeks of age or weighing less than [5][11][21][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-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/puppies 9 weeks or older and weighing [5-10][11-20][21-40][41-80] [81-120] lbs. to kill fleas and ticks and prevent fleas from developing; to repel and reduce blood-feeding by ticks, mosquitoes 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-CLEANUP for disposal instructions. Do not dispose of down the drain or sewer.

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.

[Product-Related (Non-Emergency) Questions or Comments? Call: 1-888-637-4251]

EPA Reg. No. 65331-9

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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-SHIELD for Dogs

For use ONLY on Dogs/Puppies 9 weeks or older and weighing [5-10][11-20][21-40][41-80][81-120] lbs.

KEEP OUT OF REACH OF CHILDREN WARNING

FRONTLINE® ShieldSHIELD -for Dogs

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

Ticks:

- [Starts killing ticks in 1 hour, starting 2 days after treatment]
- Repels and kills ticks for an entire month, including Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Starticks.
- Kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis

Fleas:

- [Starts killing fleas in 5 minutes, starting 2 days after treatment]
- Kills fleas, flea eggs and flea larvae for an entire month
- Prevents development of flea eggs and flea larvae, effectively breaking the flea lifecycle
- Kills fleas which may cause flea allergy dermatitis and that may transmit bartonellosis, tularemia and tapeworm

Mosquitoes and Flies:

- Repels mosquitoes which may transmit heartworm disease and West Nile Virus
- Repels and reduces blood feeding by stable flies and mosquitoes 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.

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How to Apply:

(1)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 open at slit and remove 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 SHIELD for Dogs:

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. {For puppies, extra small and small-sized dogs ONLY weighing 5-10 lbs. or 11-20 lbs.} Apply the entire contents by squeezing the applicator volume onto dog's skin, at a single site, between the shoulder blades. Ensure that **FRONTLINE® Shield-SHIELD for Dogs** is not applied superficially on dog's hair. {For medium and large-sized dogs ONLY weighing 21-40 or 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-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-SHIELD for Dogs** is not applied superficially on dog's hair.

FREQUENCY OF APPLICATION

Apply [FRONTLINE® Shield-SHIELD for Dogs] monthly to start killing ticks in 1 hour and fleas in just 5 minutes starting 2 days after treatment. FRONTLINE® Shield-SHIELD for Dogs control fleas, flea eggs, flea larvae, ticks, and chewing lice infestations. Ticks, stable flies and mosquitoes are repelled for one month by [a single application of] FRONTLINE® Shield-SHIELD [for Dogs].

[Research demonstrates that] **FRONTLINE**® **Shield-SHIELD for Dogs** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **FRONTLINE**® **Shield-SHIELD for Dogs** kills existing fleas and prevents new fleas from developing; kills all stages of ticks and chewing lice; and repels mosquitoes 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. Application of product on pets must only be done indoors.

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/puppies under 9 weeks of age or weighing less than [5][11][21] [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-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/ puppies 9 weeks or older and weighing [5-10][11-20][21-40][41-80][81-120] lbs. to kill fleas and ticks and prevent fleas from developing; to repel and reduce blood-feeding by ticks, mosquitoes 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 does not absorb the product.

Reason to Issue: Update alternate trade names, typographical errors EPA Reg. No.: 65331-9

FIRST AID	
IF IN EYES:	 Hold eye open and rinse slowly and gently with water for 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 SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have a 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 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.

Date: <u>0</u>10/<u>22</u>04/2024<u>5</u> Supersedes: 09/08/2023

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222. For general information on this product, call 1-888-637-4251, or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at http://npic.orst.edu.

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-CLEANUP for disposal instructions. Do not dispose of down the drain or sewer.

Reason to Issue: Update alternate trade names, typographical errors Date: 010/2204/20245 Supersedes: 09/08/2023 EPA Reg. No.: 65331-9

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.

HAZARDS TO DOMESTIC ANIMALS

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

Do not use on dogs/puppies under 9 weeks of age or weighing less than [5][11][21][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 quidance on use against Sarcoptes mites. This product is not a substitute for a prescribed heartworm preventative. Call 1-888-637-4251 for assistance.

{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 1-888-637-4251.

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

[Product-Related (Non-Emergency) Questions or Comments? Call: 1-888-637-4251]

Boehringer Ingelheim Animal Health USA Inc. 3239 Satellite Blvd.

Duluth, GA 30096

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{Front of Calendar Reminder Stickers. This promotional piece is an optional addition to the carton to promote repurchase of product. It does not provide any further directions for use or precautions that are not found on several other labeling components included with the product.}

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 mosquitoes and stable flies, treat all dogs with the correct dose of **FRONTLINE®** <u>SHIELD</u> 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 does not absorb the product.

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

{PICTOGRAMS: icon with slash through}
Adult fleas
Flea eggs
Flea larvae
Adult ticks
Chewing lice

Mosquitoes

Stable flies

{Back of Calendar Reminder Stickers. This promotional piece is an optional addition to the carton to promote repurchase of product. It doesn't provide any further directions for use or precautions that are not found on several other labeling components included with the product.}

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **FRONTLINE®** Shield-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 SHIELD for Dogs** monthly. Don't forget to re-purchase!

QUESTIONS? Contact your veterinarian or call our technical experts at 1-888-637-4251.

6 months Use all 6 stickers

3 months Use all 3 stickers 2 or 5 stickers that read, "APPLY FRONTLINE® ShieldSHIELD", with the 3rd or 6th sticker reads "Re-purchase FRONTLINE® ShieldSHIELD".

FRONTLINE® is a registered trademark and FRONTLINE SHIELD SHEILD™ is a trademark of Boehringer Ingelheim Animal Health France, used under license.

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Reason to Issue: Update alternate trade names, typographical errors EPA Reg. No.: 65331-9Supersedes: 09/08/2023

{Front Label of Individual Applicator}

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

Date: <u>0</u>10/<u>22</u>04/2024<u>5</u>

FRONTLINE® Shield SHIELD for Dogs

For use ONLY on Dogs/Puppies 9 weeks or older and [5-10][11-20][21-40][41-80] [81-120] lbs.

[0.017][0.034][0.068][0.135][0.203] fl. oz. [0.5][1.0][2.0][4.0][6.0] ml



{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.

Reason to Issue: Update alternate trade names, typographical errors EPA Reg. No.: 65331-9Date: <u>0</u>10/<u>22</u>04/202<u>45</u> Supersedes: 09/08/2023

{Blister Package}

FRONTLINE® SHIELD for Dogs

 $[0.017][0.034][0.068][0.135][0.203] \ fl. \ oz.$ [0.5][1.0][2.0][4.0][6.0] ml

KEEP OUT OF REACH OF CHILDREN WARNING

Read accompanying label before use For external use only

Lot No.

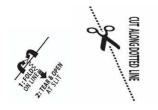


Illustration of dog with 1, 3 or 4 arrows pointing to dog's back showing where to apply product according to the volume and weight range.

{Same illustration used on Pages 6 and 8}

For use ONLY on dogs/puppies 9 weeks or older and [5-10][11-20][21-40][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

- · Long-lasting, monthly control of fleas, ticks, mosquitoes, 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)(larvae)(adults)] from developing
- Shields your dog from the relentless attack of ticks, mosquitoes and fleas
- Has an additional powerful ingredient to repel ticks, mosquitoes and flies
- · Best for dogs at high risk for tick and mosquito-borne illnesses
- Kills fleas and ticks [for an entire month] including Deer ticks, Brown dog
- ticks, American Dog ticks, and Lone Star ticks
- Repels [mosquitoes][and][stableflies].
- Repels mosquitoes for one month.
- Repels mosquitoes 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-SHIELD spreads over the dog's body to provide
 [full body] [all over] protection against fleas, ticks, mosquitoes, stable flies, and chewing
 lice
- **FRONTLINE**® **Shield**-**SHIELD** [for **Dogs**] provides ongoing protection against fleas, ticks, mosquitoes, stable flies, and chewing lice for one month.
- FRONTLINE® Shield-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—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 mosquitoes][control of stable flies][repellency of stable flies][control of
 chewing lice]
- **FRONTLINE®** Shield-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 mosquitoes]
- For convenient, long-lasting one month control of fleas, ticks, and chewing lice.
- [When] Applied topically on a monthly basis, FRONTLINE® Shield-SHIELD for Dogs
 kills existing fleas and prevents new fleas from developing on your dog; kills ticks and
 chewing lice, aids in control of Sarcoptes mites, and [repels][reduces blood feeding by]
 stable flies, and mosquitoes.
- FRONTLINE® <u>Shield-SHIELD</u> contains the active ingredients fipronil, permethrin and pyriproxyfen, which control infestations caused by fleas, ticks and chewing lice; and repels [against] stable flies and mosquitoes.
- To kill fleas and ticks and prevent fleas from developing
- Repels and reduces blood-feeding by ticks, mosquitoes, and stable flies
- To kill chewing lice and to aid in control of Sarcoptes mites

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Reason to Issue: Update alternate trade names, typographical errors EPA Reg. No.: 65331-9

- · Kills fleas, ticks, chewing lice, and stable flies
- Repels [and reduces blood feeding by] stable flies and mosquitoes for [a][one] month

Date: <u>0</u>10/<u>22</u>04/2024<u>5</u> Supersedes: 09/08/2023

- Kills [all stages of] fleas and ticks
- Kills [all stages of][ticks][and][chewing lice] and repels mosquitoes and stable flies.
- Repels ticks, stable flies and mosquitoes
- 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-SHIELD for Dogs.
- Stable flies and mosquitoes are [also] repelled by FRONTLINE® Shield-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 for one month of fleas, ticks, and lice, and repellency of mosquitoes and stable flies
- **FRONTLINE** Shield-SHIELD for Dogs is indicated for the prevention and control of fleas, ticks, and chewing lice for use ONLY on [dogs/puppies 9 weeks or older and weighing 5-10 lbs.][dogs/puppies 9 weeks or older and weighing 11-20 lbs.][dogs/puppies 9 weeks or older and weighing 21-40 lbs.][dogs/puppies 9 weeks or older and weighing 80 lbs.][dogs/puppies 9 weeks or older and weighing 81-120 lbs.]
- FRONTLINE® Shield-SHIELD for Dogs kills and repels stable flies, and repels mosquitoes
- Kills fleas, ticks, chewing lice, and aids in control of Sarcoptes mites
- Repels ticks and mosquitoes
- 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 on your dog 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-SHIELD for Dogs.
- The active ingredients in FRONTLINE® Shield-SHIELD provide [long-lasting] control for one month of fleas, ticks, mosquitoes, stable flies, and chewing lice on dogs.
- To [successfully] treat fleas, ticks, and chewing lice, and repel mosquitoes and stable flies, all dogs must be treated with the correct dose of FRONTLINE® Shield— SHIELD for Dogs for their weight range.
- Convenient, [long-lasting] monthly topical for treatment of fleas, ticks, and chewing lice, and repellency of mosquitoes and stable flies.
- Effectively controls existing infestations and prevents re-infestations of fleas, ticks, and chewing lice.

Fleas

- Starts killing fleas within 5 minutes, [beginning][starting] 2 days after [treatment][application]
- Kills fleas within 6 hours, beginning 2 days after treatment [of dogs with FRONTLINE® ShieldSHIELD]
- Prevents fleas on treated dogs from infesting your home
- Prevents fleas from developing on your dog
- Prevents fleas, flea eggs and flea larvae from developing on your dog
- 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 [and that may transmit bartonellosis, tularemia and tapeworm]
- 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 SHIELD kills fleas that may cause this condition
- FRONTLINE® Shield-SHIELD kills existing fleas on dogs
- Re-infesting fleas are killed within 5 minutes, [starting][beginning] 2 days after [treatment][application] with protection against further flea infestation lasting a [full]
- Kills [newly emerged] fleas [before they lay eggs] for one month
- FRONTLINE® Shield-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-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 SHIELD for Dogs kills fleas on your dog
- Once a month topical flea control for use ONLY on [dogs/puppies 9 weeks or older and weighing 5-10 lbs.][dogs/puppies 9 weeks or older and weighing 11-20 lbs.][dogs/puppies 9 weeks or older and weighing 21-40 lbs.][dogs/puppies 9 weeks or older and weighing 41-80 lbs.][dogs/puppies 9 weeks or older and weighing 81-120 lbs.]
- FRONTLINE® <u>Shield SHIELD</u> for Dogs is indicated for the prevention and control of fleas, for use ONLY on dogs/puppies 9 weeks or older and weighing [5-10 lbs.][11-20 lbs.][21-40 lbs.] [41-80 lbs.][81-120 lbs.]
- One application prevents further flea infestations on your dog 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 on yourdog]
- Kills [all life stages of fleas][fleas before they lay eggs]
- [Prevents] re-infestations by killing adult fleas [before they lay eggs]
- Treatment with FRONTLINE® Shield-SHIELD kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity
- Use flea [prevention][protection] year-round
- FRONTLINE[®] <u>SHIELD</u> for Dogs kills flea eggs and larvae for one month

- FRONTLINE® Shield—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 on your dog
- FRONTLINE® Shield-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 reinfestation]
- 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 for (30 days)(1 month)
- Fleas do not have to bite to [die][be controlled][be killed][be inhibited from developing].
- Prevents development of [immature flea stages][flea eggs][and][flea larvae][on your dog], [effectively] breaking the flea lifecycle
- FRONTLINE® Shield-SHIELD for Dogs kills existing fleas and prevents new fleas from developing on your dog
- A monthly application of FRONTLINE® Shield-SHIELD for Dogs kills existing fleas and prevents ——new fleas from developing on yourdog
- Kills fleas, flea eggs and flea larvae [for an entire month]

Ticks

- Starts killing ticks in 1 hour, [starting][beginning] 2 days after[treatment][application]
- [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-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-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
- [Repels][and][Kills] ticks for an entire month, including Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Starticks

Mosquitoes and stable flies

- · Repels mosquitoes and stable flies
- Repels and reduces blood-feeding by stable flies and mosquitoes
- Stable flies and mosquitoes: When applied [monthly], FRONTLINE® SHIELD for Dogs [repels][and][reduces blood feeding by] stable flies and mosquitoes for [one][a] month
- Stable flies: FRONTLINE® Shield-SHIELD for Dogs kills stable flies for one month
- Stable flies and mosquitoes are repelled by FRONTLINE® Shield-SHIELD for Dogs for one month
- Repels and reduces blood-feeding by stable flies and mosquitoes for a month
- Repels mosquitoes for one month
- · Reduces blood-feeding by [and repels] mosquitoes
- Repels mosquitoes that may [transmit][carry vector borne diseases][such as][heartworm disease][and][West Nile Virus]
- 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 mosquitoes 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-SHIELD for Dogs can kill chewing lice for one month Apply monthly where lice control is consistently needed
- Sarcoptes mites: FRONTLINE® Shield-SHIELD for Dogs aids in the control of Sarcoptes mites that may cause Sarcoptic mange
- FRONTLINE® <u>Shield-SHIELD</u> for Dogs aids in [the] control of Sarcoptes mite infestations [that may cause Sarcoptic mange]
- [Apply,] FRONTLINE® Shield-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][which may cause Sarcoptic mange]
- [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-SHIELD for Dogs aids in the control of Sarcoptes mite infestations [that may lead to Sarcoptic mange]

Miscellaneous

- **FRONTLINE®** Shield-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][fordogs]
- [Patented] applicator [trademark] for easy application directly to the skin
- Quick-drying
- For easy and convenient application, **FRONTLINE®** Shield-SHIELD for **Dogs** is available in sizes for use ONLY on extra small dogs/puppies 9 weeks or older and weighing 5-10 lbs. [0.17 fl. oz.] [0.5 ml], small dogs/puppies 9 weeks or older and weighing 11-20 lbs.[0.34 fl. oz.] [1.0 ml], medium dogs/puppies 9 weeks or older and weighing 21-40 lbs. [0.68 fl. oz.] [2.0 ml], large dogs/puppies 9 weeks or older and weighing 41-80 lbs. [0.135 fl. oz.][4.0 ml], extra-large dogs/puppies 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 24 hours after application [for 30days]
- [For use][Can be used] ONLY on dogs/puppies 9 weeks or older and weighing [5-10] [11-20][21-40][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/puppies 9 weeks or older and weighing [5-10][11-20] [21- 40][41-80 lbs.][81-120 lbs.]
- Controls existing infestations and prevents establishment of new infestations on your dog
- Prevents (re-)infestation on your dog for [one][an entire]month
- Once monthly application
- FRONTLINE® Shield 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 24 hours after application [remains effective after bathing and swimming] for [a][one] month
- Remains effective after exposure to sunlight for 24 hours after application
- FRONTLINE® Shield-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

Reason to Issue: Update alternate trade names, typographical errors EPA Reg. No.: 65331-9

- For indoor and outdoor dogs
- Convenient topical treatment for dogs that enjoy the outdoors
- Extra strength [triple action for] monthly protection
- Illustration of [adult flea][flea eggs][flea larvae][adult tick][chewing lice] [mosquitoes][and][stable flies]{Background colors, e.g., blue, may differ for each weight range}















Date: <u>0</u>10/<u>22</u>04/2024<u>5</u> Supersedes: 09/08/2023

• Illustration of tick, flea and mosquito.







Picture or illustration of a dog.



{Representative dog; each carton may have a representative picture of a dog in that weight range}

• Picture or illustration of the Boehringer Ingelheimlogo.



Picture or illustration of the primary package [applicators].

