

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 12, 2014

Mr Timothy Dotson Merial 3239 Satellite Blvd. Duluth, GA 30096

Dear Mr. Dotson:

Subject: Amendment-new companion animal safety study (MRID 49316201)

Product Name: CERTISHIELDTM for Dogs

EPA Registration Number 65331-8 Your submission dated May 10, 2013

Decision No.: 480831

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

Please note that all previous mitigation requirements outlined in the Agency's Notice of Registration dated May 11, 2012 are still required. Merial must submit a request to extend the time limited registration prior to the expiration date identifying all dates of submission for first shipment notification, enhanced incident reporting, and quarterly sales information. This amendment does not supersede any of these requirements.

A stamped label 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 it's implementing regulation at 40 CFR 152.3.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely,

Richard Gebken Product Manager 10

Insecticide Branch

Office of Pesticide Programs

Richard J. Ceelle

Date: August 12, 2014

Enclosure

Date: 08/8/14 Supersedes: 04/15/14

Draft Master Label

Includes label text for four different applicator sizes corresponding to four dog weight ranges, and including a 1x, 3x and 6x applicator presentation. Optional text appears in brackets.

(For alternate marketing text to use on carton and insert, see pages 12-16)

(CARTON FRONT PANEL)

CERTISHIELD™ for dogs [From the makers of FRONTLINE®]

Picture of representative size dog

ACCEPTED

08/12/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

65331-8

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

Long-lasting control of fleas, ticks, and lice, and repellency of mosquitoes and stable flies for [se on (Dogs & Puppies ONLY 9 weeks or older and 11-20 lbs.)]

(Dogs ONLY 21 – 40 lbs.)

(Dogs ONLY 41 – 80 lbs.)

(Dogs ONLY 81 – 120 lbs.)

KEEP OUT OF REACH OF CHILDREN WARNING

For First Aid and other precautionary statements, refer to product package insert.

READ THE ENTIRE LABEL BEFORE EACH USE

ACTIVE INGREDIENTS

Fipronil	6.01%
Permethrin*	44.88%
OTHER INGREDIENTS	49.11%
TOTAL	100.0%

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

Net Contents: 1-[0.034 fl. oz. (1.0 ml), 0.068 fl. oz. (2.0 ml), 0.135 fl. oz. (4.0 ml), 0.203 fl.

oz. (6.0 ml)]

Net Contents: 3-[0.102 fl. oz. (3.0 ml), 0.204 fl. oz. (6.0 ml), 0.405 fl. oz. (12.0 ml), 0.609 fl.

oz. (18.0 ml)]

Net Contents: 6-[0.204 fl. oz. (6.0 ml), 0.408 fl. oz. (12.0 ml), 0.810 (24.0 ml), 1.218 fl. oz. (36.0 ml)]

> Do Not Use on Cats Pictogram

[1.5 x 1.5 cm]

DO NOT USE ON CATS

Track & Trace

Reason to Issue: Final Label Approval

Date: 08/8/14
Supersedes: 04/15/14

(CARTON BACK PANEL)

CERTISHIELD™ for dogs

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS and DOMESTIC ANIMALS

HAZARDS TO HUMANS

May cause 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.

(Single presentation on insert)

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.

DO NOT USE ON CATS PICTOGRAM [1.5 x 1.5 cm]

DO NOT USE ON CATS -- MAY BE FATAL Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

Do not use on puppies under 9 weeks of age or weighing less than 11 lbs. Individual sensitivities, while rare, 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 pet 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 animals known to be sensitive to pesticide products. Call 1-800-660-1842 for 24-hour assistance.

Supersedes: 04/15/14

(CARTON BACK PANEL)(CONT'D.)

(Single presentation on insert)

FIRST AID		
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 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 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. 	
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.		

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

MADE IN FRANCE

EPA Reg. No. 65331-8 EPA Est. No. 65331-FR-2 Satisfaction Guaranteed Graphic

Please call our experts at 1-800-660-1842 if you have any questions or comments about flea, tick, mosquito, stable fly and lice control or **CERTISHIELD™**.

Supersedes: 04/15/14

(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. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS.

FOR EXTERNAL USE ON DOGS and PUPPIES ONLY. Do not use on dogs or puppies under 9 weeks of age or weighing less than 11 lbs. Do not split applicators between dogs. Do not use multiple applicators on one dog. 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.

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. Do not apply more often than once a month.

For use in DOGS and PUPPIES 9 weeks old or older. To kill fleas and ticks; to repel and prevent blood-feeding by ticks, mosquitoes and stable flies; to kill chewing lice and to aid in control of sarcoptic mange mites. Apply monthly according to the following directions:

APPLICATION DIRECTIONS

(Instructions for the 3x/6x Carton):



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

Step 4: [graphic] Apply CERTISHIELD™

Part dog's hair until skin is visible. Place applicator tip directly against exposed skin. For small dogs and puppies 9 weeks or older and weighing 11-20 lbs.: Deposit entire contents by squeezing the entire applicator contents onto dog's skin, at a single site, between the shoulder blades. For medium dogs 21-40 lbs. or large dogs 41-80 lbs.: Apply the product evenly to three

Supersedes: 04/15/14

(CARTON INSIDE FRONT PANEL)(CONT'D.)

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.

For extra-large dogs 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 CERTISHIELD $^{\text{TM}}$ for dogs is not applied superficially on dog's hair.

(CARTON INSIDE FLAPS)

CERTISHIELD™ for dogs

Kills fleas and ticks; repels mosquitoes and stable flies for one month, and kills chewing lice for up to a month.

Fleas do not have to bite to die.

CERTISHIELD™ for dogs provides efficacy against fleas and ticks. The active ingredients in **CERTISHIELD™** provide for long-lasting control of fleas, ticks and chewing lice on dogs.

[PICTOGRAMS (icon with slash through)]

Adult Flea
Adult Tick
Chewing Lice
Mosquitoes
Stable Flies
Sand Flies
Sarcoptic mange mites

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Date: 08/8/14 Supersedes: 04/15/14

(PACKAGE INSERT FRONT)

CERTISHIELD™ for dogs

For use ONLY on dogs and puppies 9 weeks or older

Convenient, long-lasting spot-on for treatment of fleas, ticks, and chewing lice, and repellency of mosquitoes and stable flies

ACTIVE INGREDIENTS

Fipronil	6.01%
Permethrin*	44.88%
OTHER INGREDIENTS	49.11%
TOTAL	100.0%

^{*}cis/trans ratio: max 55% (±) cis and min 45% (±) trans

KEEP OUT OF REACH OF CHILDREN WARNING

See Carton for First Aid and Precautionary Statements.

CERTISHIELD™ for Dogs

Kills fleas and ticks; repels mosquitoes and stable flies; and kills chewing lice

- Repels and prevents blood feeding by stable flies and mosquitoes for up to a month
- Effectively stops existing infestations and prevents re-infestations of fleas, ticks and chewing lice
- · Kills ticks which may transmit Lyme disease, Rocky Mountain spotted fever, Anaplasmosis, Babesiosis, canine Ehrlichiosis or cause tick paralysis
- Kills fleas and ticks for an entire month, including Deer ticks, Brown Dog ticks, American Dog ticks, and Lone Star ticks
- Kills fleas which may cause flea allergy dermatitis
- Kills fleas that may transmit bartonellosis, turalemia and tapeworm
- Repels mosquitoes which may be a vector of heartworm (Dirofilaria immitis)
- Aids in control of sarcoptic mange infestations
- Can be used on dogs and puppies 9 weeks or older

Do not use on cats pictogram

DO NOT USE ON CATS [1.5 x 1.5 CM]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR RABBITS. DO NOT USE ON OTHER ANIMALS.

DO NOT USE ON CATS

Supersedes: 04/15/14

(PACKAGE INSERT FRONT) (CONT'D.)

(Instructions for the 1x blister pack):

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.

(Open the child-resistant packaging according to the instructions found on the inside front panel of the carton)

FOR EXTERNAL USE ON DOGS ONLY. Do not use on dogs or puppies under 9 weeks of age or weighing less than 11 lbs. Do not split pipettes between dogs. Do not use multiple pipettes on one dog. 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. 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.

(PACKAGE INSERT BACK)

Supersedes: 04/15/14

FREQUENCY OF APPLICATION

Fleas, ticks, and chewing lice infestations can be controlled with monthly applications of **CERTISHIELD™** for **Dogs**. Stable flies and mosquitoes are repelled by **CERTISHIELD™** for **Dogs**.

Sand flies are (killed)(repelled) for up to 3 weeks by **CERTISHIELD™** for **Dogs**.

CERTISHIELD™ for **Dogs** kills adult fleas for up to one month. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if re-infestation is likely.

CERTISHIELD™ for **Dogs** can kill ticks for up to one month. Apply monthly where tick control is consistently needed.

CERTISHIELD™ for **Dogs** can kill chewing lice for up to a month. Apply monthly where lice control is consistently needed.

CERTISHIELD™ for **Dogs** aids in the control of sarcoptic mange.

When applied monthly, **CERTISHIELD™** for **Dogs** repels and prevents blood feeding by stable flies and mosquitoes.

Wait at least 30 days before re-application of **CERTISHIELD™** for **Dogs**. Avoid contact with treated area until dry. **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight. A monthly application of **CERTISHIELD™** kills fleas, all stages of ticks, chewing lice, and repels mosquitoes and stable flies. Do not apply more than once a month. Research demonstrates that **CERTISHIELD™** remains effective even after bathing, water immersion, or exposure to sunlight.

PESTICIDE STORAGE AND DISPOSAL

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

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

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

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling, if available.

How Supplied

For easy and convenient application, **CERTISHIELD™** for dogs is available in sizes for small dogs & puppies ONLY 9 weeks or older and 11-20 lbs., medium dogs 21-40 lbs., large dogs 41-80 lbs., and extra-large dogs 81-120 lbs.

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. 65331-8

Merial Limited 3239 Satellite Blvd. Duluth, GA 30096-4640, USA **CERTISHIELD™** is a trademark of Merial. © 2014 Merial Limited, Duluth, GA. All rights reserved.

Reason to Issue: Final Label Approval

Date: 08/8/14
Supersedes: 04/15/14

(COMPLIANCE CARD)

(FRONT)

See other side for more

CERTISHIELD™ for dogs

Pipette pictogram Adult flea pictogram

Adult Tick pictogram

Chewing lice pictogram

Some tips and other information:

DO NOT USE ON CATS.

To successfully treat fleas, ticks, and chewing lice, and repel mosquitoes and stable flies, all dogs must be treated with their own dose of **CERTISHIELD™**.

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 **CERTISHIELD™** is applied and remain dry 24 hours after application.

Mosquito

Verify applicator is empty after applying to your dog.

Even indoor dogs need flea and tick control because you or other dogs in the household may bring fleas and ticks into the home.

Sand fly

Stal

pictogram

Stable fly pictogram

pictogram

(BACK)

Calendar reminder stickers

Do not use on cats pictogram

To ensure continued protection of your dog, use these stickers as a reminder to apply and repurchase **CERTISHIELD** $^{\text{TM}}$.

After treating your pet 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 **CERTISHIELD™** monthly.

Don't forget to re-purchase!

6 months Use all 6 stickers

3 months

5 stickers that read "Apply CERTISHIELD™", with the 6th sticker "Re-purchase CERTISHIELD™"

QUESTIONS? Contact your veterinarian or call our technical experts at 1-800-660-1842, Monday-Friday, 8am-8pm. For more information, visit **www.CERTISHIELD™.com**.

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Supersedes: 04/15/14

(LABEL ON INDIVIDUAL APPLICATOR)

CERTISHIELD™ for Dogs

6.01% fipronil 44.88% Permethrin

ONLY for dogs & puppies (9 weeks or older and 11-20 lbs.) (21-40 lbs.) (41-80 lbs.) (81-120 lbs.)

EPA Reg. No. 65331-8

KEEP OUT OF REACH OF CHILDREN WARNING

Lot No.

(0.034)(0.068)(0.135)(0.203) fl. oz.

Do not use on cats pictogram

Supersedes: 04/15/14

(LABEL ON BLISTER PACK)

CERTISHIELD™ for Dogs

(0.034 fl. oz.)

(0.068 fl. oz.)

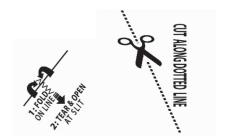
(0.135 fl. oz.)

(0.203 fl. oz.)

KEEP OUT OF REACH OF CHILDREN WARNING

(DOG 20)(DOG 40)(DOG 80)(DOG 120)

Lot No.



Supersedes: 04/15/14

Alternate marketing text for carton or insert

CERTISHIELD™ for dogs kills fleas, ticks and chewing lice providing a convenient, effective treatment for dogs. **CERTISHIELD™** kills ticks, repels mosquitoes and stable flies, and kills chewing lice; ONLY for (dogs and puppies 9 weeks or older and 11-20 lbs.)(dogs weighing 21 – 40 lbs.)(dogs weighing 41 – 80 lbs.)(dogs weighing 81 – 120 lbs.).

[Multiple Infestations]

- Kills ticks including Deer ticks, Brown dog ticks, American Dog ticks and Lone Star ticks
- Repels ticks, mosquitoes, and stable flies
- Repels mosquitoes for up to 4 weeks
- Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Babesiosis, or cause tick paralysis
- (Kills)(Stops)(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, CERTISHIELD™ spreads over the dog's body to provide (full body) (all over) protection against fleas, ticks, mosquitoes, stable flies, and chewing lice
- **CERTISHIELD™** provides ongoing protection against fleas, ticks, stable flies, and chewing lice [for at least one month (30 days)]
- Effective monthly treatment of fleas and ticks
- Easy and effective control of fleas and ticks that lasts at least 1 month (30 days)
- Using the (patented)(trademark) applicator, CERTISHIELD™ is specially designed to spread over the dog's body providing effective control of fleas and ticks
- Prevents reinfestation (of fleas) (of ticks) for up to one month
- Monthly treatment is recommended for optimal control and prevention of fleas and ticks
- Proven treatment technology for (the control of flea(s)(infestations), [(the control (the repellency) of ticks)], (the repellency of mosquitoes), [(the control)(the repellency)(of stable flies)], (the control of chewing lice)
- **CERTISHIELD™** uses (different) (multiple) modes of action to (kill and repel ticks) (kill fleas and chewing lice) (kill and repel stable flies) (repel mosquitoes)
- For convenient, long-lasting control of fleas, ticks, and chewing lice.
- (When) Applied topically on a monthly basis, **CERTISHIELD™** for dogs kills fleas, ticks, chewing lice, aids in control of sarcoptic mange mites, and repels (inhibits blood feeding) stable flies and mosquitoes.
- **CERTISHIELD™** contains the active ingredients fipronil and permethrin, which control infestations caused by fleas, ticks and chewing lice; repels (against) stable flies and mosquitoes.
- Kills fleas, ticks, chewing lice, and stable flies
- Repels stable flies and mosquitoes
- Kills fleas and ticks
- Repels ticks, stable flies and mosquitoes
- Repels sand flies for up to 3 weeks
- For the control and prevention of flea [and chewing lice] infestations
- Flea, tick, and chewing lice infestations can be controlled with monthly applications of CERTISHIELD™ for dogs.
- Stable flies and mosquitoes are (also) repelled by **CERTISHIELD™** for dogs.
- Monthly application against fleas and ticks
- Kills fleas and ticks for (up to) one month
- Monthly application is recommended for control and prevention of fleas and ticks
- Long lasting flea and tick control for your pet

Reason to Issue: Final Label Approval

Date: 08/8/14 Supersedes: 04/15/14

 CERTISHIELD™ for dogs is indicated for the prevention and control of fleas, ticks, and chewing lice on dogs and puppies 9 weeks of age or older

- Kills fleas, ticks, chewing lice, and aids in control of sarcoptic mange mites
- Repels ticks and mosquitoes.

[Fleas]

- Prevents fleas on treated dogs from infesting your home
- 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 CERTISHIELD™ kills fleas and may reduce the incidence of this condition.
- **CERTISHIELD™** kills existing fleas on dogs.
- Re-infesting fleas are killed quickly with protection against further flea infestation lasting four weeks. Pre-existing pupae in the environment may continue to emerge for six weeks or longer depending upon climatic conditions.
- Prevents fleas on treated dogs from infesting your home.
- Kills fleas on dogs and continues to prevent infestations for a month.
- May reduce the incidence of 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 CERTISHIELD™ kills fleas and may reduce the incidence of FAD.
- Kills (newly emerged) fleas (before they lay eggs) for up to one month (4 weeks).
- CERTISHIELD™ for dogs can kill adult fleas and lasts for up to 4 weeks. Apply monthly if your dog has fleas that may cause flea allergy dermatitis (FAD), or if reinfestation is
- Kills newly emerged adult fleas prior to egg laying.
- Kills fleas that may transmit bartonellosis, (tularemia) [(and tapeworm (infections)].
- Kills fleas that may transmit bartonellosis and tularemia.
- 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)
- Fleas do not have to bite to die.
- **CERTISHIELD™** for dogs kills fleas that may cause FAD (Flea Allergy Dermatitis).
- Kills (adult) fleas.
- Easy to apply, control of (for) fleas that lasts up to one month (4 weeks).
- **CERTISHIELD™** for dogs kills fleas on your dog.
- Once a month topical flea control for dogs and puppies 9 weeks of age or older.
- **CERTISHIELD™** for dogs is indicated for the prevention and control of fleas on dogs and puppies 9 weeks of age or older.
- One application prevents further flea infestations for up to (4 weeks) (one month).
- Monthly treatment (all year) is recommended for control and prevention of fleas.
- Provides ongoing protection against fleas.
- Stops existing flea infestations by killing adult fleas.
- Kills fleas before they lay eggs.
- Prevents [Stops] re-infestations by killing adult fleas (before they lay eggs).
- Treatment with **CERTISHIELD™** kills fleas which may cause flea allergy dermatitis [FAD] or flea bite hypersensitivity.
- Use flea [prevention][protection] year-round.

Supersedes: 04/15/14

[Ticks]

• (Kills)(and)(repels) all stages of ticks infesting dogs.

- (Kills)(and)(repels)(ticks)(which may cause)(which may transmit) (Lyme disease), (Ehrlichiosis), (Anaplasmosis), (Babesiosis), (Tick Paralysis), (Rocky Mountain Spotted Fever), and (Southern Tick Associated Rash Illness).
- (Kills)(and)(repels) ticks for (up to) (at least) 4 weeks.
- **CERTISHIELD™** 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, and heartworm disease.
- Ticks: CERTISHIELD™ for dogs can (kill)(repel) ticks for (up to) a [one] month. Apply monthly where tick control is consistently needed.
- (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 up to one month (4 weeks).
- (Kills)(and)(repels) Brown dog ticks (*Rhipicephalus* spp.), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes* spp.) and Lone Star ticks (*Amblyomma americanum*) for up to one month (4 weeks).
- (Kills)(and)(repels) Amblyomma americanum (Lone Star tick) for up to 4 weeks (for up to one month).
- Monthly application against ticks.

[Mosquitoes, stable flies and sand flies]

- Repels and inhibits blood feeding by stable flies and mosquitoes.
- Stable flies and mosquitoes: When applied monthly, **CERTISHIELD™** for dogs (prevents blood feeding by) (and) repels) stable flies and mosquitoes for (up to) 4 weeks (a [one] month).
- Repels and prevents blood-feeding by stable flies and mosquitoes for up to (one) a month.
- Repels mosquitoes for up to four (4) weeks.
- Prevents blood feeding by mosquitoes.
- Prevents blood feeding by stable flies.
- Kills stable flies.
- Repels and prevents (inhibits) blood-feeding by stable flies.
- Repels and prevents (inhibits) blood-feeding by sand flies for up to 3 weeks.
- [(Prevents blood-feeding by) (and repels)] mosquitoes.
- Repels stable flies.
- (Repels)(Kills) sand flies for up to 3 weeks.
- Repels [(annoying)(bothersome)(nuisance)](stable flies)(and)(sand flies for up to 3 weeks).
- [(Prevents)(inhibits)] blood-feeding by (stable flies)(sand flies for up to 3 weeks).
- Repels mosquitoes which may (carry)(be (a) vector(s) of) heartworm (*Dirofilaria immitis*) for up to one month.
- Repels and prevents blood-feeding by (stable flies) (sand flies for up to 3 weeks).

Reason to Issue: Final Label Approval

Date: 08/8/14

[Chewing lice and Sarcoptic mange mites]

(For treatment of) (Treats and controls) (Provides effective control of) (For treatment of infestations with)(Kills)(Stops existing) chewing lice (infestations).

Supersedes: 04/15/14

- Kills chewing lice.
- Chewing lice: CERTISHIELD™ for dogs can kill chewing lice for (up to) a [one] month. Apply monthly where lice control is consistently needed.
- Sarcoptic mange mites: (CERTISHIELD™ for dogs) aids in the control of sarcoptic
- **CERTISHIELD™** for dogs aids in (the) control of sarcoptic mange mite infestations
- (When applied monthly,) **CERTISHIELD™ for dogs** aids in the control of sarcoptic
- Aids in the control of sarcoptic mange mite infestations.
- Kills chewing lice.
- (Also) Kills chewing lice and aids in control of sarcoptic mange mites.
- Eliminates infestations with chewing lice.
- Aids in control of sarcoptic mange infestations.
- Controls existing chewing lice infestations.
- Kills chewing lice.
- For control and prevention of chewing lice (infestations).
- Stops existing 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.

[Miscellaneous]

- **CERTISHIELD™** is (water-resistant) (waterproof) and remains effective following bathing, shampooing, swimming (water immersion) or after exposure to rain or sunlight.
- Convenient topical treatment for dogs that enjoy the outdoors.
- (Easy and convenient)(Convenient)(to use)(Easy to apply)(spot-on) application(s).
- Persistent (sustained) efficacy through 30 days.
- Protects for (at least) one 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, CERTISHIELD™ for dogs is available in sizes for puppies and small dogs ONLY (9 weeks old or older) 11-20 lbs. (0.034 fl. oz.)(1.0 ml), medium dogs 21-40 lbs. (0.068 fl. oz.) (2.0 ml), large dogs 41-80 lbs. (0.135 fl. oz.) (4.0 ml), and extra-large dogs 81-120 lbs. (0.203 fl. oz.)(6.0 ml).
- Easy, spot-on (topical) application.
- Non-greasy.
- (Formulated) for dogs that (enjoy)(love) the outdoors.
- Waterproof.
- Water-resistant.
- Convenient to use.
- (1)(3)(6) applicator(s) (1.0 ml, 2.0 ml, 4.0 ml, 6.0 ml).
- (1)(3)(6) applicator(s) (0.034 fl. oz., 0.068 fl. oz., 0.135 fl. oz., 0.203 fl. oz.).
- (1)(3)(6) applicator(s) (0.034 fl. oz. [1.0 ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml]).
- (1)(3)(6) applicator(s)(each) containing (0.034 fl. oz. [1.0ml], 0.068 fl. oz. [2.0 ml], 0.135 fl. oz. [4.0 ml], 0.203 fl. oz. [6.0 ml]).
- (1)(3)(6) applicator(s).
- (1)(3)(6) monthly dose(s) [application(s)].

Reason to Issue: Final Label Approval

Date: 08/8/14 Supersedes: 04/15/14

- (1)(3)(6) applicator(s).
- This product is only for use on dogs and puppies (9 weeks or older and 11-20 lbs.)(weighing 21 to 40 lbs.)(weighing 41 to 80 lbs.)(weighing 81 to 120 lbs.).
- Stops existing infestations and prevents establishment of new infestations.
- Prevents (re-)infestation for one month.
- Once monthly application.
- **CERTISHIELD™** 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 our pet.
- (In) child-resistant packaging.
- Convenient (to use), easy to apply (topical solution).
- Water-proof (remains effective after bathing and swimming) for up to four weeks (a month) (one month).
- Remains effective after exposure to sunlight.
- Remains effective even after bathing, water immersion, or exposure to rain or sunlight.
- Remains effective even after bathing (and swimming).
- Remains effective after exposure to rain and/or sunlight.
- Still works after bathing, swimming or exposure to sunlight.
- Maintains residual efficacy after bathing and swimming.
- Remains effective after bathing (and swimming) [(for a month) (for one month) (for up to four weeks)].
- For indoor and outdoor dogs.
- Convenient topical treatment for dogs that enjoy the outdoors.
- Illustration of flea life cycle.
- Illustration of tick life cycle.
- Illustration of mosquito life cycle.
- Illustration of stable fly life cycle.
- Illustration of sarcoptic mange mite life cycle.
- Illustration of chewing lice life cycle.
- Illustration of sand fly life cycle.
- Illustration of flea.
- Illustration of tick. •
- Illustration of mosquito.
- Illustration of sarcoptic mange mite.
- Illustration of chewing lice.
- Illustration of sand fly.
- Illustration of stable fly.
- Picture or illustration of a dog (or puppy).
- Picture or illustration of the Merial logo.
- Picture or illustration of the primary package (applicators).