

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 10, 2014

Cassie Alexander
Regulatory Affairs, North American
Merial Limited
3239 Satellite Blvd. Bldg 500, office 113
Duluth, GA 30096

Subject: Label Amendment – to review new data to support some previously accepted efficacy claims that had been re-evaluated
Product Name: Certifect for Dogs
EPA Registration Number: 65331-7
Application Date: 6/16/2014
Decision Number: 492174

Dear Ms. Alexander:

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

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. 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.

Other Conditions:

This registration is time-limited and expires two years from the date of this letter.

- A. You must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product.

The quarterly reports are due two months after each quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the appropriate Product Manager for the product within the Registration Division (7504P).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

B. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label (if applicable).
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions.

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 with FIFRA section 6. If you have any questions, please contact Autumn Metzger at 703-305-5314, or metzger.autumn@epa.gov.

Sincerely,



Mark Suarez, Product Manager 07
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

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. Due to space limitations the layout of the 1x hanging card may differ from the 3x and 6x cartons (NOTE: The 1x hanging card will not utilize a carton or compliance cards, so all required information will be located on the Insert, blister pack or pipette for the 1x presentation).

[Optional text appears in brackets-the final product label may include some or all of the optional text on the front, back, side panels, or insert.]

(Text that appears in the parentheses-the final product label will include the information specific to that particular dog label (ex: 5-22 lbs., 23-44 lbs.) or pipette presentation size (ex: 1x, 3x, or 6x))

For alternate marketing text, see Pages –19-21

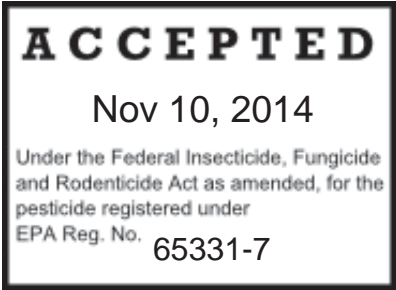
CARTON FRONT PANEL FOR 3x and 6x presentations: INSERT FRONT PANEL for 1x presentation

CERTIFECT® FOR DOGS

(Note: font size of FOR DOGS will be 40% of the size of the largest letter in the brand name on the front panel)

- [Rapidly/Quick/Quickly/Fast Acting in 18 hours]
 - [Kills Ticks in 18 hours]
 - [Starts (rapidly) killing ticks [in][as little as][within] 6 hours]
- [Ticks & all stages of fleas]

(For Dogs & Puppies ONLY 8 weeks or older and 5-22 LBS)
(For Dogs ONLY 8 weeks or older and 23 - 44 LBS)
(For Dogs ONLY 45 – 88 LBS)
(For Dogs ONLY 89 – 132 LBS)



(1)(3)(6) Monthly Doses

Picture of Dog

Tick pictogram

Flea eggs and larvae pictogram

Adult flea pictogram

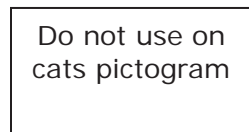
- Long-lasting for [1 month against ticks](and)[3 months against fleas] & Waterproof

CARTON FRONT PANEL FOR 3x and 6x presentations; INSERT FRONT PANEL for 1x presentations-Cont'd

[Kills ticks that may transmit tick-borne diseases including Lyme disease, Anaplasmosis, Ehrlichiosis, Babesiosis and Rocky Mountain Spotted Fever]

[AVAILABLE [THROUGH VETERINARIANS][FROM A LICENSED VETERINARY PROFESSIONAL][FROM A LICENSED VETERINARIAN]

NET CONTENTS: X fl oz (Y-X fl oz applicators)
1, 3 or 6-(0.036 fl. oz. (1.07 ml), 0.072 fl. oz. (2.14 ml), 0.145 fl. oz. (4.28 ml), 0.217 fl. oz. (6.42 ml)) applicators



Do not use on cats

[1.5 x 1.5 cm]

KEEP OUT OF REACH OF CHILDREN
CAUTION

For first aid and other precautionary statements, refer to product package insert

The amount of active ingredients in the total volume is equivalent to 6.4% Fipronil, 5.8% (S)-Methoprene, and 7.6% Amitraz.

Side A

ACTIVE INGREDIENTS

| | |
|--------------------------------|--------|
| Fipronil..... | 9.8% |
| (S)-methoprene..... | 8.8% |
| OTHER INGREDIENTS | 81.4% |
| TOTAL | 100.0% |

Side B

ACTIVE INGREDIENT

| | |
|--------------------------------|--------|
| Amitraz..... | 22.1% |
| OTHER INGREDIENTS | 77.9% |
| TOTAL | 100.0% |

CARTON INSIDE FRONT PANEL for 3x and 6x presentations

CERTIFECT® for dogs starts rapidly killing ticks within 6 hours providing a convenient, effective treatment for all stages of ticks. **CERTIFECT®** kills fleas, flea eggs, flea larvae, prevents the development of all stages of fleas, and kills chewing lice, and all stages of ticks; ONLY for (dogs and puppies 8 weeks or older and 5-22 lbs)(dogs 8 weeks or older and 23 – 44 lbs)(dogs weighing 45 – 88 lbs)(dogs weighing 89 – 132 lbs).

- **Rapidly** starts killing all stages of ticks in [as little as] 6 hours, including Gulf Coast ticks, Black Legged ticks, Brown Dog ticks, American Dog ticks, Lone Star ticks and Wood ticks]
- [Kills ticks which may transmit Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Hepatozoonosis, Babesiosis, or cause tick paralysis]
- [Kills][Stops][Controls] existing infestations and prevents re-infestations of fleas and ticks]
- [Detaches ticks when applied to a dog with a pre-existing infestation]
- [Kills adult fleas, flea eggs & flea larvae]
- [Prevents all flea stages (eggs, larvae, pupae) from developing]
- [Kills fleas which may cause flea allergy dermatitis]
- [Eliminates infestations with chewing lice]
- [Aids in control of sarcoptic mange infestations]
- [Can also be used on breeding, pregnant and lactating bitches]
- [Fast-acting, starts killing ticks in [as little as] 6 hours]
- [Long-lasting for [1 month against ticks)][and][3 months against fleas]]
- [Waterproof]
- [Convenient to use]

Questions or Comments?

Call: 1-800-660-1842

CARTON INSIDE PANEL for 3x and 6x presentations-Cont'd

[Instructions for the 3x/6x blister pack]:

How to apply **CERTIFECT®**



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

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 to open.
Do not allow your dog to ingest product.
Do not allow product to runoff.
Do not apply to dogs weighing less than (5 lbs.)(23 lbs.)(45 lbs.)
(89 lbs.) or younger than 8 weeks of age. {This statement will be
used on the 89-132 lb. labeling} (Do not use two applications on
dogs weighing more than 132 lbs.) Do not use more than one
application per dog per month.



4. **APPLY CERTIFECT®**
Place applicator tip through dog's hair
to the skin level.
Squeeze applicator, applying entire
contents in two separate spots on the
neck between the base of the skull
and the shoulder blades
where the dog cannot lick.

CARTON BACK PANEL for 3x and 6x presentations

CERTIFECT® FOR DOGS

[AVAILABLE [THROUGH VETERINARIANS][FROM A LICENSED VETERINARY
PROFESSIONAL][FROM A LICENSED VETERINARIAN]
READ ENTIRE LABEL BEFORE USE

CERTIFECT® for dogs starts rapidly killing ticks within 6 hours (providing a convenient, effective treatment for all stages of ticks). **CERTIFECT®** kills fleas, flea eggs, flea larvae, prevents the development of all stages of fleas, and kills chewing lice, and all stages of ticks; **ONLY** for (dogs and puppies 8 weeks or older and 5-22 lbs)(dogs 8 weeks or older and 23 – 44 lbs)(dogs weighing 45 – 88 lbs)(dogs weighing 89 – 132 lbs).

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. **Read entire label and enclosed directions before each use. Follow all directions and precautionary statements carefully.** Restrictions: Do not allow children to apply product. Use on dogs **ONLY**. Do not use on cats, rabbits or other animals. **DO NOT** use on dogs diagnosed with diabetes or heart problems. Consult a veterinarian before using on dogs that are medicated, debilitated, aged or obese. Your dog needs to be dry at the time **CERTIFECT®** is applied and remain dry 24 hours after application. **DO NOT** contact the treated area until completely dry. Verify that the applicator is empty after applying to your dog. Do not allow your dog to ingest this product. Do not apply to dogs weighing less than (5 lbs.)(23 lbs.)(45 lbs.)(89 lbs.) or younger than 8 weeks of age. {This statement will be used on the 89-132 lb. labeling} (Do not use two applicators on dogs weighing more than 132 lbs.) Do not use more than one application per dog per month.

To kill all stages of ticks, fleas and chewing lice apply topically to the skin of dogs or puppies (8 weeks or older) as follows:

Open the child-resistant packaging according to the instructions found on the inside back panel of the carton. Hold applicator upright away from you and your dog's face, cut applicator tip with scissors to open. Place applicator tip through dog's hair to the skin level. Squeeze applicator, applying entire contents in two separate spots on the neck between the base of the skull and the shoulder blades where the dog cannot lick. Do not allow your dog to ingest this product. Do not allow product to runoff.

Frequency of Application

A monthly application of **CERTIFECT®** kills ticks, completely breaks the flea life cycle and controls chewing lice infestations.

Research demonstrates that **CERTIFECT®** kills adult fleas (*Ctenocephalides felis* and *Ct. canis*), flea eggs, and flea larvae for up to three months. **CERTIFECT®** also prevents development of all flea stages for up to three months. Although **CERTIFECT®** can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

CERTIFECT® aids in the control of sarcoptic mange infestations. Apply once per month for at least two months for the elimination of mites.

CARTON BACK PANEL for 3x and 6x presentations-Cont'd

CERTIFECT® can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant, and lactating bitches.



Please call our experts at
1-800-660-1842 if you have any
questions or comments about flea,
tick and lice control or CERTIFECT®.

SIDE EFFECTS: Transient lethargy of variable duration and pruritis (itching) may occur with the use of this product. In very rare instances, certain sensitive dogs may develop skin irritation at the application site or other forms of dermatitis including pemphigus-like conditions (skin thickening, flaking skin). Should this occur, contact your veterinarian for treatment advice promptly and discontinue use of the product.

Do not use on
cats pictogram

DO NOT USE ON CATS

[1.5 x 1.5 cm]

Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

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

Track and
Trace
pictogram

EPA Reg. No. 65331-7
EPA Est. No. 65331-FR-2

INSIDE CARTON FLAPS for 3x and 6x presentations

CERTIFECT® for dogs

[Rapidly][Quick][Quickly][Fast Acting] in 18 hours]

[Kills Ticks in 18 hours]

[Starts rapidly killing ticks in [as little as] 6 hours]

CERTIFECT® for dogs provides potentiated efficacy against ticks with a rapid [quick] onset of activity in [as little as][within] 6 hours. [The active ingredients in **CERTIFECT®** provide for fast acting [and long-lasting] control of fleas, ticks, and chewing lice [for at least 30 days] on dogs.] **CERTIFECT®** acts on multiple sites of the nervous systems of fleas and ticks.

[PICTOGRAMS (icon with slash through)]

[Adult Flea]

[Flea Eggs]

[Flea Larvae]

[Flea Pupae]

[Adult Tick]

[Tick Larvae]

[Tick Nymph]

[Chewing Lice]

FRONTLINE® and **CERTIFECT®** are registered trademarks of Merial.

©2014 Merial Limited, Duluth, GA. All rights reserved.

Bar code

TOP OUTER PANEL, LEFT SIDE OUTER PANEL, and BOTTOM OUTER PANEL OF 3x and 6x
CARTON

CERTIFECT® FOR DOGS

(For use ONLY on DOGS & PUPPIES 8 Weeks or Older and **5-22 lbs**)

(For Dogs ONLY 8 weeks or older and 23-44 LBS)

(For use ONLY on Dogs **45 to 88 lbs**)

(For use ONLY on DOGS **89 to 132 lbs**)

(3)(6) monthly doses

RIGHT OUTER PANEL OF 3x and 6x CARTON

LOT NO:

PACKAGE INSERT for 3x and 6x presentations; INSERT INNER PANELS of 1x presentation

CERTIFECT® FOR DOGS

{Insert inner panel of 1x presentation will read} For dogs & puppies ONLY 8 weeks or older and weighing at least (5 lbs.)(23 lbs.)(45 lbs.)(89 lbs).

{Package insert front of 3x and 6x presentations will read} For dogs & puppies ONLY 8 weeks or older and weighing at least 5 lbs. for small dogs, 23 lbs. for medium dogs, 45 lbs. for large dogs, and 89 lbs. for extra-large dogs.

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

The amount of active ingredients in the total volume is equivalent to 6.4% Fipronil, 5.8% (S)-Methoprene, and 7.6% Amitraz

Side A

ACTIVE INGREDIENTS

| | |
|-------------------------------|---------------|
| Fipronil..... | 9.8% |
| (S)-methoprene..... | 8.8% |
| OTHER INGREDIENTS..... | 81.4% |
| TOTAL..... | 100.0% |

Side B

ACTIVE INGREDIENT

| | |
|-------------------------------|---------------|
| Amitraz..... | 22.1% |
| OTHER INGREDIENTS..... | 77.9% |
| TOTAL..... | 100.0% |

KEEP OUT OF REACH OF CHILDREN

CAUTION

CERTIFECT® for dogs

Starts rapidly killing all stages of ticks in (as little as) 6 hours, including **Gulf Coast ticks, Black Legged ticks, Brown Dog ticks, American dog ticks, Lone Star ticks and Wood ticks**

- [Kills ticks which may transmit **Lyme Disease, canine Ehrlichiosis, Anaplasmosis, Rocky Mountain Spotted Fever, Hepatozoonosis, Babesiosis**, or cause **tick paralysis**]
- [Effectively [Kills][Stops][Controls] existing infestations and prevents re-infestations of fleas and ticks]
- [Detaches ticks when applied to a dog with a pre-existing infestation]
- [Kills adult fleas, flea eggs & flea larvae]
- [Prevents all flea stages (eggs, larvae, pupae) from developing]
- [Kills fleas which may cause flea allergy dermatitis]
- [Eliminates infestations with chewing lice]
- [Aids in control of sarcoptic mange infestations]

Do not use on cats pictogram

DO NOT USE ON CATS

PACKAGE INSERT for 3x and 6x presentations; INSERT INNER PANELS of 1x presentation- Cont'd

- [Can also be used on breeding, pregnant and lactating bitches]
- [Fast-acting in [as little as] 6 hours]
- [Long-lasting for 1 month against ticks and 3 months against fleas]
- [Waterproof]
- [Convenient to use]

[AVAILABLE [THROUGH VETERINARIANS][FROM A LICENSED VETERINARY PROFESSIONAL][FROM A LICENSED VETERINARIAN]

CERTIFECT[®] aids in the control of sarcoptic mange infestations. Apply once per month for at least two months for the elimination of mites.

CERTIFECT[®] can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant, and lactating bitches.

CERTIFECT[®] contains fipronil, (S)-methoprene, an insect growth regulator (IGR), and amitraz. **CERTIFECT**[®] effectively targets all stages of ticks and fleas.

PRECAUTIONARY STATEMENTS

HAZARDOUS TO HUMANS and DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Prolonged or frequent repeated skin contact may cause allergic reactions in some individuals.

{Insert inner panel of 1x presentation will read} For external use on dogs and puppies ONLY 8 weeks or older and weighing at least (5 lbs.)(23 lbs.)(45 lbs.)(89 lbs.).

{Package insert for 3x and 6x presentations will read} For external use on dogs and puppies ONLY 8 weeks or older and weighing at least 5 lbs. for small dogs, 23 lbs. for medium dogs, 45 lbs. for large dogs, and 89 lbs. for extra-large dogs. Individual sensitivities, while rare, may occur after using any pesticide product.

SIDE EFFECTS: Transient lethargy of variable duration and pruritis (itching) may occur with the use of this product. In very rare instances, certain sensitive dogs may develop skin irritation at the application site or other forms of dermatitis including pemphigus-like conditions (skin thickening, flaking skin). Should this occur, contact your veterinarian for treatment advice promptly and discontinue use of the product.

DO NOT use on dogs that have been diagnosed with diabetes or heart problems. Consult a veterinarian before using on dogs that are medicated, debilitated, aged or obese. Certain medications can interact with pesticides. Amitraz is a monoamine oxidase inhibitor (MAOI); therefore, people taking MAOI-containing medication must take particular care when handling this product. Call 1-800-660-1842 for 24-hour assistance.

PACKAGE INSERT for 3x and 6x presentations; INSERT INNER PANELS of 1x presentation- Cont'd

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the 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 assistance, Monday-Friday, 8am-8pm EST.

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. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Read entire label and enclosed directions before each use. Follow all directions and precautionary statements carefully. Restrictions: Do not allow children to apply product. Use on dogs ONLY. Do not use on cats, rabbits or other animals. [Open the child-resistant packaging according to the instructions found on the inside back panel of the carton.] Do not allow your dog to ingest this product.

{Insert inner panel of 1x presentation will read} Do not apply to dogs weighing less than (5 lbs.) (23 lbs.) (45 lbs.) (89 lbs.)

{Package insert front of 3x and 6x presentations will read} Do not apply to dogs weighing less than 5 lbs. for small dogs, 23 lbs. for medium dogs, 45 lbs. for large dogs, and 89 lbs. for extra-large dogs or younger than 8 weeks of age.

{This statement will be used on the 89-132 lb. labeling} (Do not use two applicators on dogs weighing more than 132 lbs.) Do not use more than one application per dog per month. Your dog needs to be dry at the time CERTIFECT® is applied and remain dry 24 hours after application. Do not contact the treated area until completely dry. Verify that the applicator is empty after applying to your dog.

FREQUENCY OF APPLICATION

A monthly application of CERTIFECT® kills all stages of ticks, completely breaks the flea life cycle and controls chewing lice infestations. Do not apply more than once a month. Research demonstrates that CERTIFECT® kills adult fleas (*Ctenocephalides felis* and *Ct. canis*), flea eggs, and flea larvae for up to three months. CERTIFECT® also prevents development of all flea stages for up to three months. Although CERTIFECT® can

PACKAGE INSERT for 3x and 6x presentations; INSERT INNER PANELS of 1x presentation-
Cont'd

control fleas for up to three months, if there is a high risk of reinfestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. CERTIFECT® remains effective even after bathing, water immersion, or exposure to sunlight

HOW SUPPLIED

For easy and convenient treatment, CERTIFECT® for dogs is available in sizes for small dogs and puppies ONLY 8 weeks or older and 5-22 lbs., medium dogs ONLY 8 weeks or older and 23-44 lbs., large dogs ONLY 45-88 lbs., and extra-large dogs ONLY 89-132 lbs.

STORAGE AND DISPOSAL

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

PESTICIDE 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.

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.

EPA Reg. No. 65331-7

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

FRONTLINE® and CERTIFECT® are registered trademarks, of Merial.

©2014 Merial Limited, Duluth, GA.

All rights reserved.

INSERT BACK PANEL of 1x presentation

CERTIFECT® FOR DOGS

[Instructions for the 1x blister pack]:

To kill all stages of ticks, fleas and chewing lice apply topically to the skin of dogs or puppies (8 weeks or older) as follows:

How to Apply CERTIFECT® FOR DOGS

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 and open at slit** and remove the applicator.



2. **HOLD Applicator Upright** away from you and your dog's face, cut applicator tip to open. Do not allow your dog to ingest product. Do not allow product to runoff. Do not apply to dogs weighing less than (5 lbs.)(23 lbs.)(45 lbs.)(89 lbs.) or younger than 8 weeks of age. {This statement will be used on the 89-132 lb. labeling} (Do not use two applications on dogs weighing more than 132 lbs.) Do not use more than one application per dog per month.



3. **APPLY CERTIFECT®**
Place applicator tip through dog's hair to the skin level. Squeeze applicator, applying entire contents in two separate spots on the neck between the base of the skull and the shoulder blades **where the dog cannot lick.**

INSERT BACK PANEL of 1x presentation-Cont'd

SIDE EFFECTS: Transient lethargy of variable duration and pruritis (itching) may occur with the use of this product. In very rare instances, certain sensitive dogs may develop skin irritation at the application site or other forms of dermatitis including pemphigus-like conditions (skin thickening, flaking skin). Should this occur, contact your veterinarian for treatment advice promptly and discontinue use of the product.

Do not use on
cats pictogram

DO NOT USE ON CATS

[1.5 x 1.5 cm]

Questions or
Comments?

Call: 1-800-660-1842

COMPLIANCE CARD for 3x and 6x presentations
FRONT

See other side for more

CERTIFECT® for dogs

Some tips and other information:

DO NOT USE ON CATS.

Detaches ticks when applied to a dog with a pre-existing infestation.

To successfully control ticks & fleas, all dogs must be treated with their own dose of **CERTIFECT®**.

Apply according to label instructions, ensuring the product is applied to the skin. It must be applied between the base of the skull and the shoulder blades where the dog cannot lick. 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 **CERTIFECT®** is applied and remain dry 24 hours after application.

Verify applicator is empty after applying to your dog.

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

Pipette
pictogram

Tick
pictogram
Ticks

Flea eggs,
larvae, and
adult flea
pictogram

Chewing lice
pictogram

COMPLIANCE CARD for 3x and 6x presentations
BACK

Do not use on
cats pictogram

Calendar reminder stickers

To ensure continued protection of your dog, use these stickers as a reminder to apply and re-purchase **CERTIFECT**[®].

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 **CERTIFECT**[®] monthly.

Don't forget to re-purchase!

6 months
Use all 6 stickers

5 stickers that read "Apply
CERTIFECT[®]", with the 6th sticker
"Re-purchase **CERTIFECT**[®]"

3 months

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

CERTIFECT[®] is a trademark of Merial.

©2014 Merial Limited, Duluth, GA. All rights reserved.

LABEL ON INDIVIDUAL APPLICATOR

CERTIFECT® for dogs

Side A: 9.8% fipronil - 8.8% (S)-methoprene

Side B: 22.1% Amitraz

FOR USE ONLY ON DOGS (& puppies 8 WEEKS OR OLDER AND 5-22 LBS)(8 WEEKS OR OLDER AND 23 to 44 LBS)(FROM 45 to 88 LBS)(FROM 89 to 132 LBS)

Read the entire label before use

Application to
dog pictogram

EPA Reg. No. 65331-7

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Lot No.

Do not use on
cats pictogram

(0.036)(0.072)(0.145)(0.217) fl. Oz.

LABEL ON BLISTER PACK

CERTIFECT® FOR DOGS

(S)(M)(L)(XL)

(For dogs & puppies ONLY 8 weeks or older and 5-22 lbs.)

(For dogs ONLY 8 weeks or older and 23 – 44 lbs.)

(For dogs ONLY 45 – 88 lbs.)

(For dogs ONLY 89 – 132 lbs.)

Do not remove applicator until ready to use

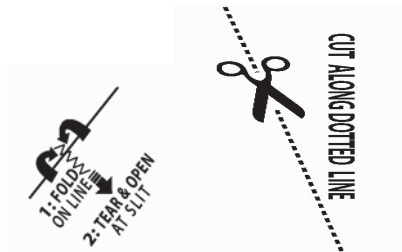
EPA Reg. No. 65331-7

Contains (0.036 fl. oz.)(0.072 fl. oz.)(0.145 fl. oz.)(0.217 fl. oz.)

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Read the entire label before use

Lot No.



Do not use on
cats pictogram

MERIAL

Alternate marketing text

- [[Remains effective][Still works](even) after [bathing], [water immersion][swimming] or exposure to [rain] or [sunlight]]
- [Kills all stages of [all] ticks infesting dogs]
- [Convenient topical treatment for dogs who enjoy the outdoors]
- [(formulated) for dogs that [enjoy][love] the outdoors]
- [The killing of fleas and ticks is important in the prevention of disease transmission by these parasites] '
- [For treatment of][Treats and controls][Provides effective control of][For treatment of infestations with][Kills][Stops existing] chewing lice [infestations]]
- [9-way protection against fleas, flea eggs, flea larvae, flea pupae, ticks, tick larvae, tick nymphs, chewing lice, and sarcoptic mange mites]
- [Tested on puppies from 8 weeks of age]
- [After application, **CERTIFECT**[®] spreads over the dog's body to provide [full body] [all over] protection against fleas, ticks, and chewing lice]
- [**CERTIFECT**[®] provides ongoing protection against fleas, ticks, and chewing lice [for at least one month [30 days]]]
- [**CERTIFECT**[®] also contains amitraz, an effective acaracide that potentiates fipronil efficacy to rapidly kill ticks starting in [as little as] 6 hours]
- [**CERTIFECT**[®] contains the insect growth regulator (S)-methoprene that acts to prevent the development of all flea stages]
- [Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment]
- [[Starts rapidly][Rapidly starts] killing ticks in [as little as][within] 6 hours][kills][detaches][ticks][including those][vectors][which may cause][which may transmit] Lyme disease, [Ehrlichiosis], [Anaplasmosis], [Babesiosis], [Tick Paralysis], [Rocky Mountain Spotted Fever], [Southern Tick Associated Rash Illness], and [Hepatozoonosis]
- [Effective monthly treatment of fleas and ticks]
- [Easy and effective control of fleas and ticks that lasts at least 1 month [30 days]]
- [For treatment of][Kills] sarcoptic mange mites]
- [Kills fleas [before they lay eggs] [that may transmit disease, including bartonellosis and tapeworm disease]]
- [[Regular use] protects against all stages of the flea life cycle]
- [Kills fleas which 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 **CERTIFECT**[®] kills fleas and may reduce the incidence of FAD]
- [**CERTIFECT**[®] is useful for dogs susceptible to flea allergy dermatitis (FAD)]
- [Regular use of **CERTIFECT**[®] breaks the flea life cycle]
- [Prevents development of all flea stages for at least 1 month [30 days]]
- [Convenient [easy to apply] topical treatment [with [patented] applicator][that allows application down to the skin]]
- ([Patented] dual applicator [trademark] for easy application directly to the skin)
- [Prevents development of fleas, flea eggs, flea larvae and pupae [for one month or more]]
- [[Available][from][through][Sold by][veterinarians][a licensed veterinarian][a licensed veterinary professional]]

Alternate marketing text-Cont'd

- [Quick-drying]

-
- [Non-greasy]
 - [[For year long control][Apply **CERTIFECT**®][monthly][year round][for optimum control of] [fleas][and][ticks][following your veterinarian's advice]]
 - [Starts rapidly killing 6 types of ticks in [as little as] 6 hours][Starts rapidly killing 6 species of ticks in [as little as] 6 hours][Kills] [Protects against][and controls][the following ticks][including]: Black-legged ticks [*Ixodes scapularis*, *Ixodes pacificus*] [which may transmit Lyme disease], Brown dog ticks [*Rhipicephalus sanguineus*] [which may transmit *Ehrlichia canis*], American dog ticks [*Dermacentor variabilis*][which may transmit Rocky Mountain Spotted Fever] Lone star ticks [*Amblyomma americanum*] [which may transmit *Ehrlichia chaffeensis*] Gulf Coast ticks [*Amblyomma maculatum*] Wood ticks [*Ixodes ricinus*] Chewing lice [*Trichodectes canis*], Sarcoptic mange mites [*Sarcoptes scabiei* var. *canis*], and all stages of [*Ctenocephalides felis* and *Ctenocephalides canis*] fleas
 - [Amitraz provides control of [ticks][and][sarcoptic mange mites] by affecting octopamine receptors
 - [Kills [newly emerged] fleas [before they lay eggs]for up to 12 weeks]
 - [Kills ticks [for] 1 month]
 - [Easy, spot-on (topical) application]
 - [(S)-methoprene is an insect growth regulator which prevents development of all flea stages]
 - [Using the [patented][trademark] dual applicator, **CERTIFECT**® is specially designed to spread over the dog's body providing effective control of fleas and ticks]
 - [Protects for [at least] one month]
 - [[Quick onset of activity starting in][Starts killing ticks][within][in] 6 hours]]
 - [Persistent [sustained] efficacy through 30 days]
 - [Prevents reinfestation [of fleas][of ticks] for up to one month]
 - [Monthly treatment is recommended for optimal control and prevention of fleas and ticks]
 - [Guaranteed effective for [at least] 1 month]
 - [Once monthly application]
 - [[Convenient][to use][Easy to apply) spot-on application]
 - [Pleasant smell]
 - [Kills fleas that may transmit disease, including [bartonellosis] and [tapeworm disease]
 - [Proven treatment technology for [the control of] flea[s][infestations] , [ticks] [and chewing lice]]
 - [S-methoprene [arrests the development of immature flea stages][metabolically attacks fleas]]
 - [**CERTIFECT**® uses [different][multiple] modes of action to kill [ticks]]
 - [The small amount of amitraz potentiates fipronil efficacy to [rapidly] kill ticks [faster starting in 6 hours][in 18 hours]]
 - [**CERTIFECT**® starts [rapidly][quickly][killing][kills] all stages of ticks starting in [as little as] 6 hours [in 18 hours], including but not limited to deer ticks, brown dog ticks, American dog ticks, and lone star ticks]
 - [[**CERTIFECT**® is brought to you][by][from][the makers of **FRONTLINE**®]
 - [**CERTIFECT**® [has][is a] low odor [formulation]]
 - [**CERTIFECT**® contains 80, 160, 320, and 480 mg of amitraz in the small, medium, large and x-large pipettes, respectively]
 - [**CERTIFECT**® provides 75 mg/ml of amitraz when applied to the dog [at a dose of 8 mg/kg]]

Alternate marketing text-Cont'd

- [**CERTIFECT**[®] provides 6.4% Fipronil when applied in the total volume of [[1.07 ml][2.14 ml][4.28 ml][6.42 ml]]
- [**CERTIFECT**[®] provides 5.8% (S)-Methoprene when applied in the total volume of [[1.07 ml][2.14 ml][4.28 ml][6.42 ml]]
- [**CERTIFECT**[®] provides 7.6% Amitraz when applied in the total volume of [[1.07 ml][2.14 ml][4.28 ml][6.42 ml]]
- [(S)-methoprene is an insect growth regulator which kills flea eggs and larvae]