



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

53883-360

Date of Issuance:

7/24/15

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 7/24/17

Name of Pesticide Product:

Flee Multi-Dose for Dogs

Name and Address of Registrant (include ZIP Code):

Control Solutions, Inc.,
 5903 Genoa-Red Bluff
 Pasadena, TX 77507-1041

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

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

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Davis, Product Manager 3
 Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

7/24/15

2. This registration is time-limited and expires 7/24/17.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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
4. 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 dogs 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 cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs 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 dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. You have 18 months from the date of registration to provide these data.
6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 53883-360."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/31/2014

If you have any questions, please contact me by phone at (703) 306-0415, or via email at davis.kable@epa.gov.

Enclosure

Control Solutions, Inc. Master Label

23 July 2015

Information in [] is optional.

EPA No. 53883-GAN

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.] Information in italics is included for the reviewer only.

Flee Multi-Dose for Dogs

FOR USE ONLY BY LICENSED VETERINARIANS ON DOGS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

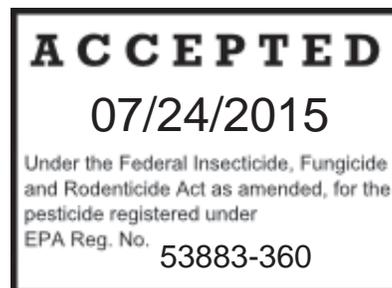
For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Keep product in its original container. Do not repackage. Do not use bottle and applicator with any other product.

One of the following statements will appear on the front panel.

Use **ONLY** on dogs [&] [and] puppies 5 to 132 lbs., over 8 weeks old *OR*

ONLY For Dogs & Puppies, older than 8 weeks [&] [and] 5 to 132 lbs.

[1.5 x 1.5 cm on front panel]



ACTIVE INGREDIENT:

Fipronil..... 9.70%

OTHER INGREDIENTS:..... 90.30%

TOTAL **100.00%**

KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back][Label] for Additional Precautionary Statements]

Net Contents: [0.68 fl oz (20.10 ml)]

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FIRST AID	
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	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:	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also want to contact SafetyCall at 1-866-897-8050 for emergency medical treatment information.	

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.**

[[**Brand Name**] for dogs delivers [effective] protection against fleas, ticks, [and chewing lice]. [This product aids in the control of sarcoptic mange mites.] [**Brand Name** kills] [Kills] deer ticks, brown dog ticks, American dog ticks, and lone star ticks, including those transmitting Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases. Stops existing flea infestation and reinfestation for [[4] [four] weeks] [[1] [one] month] [30 days].]

Apply as a [spot] [stripe] to your dog to kill fleas, ticks [mosquitoes] and chewing lice.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

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HAZARDS TO DOMESTIC ANIMALS.

For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. As with any product, use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION. DO NOT ALLOW CHILDREN TO APPLY PRODUCT.** TO PREVENT HARM TO YOU AND THE DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on rabbits or animals other than dogs. Do not allow the dog to ingest this product. Do not use on puppies under 8 weeks of age. Weigh dog to be sure you are applying the right dose formulated for the weight of the dog. Do not apply more than once every [4 weeks] [30 days]. Do not double-dose dogs larger than 132 lbs. Instruct the dog owner to separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

{ Back Panel }

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, advise dog owner to consult with veterinarian or SafetyCall at 1-866-897-8050.

[1.5 x 1.5 cm on back panel]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

For use only by licensed veterinarians on dogs in their control or under their immediate supervision

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How to Apply

Accurately weigh the dog or puppy. Use the dog or puppy weight to determine the correct application rate, using the following chart.

Application Rate*		
Only for dogs weighing	Apply	Number of Applicator Tip Pumps/Squeezes
5 [-][to] 22 lbs.	0.67 ml	1
23 [-][to] 44 lbs.	1.34 ml	2
45 [-][to] 88 lbs.	2.68 ml	4
89 [-][to] 132 lbs.	4.02 ml	6

*Do not apply to dogs weighing less than 5 lbs. or less than 8 weeks of age. Do not double-dose dogs larger than 132 lbs.

Remove the applicator tip from its packaging. **Note:** The applicator tip has been preset to deliver 0.67 ml with each [pump] [squeeze] application.

APPLICATOR TIP PICTURE



Attach the applicator tip to the bottle by screwing the applicator tip onto the threads and tighten securely. Prior to the initial application of the product to the dog, you will need to prime the [pump] [squeeze] applicator.

Applicator Priming Steps:

1. Use a trash can (for immediate disposal) and/or paper towels (or similar material) to catch and absorb any product expelled from the applicator tip during priming
2. Invert the bottle with the attached applicator tip over the trash can and/or paper towel (or similar material); pointing the tip down
3. [Pump] [Squeeze] applicator tip all the way until it stops
4. Repeat step 3 again, squeezing all the way until it [meets resistance] [stops]
5. Any expelled product will end up in the trash or on the paper towel (or similar material)
6. Dispose of paper towel in garbage or in accordance with State and Local laws

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Please Note: These steps do not have to be repeated after initial priming

The applicator tip is now ready for use. Always apply product with bottle in the inverted position with the tip pointing down. Each [pump] [squeeze] of the applicator applies 0.67 ml of product. Refer to table above to determine the volume of product to apply. Adjust the number of pumps according to the dog's actual weight. [For example, 2 [pumps] [squeezes] are required for dogs weighting 21 to 44 lbs.]

Dog/Puppy (over 8 weeks old) Application Steps:

1. Invert the bottle with the attached applicator tip over the dog's back
2. Part the dog's hair, so that the product can be applied directly to the skin
3. Apply as a spot to the [back] [base] of the dog's neck. *OR* Apply as a strip to the [back] [base] of the dog's neck above the shoulder blades. Start at the shoulder and apply towards the tail.
4. First Application: [Pump] [Squeeze] the applicator tip all the way until it stops expelling the product
5. Multiple Applications: Repeat step 3, for each [pump] [squeeze] (see table above)
6. Count and keep track of each [pump] [squeeze] application to the dog's skin, if more than one [pump] [squeeze] is required for the weight of the dog. Do not apply more product than what is listed for your dog's weight
7. Replace the cap on the applicator tip after application

Do not apply more frequently than once every 4 weeks.

FREQUENCY OF APPLICATION

[Brand Name] [This product] should be applied once every [30 days] [4 weeks] [month]. Treatment remains effective, even after bathing, water immersion, or exposure to sunlight. Do not reapply [Brand Name] for 30 days [4 weeks] [1 month].

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STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep product in its original container. Do not repack. Store in a cool (below 77°F []/[25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

APPLICATOR DISPOSAL: Do not reuse the applicator once the bottle is empty. Discard disposable applicator in accordance with State and Local regulations.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Optional recycling graphic]

LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application, all of which are beyond the control of Control Solutions, Inc. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Control Solutions, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Control Solutions, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Control Solutions, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Control Solutions, Inc. election, the replacement of product.

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[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

[In Case of Emergency, call: XXX-XXX-XXXX]

[Non-Emergency, call XXX-XXX-XXXX]

[Formulated in the USA]

Control Solutions, Inc.
5903 Genoa-Red Bluff Road
Pasadena, TX 77507

EPA Reg. No. 53883-NEW
EPA Est. No. XXXX-XXX-XXX

[BAR CODE AREA][Lot code]

[START – METERED DOSING APPLICATOR/BOTTLE LABEL]

{Front Label}	{Back Label}
Flee Multi-Dose for Dogs Fipronil 9.7% 0.68 fl oz [(20.10 ml)] EPA REG. No. 53883-GAN	KEEP OUT OF REACH OF CHILDREN CAUTION: Read all directions and precautions on the label before using.

[END – METERED DOSING APPLICATOR/BOTTLE LABEL]

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Optional marketing claims

[Use in animal shelters, under direct supervision of a veterinarian]

[Multi-dose dispenser with metering applicator]

[Convenient multi-dose dispenser with metering applicator for in clinic use]

[Convenient multi-dose dispenser for animal facility use]

[Accurate dosing for use on all sizes of dogs]

[Convenient dosing for use on all sizes of dogs]

[Weigh dog to determine appropriate dose]

[For use only by licensed veterinarians] [and use on animals under control or immediate supervision of a licensed veterinarian]]

[Weigh dog and determine appropriate application rate using chart]

[Bottle and Applicator is specifically calibrated for this Product only.]

[Applicator is calibrated to accurately apply the specified rate for dogs]

[Refer to Application Rate Table to determine the number of pumps][squeezes][pump/squeezes]]

[Refer to Application Rate Table to determine the number of [pumps][squeezes][pump/squeezes] for each weight category]

[Product comes with cap and applicator.]

[Applicator pump works only when applicator tip is pointing down]

[Do not [activate pump][squeeze pump] while applicator tip is pointing up]

[Applicator will not deliver a full dose if applicator tip is pointing up while [squeezing pump][applying][activating pump]]

[Please refer to full label for additional information.]

[As with any product, use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction.]

[Chewing Lice Claims]

[Kills] [chewing lice] [lice] [rapidly] [infestations]

[Mite Claims]

[Controls] [Aids in the control] [of] [sarcoptic mange infestations]

[Flea Claims]

[Kill Fleas]

[Kills [adult] fleas [for] [up to] [4 weeks] [90 days] [three months] [3 months] [1 month]]

[Kills newly emerged adult fleas before they lay eggs]

[Kills [adult] [fleas] [causing] [responsible for] [flea allergy dermatitis] [and] [flea bite anemia]]

[Puts a stop to existing [flea] infestations] [and] [prevents new infestations]]

[Monthly application may be needed for dogs with high risk for flea reinfestation]

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[Tick Claims]

[Kills ticks] [,] [including those transmitting Lyme disease]
 [Kills [all stages of] ticks [up to [4 weeks] [1 month] [30 days]]
 [Kills [brown dog ticks] [(*Rhipicephalus sanguineus*)] [,] [American dog ticks] [(*Dermacentor variabilis*)] [,] [lone star ticks] [,] [and] [deer ticks] [including ticks that may cause] Lyme disease] [,Rocky Mountain spotted fever] [,ehrlichiosis] [,babesiosis] [,anaplasmosis] [and] [other tick-borne diseases]]

[Multiple Pest Claims]

[Kills chewing lice [,] [ticks] [and] [aids in control of sarcoptic mange mites]]
 [Tick [and] flea control for dogs [,including puppies over 8 weeks]]
 [Kills fleas, [&] [and] ticks, [&] [and] [chewing] [lice] [monthly]]
 [Once a monthly flea, tick, mosquito and chewing lice [application] [treatment] [protection]]
 [Effectively kills ticks, [fleas] and chewing lice [,including control of sarcoptic mange mites]]
 [[4 Week] [1 month] [30 day] [Flea and Tick Treatment]]
 [[Four (4) Week] [1 Month] [Flea, Tick, and Chewing [Lice Control] [Treatment] [Application]]
 [Use [**Brand Name**] monthly to kill ticks and chewing lice]
 [Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]

[Other Pest Claims]

[Use on Dogs and Puppies 8 weeks of age or older]
 [Apply] [to] puppies over 8 weeks of age]
 [Specially Formulated for Dogs and Puppies 8 weeks of age or older]
 [For Dogs [weighing 5 to 132 lbs.]
 [Convenient applicator]
 [Convenient spot-on product]
 [Easy to Use]
 [Apply monthly]
 [Apply once every [4 weeks] [month] [30 days]!]
 [Waterproof]
 [Fast-acting]
 [Long-lasting]
 [Effective after bathing [and] [exposure to water and sunlight]]

[Optional graphics below may or may not appear anywhere on finished label]

	Adult Flea	
	Fleas	

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	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Lone Star Tick	
	Chewing Lice	
	Mite	