

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 19, 2015

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

Subject: Notification per PRN 98-10 – Updating emergency hotline phone number and

adding optional marketing graphics

Product Name: Prefurred Plus IGR for Dogs EPA Registration Number: 53883-351

Application Date: June 1, 2015 Decision Number: 505889

Dear Ms. Adamson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Julie Chao at (703) 308-8735 or via email at chao.julie@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505P)

My Sem De for

Office of Pesticide Programs

Information in [] is optional

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Information in { } is a note to the reviewer

{CARTON LABEL - DRAFT MASTER LABEL COPY}

{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. The CRP required text will not change.}

Prefurred Plus IGR for Dogs

{ABNs:}

[Martin's FLEETM Plus IGR for Dogs]

{1.5cm x 1.5cm on final or as indicated}

[Apply to puppies over 8 weeks old] [Apply to puppies 8 weeks or older]



For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] $\{OR\}$ For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age $\{OR\}$ ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] $\{OR\}$ ONLY For Dogs & Puppies 8 weeks or older [&][and] 4[-][to] 22 lbs

{Mosquitoes

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

$\{Chewing\ Lice\}$

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

{Adult Fleas}

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

$\{Multiple\ Infestations\}$

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]

[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]

[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]

NOTIFICATION

53883-351

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

6/19/2015

Information in [] is optional

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[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Use [Brand Name][This product] monthly to break the flea life cycle.]

[Use [Brand Name][This product] monthly to control ticks and chewing lice]

[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]

[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]

[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]

[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!] [Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Kills Ticks including those that may transmit Lyme disease]

[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]

[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]

[Kills [brown dog ticks], [(Rhipicephalus sanguineus)] [American dog ticks,] [and] [lone star

[Kills American Dog Ticks [(Dermacentor variabilis)] for up to [4 weeks] [1 month] [30 days]]

{Flea Eggs and Larvae}

[Controls flea reinfestation for up to [12 weeks] [3 months]]

[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12

[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]

[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]

[With (S)-methoprene to Break Flea Life Cycle]

[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]

[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]

[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]

[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]

[Prevents Flea Eggs From Developing Into Biting Adults]

[Prevents all stages of the flea life cycle from developing]

[Controls reinfestation of fleas for up to 3 months]

[Effective against all stages of the flea life cycle] [Effectively controls all stages of the flea life cycle]

{All Others} [For Dogs and Puppies 8 weeks of age or older]

[Can be used on puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [4-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]

[Fast Acting] [Long Lasting]

Information in [] is optional

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Information in { } is a note to the reviewer

[Convenient spot treatment]

[Easy to Use [Application]]

[Best if used year round!]

[For year-round protection, apply [Brand Name] monthly]

[(ICON Showing [4 week] [1 month] [30 day] Protection)]

[Apply monthly]

[Prevents reinfestation of listed pests for [4 weeks] [1 month]]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six

Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][6 Month Supply][12 Month Supply][12 Month Supply][12 Week Supply][12 Week Supply][12 Week Supply][14 Week Supply][15 Week Supply][16 Week Supply][16 Week Supply][16 Week Supply][17 Week Supply][18 Week Supply][18 Week Supply][19 W

Week Supply][104 Week Supply]
[Controls mites that may cause sarcoptic mange]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]

[[Free] Calendar Stickers Inside!]

[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]

[Fipronil (9.8%) + (S)-methoprene (8.8%)]

Contains fipronil and (S)-methoprene, the active ingredients used in FRONTLINE® Plus for Dogs.

FRONTLINE® is a registered trademark of Merial.

Prefurred Plus IGR for Cats is not manufactured or distributed by Merial, seller of FRONTLINE® Plus for Dogs.

[[1][2][3][4][5][6][12][24] Applications]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information]

ACTIVE INGREDIENTS:

Fipronil	9.80%
(S)-methoprene	
OTHER INGREDIENT:	
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y - 0.0xx fl oz (x mL) applicators]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

[0.023 fl oz (0.67 mL) applicators] [0.045 fl oz (1.34 mL) applicators] [0.091 fl oz (2.68 mL) applicators] [0.136 fl oz (4.02 mL) applicators]

{END - FRONT PANEL}

{START - BACK/SIDE PANEL}

Information in [] is optional

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[[Brand Name] [This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks ((including those that may transmit Lyme disease).] [The active ingredients in [Brand Name][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

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

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.

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 your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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:	Flush eyes with plenty of water. Call a doctor if irritation persists.			
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.			

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact SafetyCall at 1-866-897-8050 for emergency medical treatment information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 8 weeks of age or less than [4][23][45][89] lbs. Use entire contents of tube vial on each dog. [Do not split one tube between dogs.] Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

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Information in [] is optional

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Information in { } is a note to the reviewer

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next

{1.5cm x 1.5cm on final or as indicated}

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.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Only For Dogs Weighing 4 [-] [to] 22 lbs. Do not apply to dogs weighing less than 4 lbs.

[including small dogs and puppies, 8 weeks or older]:

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Only For Dogs Weighing 23 [-] [to] 44 lbs.

Apply one tube (1.34 mL)(0.045 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Only For Dogs Weighing 45 [-] [to] 88 lbs.

Apply one tube (2.68 mL)(0.091 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Only For Dogs Weighing 89 [-] [to] 132 lbs. Do not use two tubes on dogs greater than 132 lbs

Apply one tube (4.02 mL)(0.136 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

Information in [] is optional

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STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F $[/][25^{\circ}C]$) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

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.

[[WARRANTY]

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. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, 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 buver.

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.]

[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]
[For more information]
[Non-Emergency, call XXX-XXX-XXXX]
[Made in USA]

Information in [] is optional

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Information in { } is a note to the reviewer

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



EPA Reg. No. 53883-351 EPA Est. No. XXXXX-XX-XXX

{END - BACK/SIDE PANEL}

$\{ START$ - OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE $\}$

{How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.}

[Application Instructions] [Directions for Use]

How to Open

- 1. Remove product tubes [vial] from the package.
- [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

- 1. Invert tube over dog and use open end to part dog's hair.
- 2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- · [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]

[For year-round protection, apply [Brand Name][This Product] monthly.] [Dog's Name (Empty blank for owner to fill in name)]

 $[First][1st][Second][2nd][Third][3rd][Fourth][4^{th}][Fifth][5^{th}][Sixth][6^{th}][Seventh][7^{th}][Eighth][8^{th}][Ninth][9^{th}][Tenth][10^{th}][Eleventh][11^{th}][Twelfth][12^{th}]$

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[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)] [calendar stickers with [Brand Name] [This Product] [Place stickers on your calendar as a reminder to reapply [Brand Name] [This Product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][This Product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

{Optional graphics below may or may not appear anywhere on finished label}

P	Adult Flea	
T	Fleas	
25.	Flea eggs	
つ	Flea Larvae	(3)
	Flea Pupae	
*	Ticks	
*	Brown Dog Tick	
*	Deer Tick	
*	American Dog Tick	8
*	Chewing Lice	
*	Lone Star Tick	8
7	Mosquitoes	
*	Mite	®

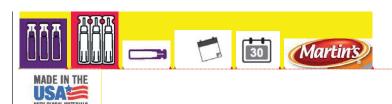


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FLEA EGGG ADULT FLEA FLEA LARVAE FLEA PUPAE		4	M
eggs			



[Flea life cycle diagram] [Flea Life Cycle]

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{END - PACKAGE COPY}

 $\{START-TUBE/VIAL\ LABEL\}$

{Front Label}

{Brand Name}
For Dogs [X-Y] lbs ≥8 wks
fipronil 9.8%, s-methoprene 8.8%
0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)
0.136 fl oz {label code}

{Back Label}

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 53883-351 {label code}

{END - TUBE/VIAL LABEL}