

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 4, 2018

Lisa Adamson Regulatory Manager Control Solutions, Inc. 5903 Genoa Red Bluff Rd Pasadena, TX 77507

Subject: Label Amendment – Addition of CRP package and retail options Product Name: PREFURRED PLUS IGR FOR CATS EPA Registration Number: 53883-352 Application Date: 26-Jan-2018 Decision Number: 538247

Dear Ms. Adamson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling 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 its implementing regulation at 40 CFR 152.3.

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.

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

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with FIFRA section 6. If you have any questions, you may contact Dr. Breeden-Alemi, DVM at 703-347-0511 or via email at <u>Breeden-Alemi.Julie@epa.gov</u>.

Sincerely,

Falul Elbrah

Elizabeth Fertich Product Manager 04 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

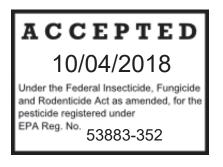
Information in [] is optional Text in () is meant to be included on the label Information in {} is a note to the reviewer

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Prefurred Plus IGR for Cats

Prefurred Plus IGR for Cats {The CRP packaging to be used for this product is described as a CRP blister applicator and is supplied as a 3 count and a 4 count in strips or as multiples of 3- and 4- counts.

The previously approved CRP packages including the applicator inside a CRP blister sold as a 3-count (strip of 3 applicators) has been removed.}



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{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.}

{start of front panel}

Prefurred Plus IGR for Cats

{The word Cat is to be at least 75% the height of the largest letter in the primary brand name.} {ABNs:}

[Martin's FLEETM Plus IGR for Cats]

{A large, clear picture of a cat in the weight range for the product as packaged will appear on the front panel of the label.}

For use ONLY on cats [[&] [and] kittens] over 1.5 lbs and over 8 weeks of age {OR} Only for cats [[&] [and] kittens] over 8 weeks of age and over 1.5 lbs {**One of the above statements will appear on front panel in a text box**}

[Prevents

infestation of listed pests for [4 weeks][1 month]] [Lift [here] for more information]

ACTIVE INGREDIENTS:

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

KEEP OUT OF REACH OF CHILDREN CAUTION

See[Back][or][Side][Label[s]][Panel[s]] for First Aid and Additional Precautionary Statements See inside flap and back panel for complete Directions for Use.

Net Contents: X fl oz [Y – 0.017 fl oz (0.503 mL) applicator(s)]

{X is the total floz, Y is the number of applicators, xx is the floz of each applicator with x being the corresponding amount in mL}

[[3][Three][4][Four][6][Six][8][Eight][12][Twelve][24][Twenty-Four] Applications] [[3][Three] [6][Six] [12] [Twelve]Month Supply] [[4][Four] [8][Eight] [12][Twelve] [24][Twenty-four] Month Supply]

{END - FRONT PANEL}

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{START – INSIDE PANEL/FLAP ON FRONT PACKAGE OR SIDE PANEL}

[[Brand name][This product] contains Fipronil and S-Methoprene [insect growth regulator] [IGR] to effectively kill fleas (all stages) 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 [1 month][4 weeks] on cats only.]

[END – INSIDE PANEL/FLAP ON FRONT PACKAGE OR SIDE PANEL}

{Start – BACK PANEL} READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE AND OVER 1.5 LBS.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes moderate 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 cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, or aged cats. Can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction. This product is not a substitute for prescribed Heartworm preventative.

FIRST AID {will be located on back panel}				
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.Call a poision control center or doctor for treatment advice.			
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.				

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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 CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

Restrictions

Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on cats or kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not double-dose cats. Use entire contents of applicator on each cat. [Do not split one applicator between two cats.] Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied. Do not apply more than one applicator per treatment for one cat regardless of cat's weight. Do not bathe or allow water immersion (swimming) for 24 hours after application. The cat needs to be dry at the time application and remain dry for 24 hours after application.

Do not apply more often than once every 4 weeks.

Side Effects: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats 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 cat 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 cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. Note to reviewer: {A box labeled "Side Effects" will be located in the lower right hand corner of the back panel.}

FREQUENCY OF APPLICATION

Use [Brand name][this product] monthly for control of flea, tick [and] chewing lice [and mosquito] infestations. [Studies show that] [Brand name] [this product] kills adult fleas for up to six weeks. Apply monthly if your cat 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 before touching. Do not reapply for [4 weeks]. [[Brand name][This product] can be used on breeding, pregnant and lactating (queens) (female cats).]

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{located on side panel}

STORAGE AND DISPOSAL

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

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** 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 must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product, 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, to the extent consistent with applicable law.

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]

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



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{END - PANEL}

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{START - FOLDED PANEL/FLAP OF FRONT OF PACKAGE } {Either the CRP blister applicator 3-Count or 4-Count SAUE opening instructions will be used and the term "applicator" will be used consistently throughout the label.}

{CRP blister applicator 3-count package}

How to Open:





Cut with scissors to open applicator



2 Fold back the safety tab

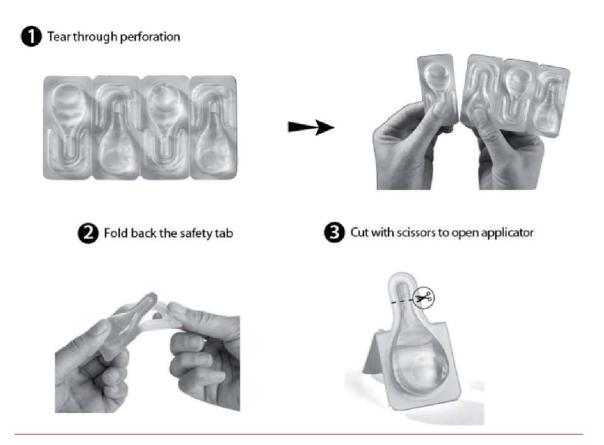


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{CRP blister applicator 4-count package}

How to Open:



{Begin "How to Apply" for applicator (3-Count and 4-count) The term "applicator" will be use with this CRP package and will be used consistently throughout the label.}

How to Apply:

- 1. Invert applicator over cat and use open end to part cat's hair.
- 2. Apply contents of one applicator of {**Brand Name**} [as a stripe, starting high [on] [to] the back of the cat's neck to in front of the shoulder blades] [as a spot between the shoulder blades]. Squeeze applicator firmly to apply all of the solution to the cat's skin.]

{END – FOLDED PANEL/FLAP OF FRONT OF PACKAGE}

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{Optional Claims} {The claims will be located on the front panel/inside front panel/front of box or back of box}

[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 all directions for use.
- [2] Weigh your cat
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate treated cats from each other and other pets until product has dried to avoid chance of ingestion
- [6] Do NOT split applicators between cats[and use the ENTIRE applicator contents]and do not use more than one tube [a month] [every 4 weeks]

[Brand Name]

[Monthly reminder card]

[3][4][6][8][12][24] Month [Treatment] [Application] Tracker]

[For year round protection apply [Brand name][This product] monthly.]

[Cat's Name {Empty blank for owner to fill in name}]

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

[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.]

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

	Adult Flea	
1PAT 1	Aduit Fica	
Toto	Fleas	
-126-	Flea eggs	N
っ	Flea Larvae	\bigcirc
	Flea Pupae	
×	Ticks	
	Brown Dog Tick	
	Deer Tick	
*	American Dog Tick	
ず	Chewing Lice	
*	Lone Star Tick	
₹.	Mosquitoes	









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[Flea life cycle diagram] [Flea Life Cycle]

{START – BLISTER APPLICATOR LABEL} {the below text will be on each separate blister applicator along with the embossed lot number} {each blister applicator has a clear plastic front and white foil backing with black printing}

{Printed on back of blister applicator}	
{Brand Name}	KEEP OUT OF REACH OF CHILDREN
For Cats over $1.5 \text{ lbs} \ge [\text{and over}] 8 \text{wks} [\text{of}]$	CAUTION: Read directions and precautions
age]	[accompanying label] before using. Use
Fipronil 9.8%, (S)-methoprene 11.8%	scissors to open.
0.017 fl oz (0.503 mL) {label code}	EPA REG. No. 53883-352 {label code}

{END – APPLICATOR LABEL}

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{Mosquitoes}

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

{Chewing Lice}

[Kills chewing lice] [Rapid elimination of chewing lice infestation] [Fast Action against chewing lice infestations]

{Adult Fleas}

[Kills adult fleas [for up to six weeks]] [Kills Fleas [Up to [4] [6] weeks]!] [Kills fleas which may be a source of flea allergy dermatitis] [or flea bite anemia]

{Ticks}

[Kills ticks including those that may transmit Lyme disease]

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

[Kills Deer Ticks (that may carry Lyme disease) for up to [4 weeks] [1 month] [30 days]]

[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]]

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

{Multiple Infestations}

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older and over 1.5 lbs.] [Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes] [Kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [and] flea larvae [and prevents the development of flea pupae]] [Breaks the Flea Life Cycle] [Monthly protection from flea, tick, [mosquito,] chewing lice, and flea eggs for cats] [Monthly protection from flea, tick, [mosquito] and chewing lice for cats] [Kills fleas, ticks, [mosquitoes,] flea eggs, and chewing lice] [[Seven] [7] [Six] [6] Way [Action] [Effectiveness] [Control] kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs, flea larvae and prevents the development of flea pupae] [[Six] [6] [Five] [5] Way [Action] [Effectiveness] [Control] kills fleas, ticks, [mosquitoes,] chewing lice, flea eggs & flea larvae] [[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!] [[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control] [Use [Brand name][this product] monthly to break the flea life cycle.] [[Four (4) Week] [1 month] [30 day] [Flea, Tick and Chewing Lice Control] [Use [Brand name][This product] monthly to control ticks and chewing lice] [Monthly protection from flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.] [[4 week] [1 month] [30 day] Flea and Tick Treatment!] [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, Ticks, Flea Eggs & Flea Larvae for up to [4 Weeks] [1 month] [30 days]] [Brand name][This product provides convenient and effective flea, tick, [and] chewing lice [and] [mosquito] control for cats and kittens 8 weeks of age and older and over 1.5 lbs.]

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{Flea Eggs and Larvae}

[Controls flea reinfestation on your cat [for up to six weeks]] [Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae [for up to six weeks]] [Kills all stages of the flea (adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)] [If cat is at high risk for flea reinfestation apply once a month] [Kills flea eggs [larvae] [and prevents the development of pupae] for up to six 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 [insect growth regulator] [IGR] Effectively Breaks the Flea Life Cycle]

[Kills Flea Eggs & Flea Larvae [for up to six weeks]!] [Prevents Flea Eggs From Developing Into Biting Adults]

{All Others}

[For Cats and Kittens over 1.5 lbs. and 8 weeks of age or older [Can be used on kittens over 1.5 lbs. and 8 weeks of age and older [Formulated for Cats and Kittens over 1.5 lbs. and Over 8 Weeks Old] [Fast Acting] [Long Lasting] [Easy to Use [Application]] [Best if used year round!] [Apply monthly] [Once a month treatment] [Apply once every [4 weeks] [month] [30 days]!] [4 Week Dose!] [1 Month Dose!] [30 Day Dose!] [Three Applications][Four Applications][Five Applications][Six Applications][Twelve Applications][24 Applications] and/or [3 Month Supply][4 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [12 Week Supply][16 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply] [Waterproof] [Effective even after bathing] [Effective after bathing and exposure to water and sunlight] [Can be used on breeding, pregnant and lactating [queens], [female] [cats]] [[Free] Calendar Stickers Inside!] [Monthly application reminder inside] [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [inside]] {Neither of the "Free" statements will stand alone. It will be placed with the Monthly application reminder}

{the three below claims will be printed together on packaging}

Contains fipronil and (S) methoprene, the active ingredients used in FRONTLINE[®] Plus for Cats]. FRONTLINE[®] is a registered trademark of Merial.

Preferred Plus IGR for Cats is not manufactured, or distributed by Merial, seller of FRONTLINE[®] Plus for Cats.