



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 29, 2015

Ann Tillman
Horizon Valley Generics Inc
c/o Pyxis Regulatory Consulting
4110 136th St. NW
Gig Harbor, WA 98332

Subject: Label Amendment – Add Marketing Statements and Correct Est. Number Info
Product Name: C710.0 FOR CATS
EPA Registration Number: 88052-14
Application Date: February 12, 2015
Decision Number: 500306

Dear Ms. Tillman:

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, please contact Maggie Rudick by phone at 703-347-0257, or via email at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be 'KBD', enclosed within a hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

(Label Directions for Container (Carton), Package Insert, Blister, and Reminder Stickers for 3 x 0.017 fl. oz. package)

(FRONT PANEL OF CARTON)

C710.0 FOR CATS

[ALTERNATE BRAND NAMES: Springline® for Cats, Springline® Spot-On for Cats, Pet Works Plus for Cats, PetLock Plus for Cats, and PetAction Plus for Cats]

Use ONLY on cats weighing over 1.5 lbs. and 8 weeks or older [picture of cat 8-weeks or older]

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease

DO NOT USE ON DOGS

[Optional text appears in brackets - the final label may include some or all of the optional text on front, back, side, or inside label panels. Optional marketing claims: see lists at the end of the label]

ACTIVE INGREDIENTS:

Fipronil9.8%
(S)-Methoprene.....11.8%

OTHER INGREDIENTS:78.4%

TOTAL:100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See label insert for FIRST AID and PRECAUTIONARY STATEMENTS

NET CONTENTS:

0.051 fl. oz. [(1.5 mL)] (3 applicators each containing 0.017 fl. oz. [(0.50 mL)]); [3 Doses]

[Manufactured for]:

[Distributed by:]

Horizon Valley Generics, Inc.
8735 Rosehill Road
Lenexa, KS 66215]

[MADE IN GERMANY]

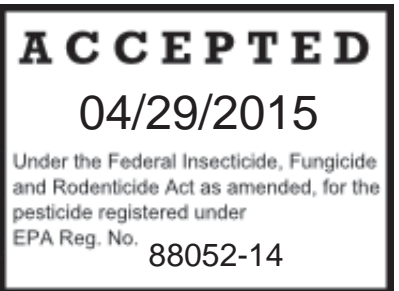
[C710.0 FOR CATS/ trade name is a registered trademark of Horizon Valley Generics, Inc.]

[©2012 Horizon Valley Generics, Inc. All rights reserved.]

[QUESTIONS OR COMMENTS ABOUT THIS PRODUCT]

[Call xxx-xxx-xxxx]

[Product Bar Code]



(BACK PANEL OF CARTON)

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

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

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

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 THE ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON DOGS, RABBITS OR OTHER ANIMALS.

SIDE EFFECTS

See package insert for side effects.

[Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you.)]

C710.0 FOR CATS

C710.0 FOR CATS contains the active ingredients fipronil and (S)-methoprene that effectively target fleas, ticks, mosquitoes, and chewing lice. C710.0 is fast-acting, long-lasting, waterproof, and easy to use.

C710.0 FOR CATS remains effective even after bathing, water immersion, or exposure to sunlight. C710.0 FOR CATS can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant and lactating queens.

Do not allow your cat to ingest this product. Do not apply to cats weighing less than 1.5 lbs. and less than 8 weeks old.

To kill fleas, flea eggs, and all stages of Brown dog ticks, American dog ticks, Lone Star ticks, and Deer ticks, chewing lice and mosquitoes, apply this product **ONLY** to cats and kittens weighing over 1.5 lbs. and 8 weeks or older as follows.

To remove and open applicator: See label insert for opening instructions.

To apply C710.0 FOR CATS: Place applicator tip through cat's hair to the skin level between the shoulder blades. Squeeze applicator, applying entire contents in a single spot on the cat's skin. Avoid superficial application to the cat's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

[PICTOGRAM ON HOW TO APPLY]

(BACK PANEL OF CARTON)

FREQUENCY OF APPLICATION

Fleas: When used monthly, C710.0 FOR CATS kills all stages of the flea life cycle and prevents reinfestation of fleas on your cat for up to six weeks after application. Although C710.0 FOR CATS can control fleas for up to six weeks, if there is a high risk of re-infestation of fleas on your cat, or if the cat has fleas which may cause flea allergy dermatitis, apply C710.0 FOR CATS once every 30 days.

Ticks: C710.0 FOR CATS kills all stages of the tick life cycle (larvae, nymph, and adult) for at least 30 days. For best control of ticks, apply once every 30 days.

Chewing Lice: C710.0 FOR CATS kills chewing lice for at least 30 days. For best control of chewing lice, apply once every 30 days.

Mosquitoes: Apply C710.0 for Cats every 30 days to kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C710.0 for Cats for 30 days.

EPA Reg. No. 88052-14

EPA Est. No.

[Manufactured for:

[Distributed by:]

Horizon Valley Generics, Inc.

8735 Rosehill Road

Lenexa, KS 66215]

[MADE IN GERMANY]

[C710.0 FOR CATS/ trade name is a registered trademark of Horizon Valley Generics, Inc.]

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[QUESTIONS OR COMMENTS ABOUT THIS PRODUCT]

[Call xxx-xxx-xxxx]

[Product Bar Code]

(SIDE PANEL OF CARTON)

For use only on Cats & Kittens weighing over 1.5 lbs. and 8 weeks or older

C710.0 for Cats

[EPA Reg. No. 88052-14]

Lot/Batch Number

[Logos and photos]

PETACTION
FOR **CATS**
Plus

PetLock
for **CATS**
Plus

PET WORKS
FOR **CATS**
Plus

[Options for cat photos]



[Optional Marketing Claims for Carton and Package Insert]

- [Kills [Fleas], [Flea Eggs] and [Larvae], [Ticks], [Chewing Lice], [Mosquitoes]]
- [Fast-acting, long-lasting, convenient spot treatment for control of [fleas], [ticks], [mosquitoes], and [chewing lice]]
- [C710.0 FOR CATS provides convenient and effective [flea], [tick], [mosquitoes], and [chewing lice] control for cats and [kittens weighing 1.5 lbs and 8 weeks and older]]
- [Fast acting and long lasting]
- [Convenient to use]
- [Prevents [flea eggs], [larvae] and [pupae]from developing]
- [Kills [flea eggs], [flea larvae] and [flea pupae]]
- [Controls adult fleas which may cause [FAD] [flea allergy dermatitis]]
- [Kills all stages of Brown Dog ticks (*R. sanguineus*), American dog ticks (*D. variabilis*), Lone Star ticks (*Amblyomma americanum*), [Deer ticks (*Ixodes scapularis*) which may transmit Lyme disease]]
- [Kills tick [nymphs] and [adults]]
- [Rapidly controls infestations of chewing lice]
- [Can be used on [breeding], [pregnant] and [lactating] queens]
- [Waterproof [water resistant]]
- [Kills adult fleas which may cause [flea allergy dermatitis] [FAD] and [flea bite dermatitis]]
- [Effective monthly treatment of [fleas], [ticks] and [lice]]
- [Remains effective after [bathing] and [swimming]]
- [Kills ticks that may transmit [Lyme disease], [haemobartonellosis], [ehrlichiosis], [babesiosis], [anaplasmosis]]
- [Easy, fast, effective control of [fleas], [ticks] and [lice]]
- [Kills fleas [ticks] [lice]]
- [Kills mosquitoes]
- [Kills fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Flea]

- [Optional graphics: Picture of tick]
 - [Optional graphics: Picture of chewing lice]
 - [Convenient to use]
 - [Long lasting]
 - [Fast acting]
 - [Controls infestations with chewing lice]
 - [Kills all stages of deer ticks]
 - [Best results when used monthly [year round]]
 - [For year round protection]
 - [Kills newly emerged fleas before they lay eggs]
 - [Calendar stickers inside]
 - [Prevents re-infestation of fleas on your cat for one month]
 - [3 Doses Inside]
 - [[Especially] [specifically] [expressly] formulated for cats and kittens [weighing over 1.5 lbs. and 8 weeks and older] [only]]
 - [Contains the same active ingredients fipronil and (S)-methoprene found in Frontline® Plus]
 - [Contains Fipronil and (S)-Methoprene [the same active ingredients used in Frontline® Plus for Cats]
 - [Contains the same active ingredients as Frontline® Plus for Cats]
- [Note to reviewer: whenever any of the three claims immediately above are included on product labels, then the label will contain the appropriate disclaimers below. The disclaimers will be placed in the same area of the label as the optional claims so that both are viewed together.]
- [C710.0 FOR CATS is not manufactured by or distributed by Merial Limited]
 - [Frontline is a registered trademark of Merial Limited.]

(LABEL DIRECTIONS FOR PACKAGE INSERT)

C710.0 FOR CATS

[ALTERNATE BRAND NAME: Springline® for Cats, Springline® Spot-On for Cats, Pet Works Plus for Cats, PetLock Plus for Cats, and PetAction Plus for Cats]

Use ONLY on cats weighing over 1.5 lbs. and 8 weeks or older [picture of cat]

Kills Fleas, Flea Eggs and Larvae, Chewing Lice, Mosquitoes
Kills all stages of Ticks, including those that may transmit Lyme disease

DO NOT USE ON DOGS

ACTIVE INGREDIENTS:

Fipronil	9.8%
(S)-Methoprene.....	11.8
OTHER INGREDIENTS:	<u>78.4%</u>
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

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 by mouth to an unconscious person.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or going for treatment. You may contact us at xxx-xxx-xxxx for emergency medical treatment information.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. 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. Do not use on kittens weighing less than 1.5 lbs. and less than 8 weeks of age. **DO NOT USE ON DOGS. DO NOT USE ON OTHER ANIMALS.** Individual sensitivities, while rare, may occur after using **ANY** pesticide product. Cats may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats. Call 1-xxx-xxx-xxxx for 24-hour assistance.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

SIDE EFFECTS

Monitor your cat after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. In some cases, vomiting or diarrhea may result due to grooming after treatment. If these or other side effects occur, consult your veterinarian or call us at xxx-xxx-xxxx.

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 THE ENTIRE LABEL AND DIRECTIONS FOR USE BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

Precaucion al consumidor: si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you.)

C710.0 FOR CATS

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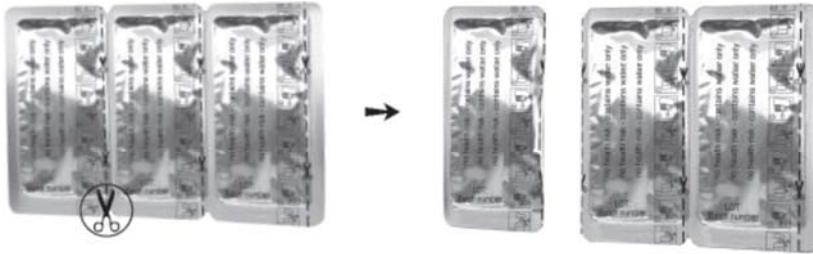
Do not allow your cat to ingest this product. Do not apply to cats weighing less than 1.5 lbs. and less than 8 weeks old.

To kill fleas, flea eggs and larvae, all stages of **Brown Dog ticks, American dog ticks, Lone Star ticks**, and **Deer ticks** (which may carry Lyme disease), mosquitoes, and chewing lice, apply this product to cats and kittens weighing over 1.5 lbs. and 8 weeks or older as follows.

(LABEL DIRECTIONS FOR PACKAGE INSERT)

To remove and open applicator:

- 1** Cut along scissor cut line to separate unit



- 2** Turn unit over and cut corner at bulb end



- 3** From cut corner, peel backing completely off from bottom to top



- 4** Remove the applicator



[ILLUSTRATIONS FOR APPLYING PRODUCT]

To apply C710.0 FOR CATS: Place applicator tip through cat's hair to the skin level between the shoulder blades. Squeeze applicator applying entire contents in a single spot to the cat's skin. Avoid superficial application to the cat's hair. Allow area to dry before touching treated area. Only one applicator per treatment is needed.

FREQUENCY OF APPLICATION

Fleas: When used monthly, C710.0 FOR CATS kills all stages of the flea life cycle and prevents reinfestation of fleas on your cat for up to six weeks after application. Although C710.0 FOR CATS can control fleas for up to six weeks, if there is a high risk of re-infestation of fleas on your cat, or if the cat has fleas which may cause flea allergy dermatitis, apply C710.0 FOR CATS once every 30 days.

Ticks: C710.0 FOR CATS kills all stages of the tick life cycle (larvae, nymph, and adult) for at least 30 days. For best control of ticks, apply once every 30 days.

Chewing Lice: C710.0 FOR CATS kills chewing lice for at least 30 days. For best control of chewing lice, apply once every 30 days.

Mosquitoes: Apply C710.0 for Cats every 30 days to kill mosquitoes within 24 hours for up to one week, and within 48 hours for up to 28 days.

Do not reapply C710.0 FOR CATS for 30 days.

EPA Reg. No. 88052-14

(LABEL DIRECTIONS FOR PACKAGE INSERT)

QUESTIONS OR COMMENTS ABOUT THIS PRODUCT

Call xxx-xxx-xxxx

[PRODUCT BAR CODE]

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE. Store unused product in original container only, out of reach of children and animals.

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

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

HOW SUPPLIED

For easy and convenient treatment, C710.0 FOR CATS is available in one convenient size.

0.051 fl. oz. (1.5 mL) (3 applicators each containing 0.017 fl. oz. (0.50 mL); 3 Doses

WARRANTY

To the extent consistent with applicable law, Horizon Valley Generics, Inc. and/or seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use resulting from the handling of this product. Seller shall return the purchase price or at the election of the seller replace the product.

Manufactured for:

[Distributed by:]

Horizon Valley Generics, Inc.
8735 Rosehill Road
Lenexa, KS 66215

MADE IN GERMANY

C710.0 FOR CATS/ trade name is a registered trademark of Horizon Valley Generics, Inc.

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(Text for CRP Blister)

TOP OF LIDDING FOIL—see back of blister on next page: Dotted line with representation of a pair of scissors and two step directions to separate blisters

KEEP OUT OF REACH OF CHILDREN

CAUTION. See full label for additional instructions

C710.0 for Cats

EPA Reg. No. 88052-14

[Lot/Batch No.; only number will appear]

0.017 fl. oz. (0.5 mL) – Only for Cats & Kittens weighing over 1.5 lbs. [and] [&] 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 11.8%

PIPETTE FOIL

KEEP OUT OF REACH OF CHILDREN

CAUTION.

Read directions before use.

C710.0 for Cats

EPA Reg. No. 88052-14

[Lot/Batch No.; only number will appear]

0.017 fl. oz. (0.5 mL) – Only for Cats & Kittens weighing over 1.5 lbs. [and] [&] 8 weeks or older

Fipronil 9.8%

(S)-Methoprene 11.8%

[Pictogram of Front of Blister With Opening Instructions – NOT PART OF LABEL]



[Pictogram of Back of Blister With Opening Instructions – NOT PART OF LABEL]



(Text for Reminder Stickers for 3 x 0.017 fl. oz. Package)

[Optional marketing claims]

[Picture of Cat or Kitten (8 weeks or older)]

[Picture of flea]

[Picture of tick]

[Picture of chewing lice]

[Picture of mosquitoes]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas, ticks, chewing lice, mosquitoes]

[Optional Bar Code]

C710.0 for Cats

The first time you treat your cat, place the First Application Sticker on your calendar. Apply Stickers 2 and 3 to the calendar 30 and 60 days after the first application to remind you it's time to reapply C710.0 for Cats.

First Application Sticker: Apply C710.0 for Cats

Month 1 Sticker: Apply C710.0 for Cats

Month 2 Sticker: Apply C710.0 for Cats

For Customer Service please call 1-xxx-xxx-xxxx.

[Distributed by:]

Horizon Valley Generics, Inc.
8735 Rosehill Road
Lenexa, KS 66215

[Optional bar code]