



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 26, 2015

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

Subject: Label Amendment – Adding general pet spot-on mitigation language
Product Name: C712.0 for Cats
EPA Registration Number: 88052-9
Application Date: August 8, 2013
Decision Number: 477843

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) lists 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.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', 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) and Package Insert for
0.017 fl. oz. (0.5 mL) (applicators) (pipettes)]**

[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]

**C712.0 FOR CATS
8 WEEKS AND OLDER AND 1.5 LBS OR GREATER**

DO NOT USE ON DOGS

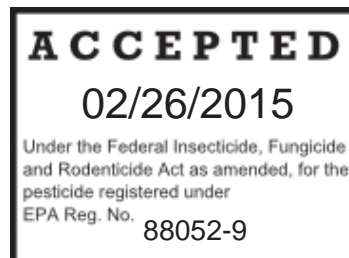
Optional Marketing Claims

[[C712.0] FOR CATS & KITTENS – use only on cats and kittens 8 weeks or older and 1.5 lbs or greater]

[distributor name]

Illustration/Picture of Cat

- [Fast-acting, long-lasting, convenient spot treatment for control of fleas, ticks and chewing lice]
- [Waterproof]
- [C712.0 FOR CATS provides convenient and effective flea, tick and chewing lice control for cats and kittens.]
- [Fast acting and long-lasting]
- [Prevents re-infestation]
- [Convenient to use]
- [Kills (newly emerged) adult fleas before they lay eggs]
- [Controls adult fleas which may cause flea allergy dermatitis [FAD]]
- [Kills [all stages of] brown dog ticks [(*R. sanguineus*)], American dog ticks [(*D. variabilis*)], lone star ticks [(*Amblyomma americanum*)], and deer ticks [(*Ixodes scapularis*)] [which may carry Lyme disease], Fleas, [Chewing] Lice]
- [Kills [all stages of] brown dog ticks [(*R. sanguineus*)], American dog ticks [(*D. variabilis*)], lone star ticks [(*Amblyomma americanum*)], and deer ticks [(*Ixodes scapularis*)] [which may carry Lyme disease]]
- [Controls infestations with chewing lice]
- [Can be used on breeding, pregnant and lactating queens]
- [Waterproof (water resistant)]
- [Kills adult fleas that may cause flea allergy dermatitis and flea bite anemia]
- [Protects for one month]
- [Effective monthly treatment of fleas, ticks and lice]
- [Remains effective after bathing and swimming]
- [Kills ticks that may transmit Lyme disease, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, and anaplasmosis]
- [Easy, fast, effective control of fleas, ticks and lice]
- [Kills fleas [ticks] [lice] [chewing lice]]
- [Kills fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Flea]
- [Optional graphics: Picture of tick]
- [Optional graphics: Picture of chewing lice]
- [Contains the active ingredient fipronil]
- [Contains the same active ingredient, fipronil, found in FIPAIRA™ for Cats]
- [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)]
- [Apply monthly for year round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [Prevents re-infestation of adult fleas and ticks for one month]
- [3 Doses Inside]
- [Contains] [3 Month Supply]
- [Contains] [3 [Pipettes][Applicators]]
- [Contains (Fipronil) the same active ingredient used in FIPAIRA™ for Cats]
- [9.7% Fipronil]
- [Fipronil 9.7%]
- [C712.0 FOR CATS is not manufactured by or distributed by Merial]. FIPAIRA™ is a trademark of Merial]
- [(Especially) (specifically) (expressly) formulated for cats and kittens (only) (8 weeks and older and 1.5 lb. or greater)]
- [C712.0 FOR CATS is not manufactured by or distributed by Merial Limited.]
- [FIPAIRA™ is a trademark of Merial Limited.]
- [Contains Fipronil (the active ingredient used in FIPAIRA™ for Cats)]
- [pictogram of [pipette(s)] [applicator(s)]]

[CARTON – 3 x 0.017 FL. OZ. PACKAGE]

EPA Reg. No. 88052-9
EPA Est. 74720-DEU-01

ACTIVE INGREDIENT:

Fipronil 9.7%

OTHER INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [back (side) panel and insert] [insert] for additional Precautionary and First Aid Statements

NET CONTENTS: 0.051 fl. oz.

Three (3) 0.017 fl. oz. [0.50 mL] (applicators) (pipettes)

Side Effects. Monitor your cat after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported as a result of grooming after treatment. If these or other side effects occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

[CARTON – 3 x 0.017 FL. OZ. PACKAGE]

**C712.0 FOR CATS
8 WEEKS AND OLDER AND 1.5 LBS OR GREATER**

C712.0 FOR CATS contains the active ingredient fipronil that effectively kills and controls fleas, ticks and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in fast-acting, long-lasting activity.

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 injury to you and your cat, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on cats. Do not use on dogs, rabbits or on 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.)]

To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks, and deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to cats and kittens (8 weeks or older and weighing 1.5 lb. or greater) as follows.

INSTRUCTIONS FOR APPLYING PRODUCT

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

To apply C712.0 FOR CATS: Place (applicator) (pipette) tip through cat's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), 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. Use one (applicator) (pipette) per treatment per month.

[ILLUSTRATIONS FOR APPLYING PRODUCT]

C712.0 FOR CATS can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, C712.0 FOR CATS controls flea, tick and chewing lice infestations. Research demonstrates that C712.0 FOR CATS kills adult fleas for up to six weeks. Although C712.0 FOR CATS can control fleas for up to six weeks, if there is a high risk of re-infestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR CATS kills all life stages of ticks (larvae, nymph, and adults) for at least one month. A once monthly application is recommended where tick control is needed. C712.0 FOR CATS kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed. C712.0 FOR CATS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR CATS for 30 days.

Manufactured for:

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

MADE IN GERMANY

C712.0 FOR CATS/ trade name is a registered trademark of Horizon Valley Generics, Inc.
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[LABEL DIRECTIONS FOR PACKAGE INSERT –
3 x 0.017 FL. OZ. PACKAGE]

**C712.0 FOR CATS
8 WEEKS AND OLDER AND 1.5 LBS OR GREATER**

EPA Reg. No. 88052-9

[EPA Est. 74720-DEU-01]

ACTIVE INGREDIENT:

Fipronil 9.7%

OTHER INGREDIENTS: 90.3%

TOTAL: 100.0%

Kills fleas and all stages of **brown dog ticks**, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease) and chewing lice.

KEEP OUT OF REACH OF CHILDREN

CAUTION

C712.0 FOR CATS contains the active ingredient fipronil that effectively kills and controls fleas, ticks and chewing lice. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

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 injury to you and your cat, read entire label and directions on the package insert before each use. Follow all directions and precautionary statements carefully. This product must only be used on cats. Do not use on dogs, rabbits or on other animals.

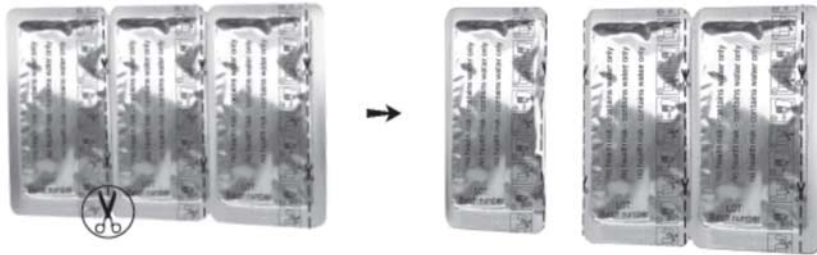
Precaucion al consumidor: Si usted no puede leer inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you.)

To kill fleas and all stages of **brown dog ticks**, **American dog ticks**, **lone star ticks**, and **deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to cats and kittens (8 weeks or older weighing 1.5 lbs or greater) as follows.

[To remove and open [applicator] [pipette]:]
[To remove and open [applicator] [pipette], see reverse side.]

[ILLUSTRATIONS FOR OPENING PRODUCT; photo on final label will reflect actual product blisters and pipettes]

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 C712.0 FOR CATS: Place (applicator) (pipette) tip through cat's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), 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) (pipette) per treatment is needed.

C712.0 FOR CATS can also be used for the treatment and control of flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, C712.0 FOR CATS controls flea, tick and chewing lice infestations. Research demonstrates that C712.0 FOR CATS kills adult fleas for up to six weeks. Although C712.0 FOR CATS can control fleas for up to six weeks, if there is a high risk of re-infestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR CATS kills all stages of ticks (larvae, nymph, and adults) for at least one month. A once monthly application is recommended where tick control is needed. C712.0 FOR CATS kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is needed. C712.0 FOR CATS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR CATS for 30 days.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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.

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 OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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 contact the ASPCA Animal Poison Control Center at 1-888-426-4435 for emergency medical treatment information.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS**

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

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on kittens under 8 weeks of age or weighing under 1.5 lb. Do not use on dogs. 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 immediately. 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 the ASPCA Animal Poison Control Center at 1-888-426-4435 for assistance.

Side Effects. Monitor your cat after application. Side effects may include skin irritation such as redness, scratching or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported as a result of grooming after treatment. If these or other side effects occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

[QUESTIONS [OR COMMENTS] ABOUT THIS PRODUCT]

Call the ASPCA Animal Poison Control Center at 1-888-426-4435

[GRAPHICS/PICTURES of cat]

[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 [or 1-800-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

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

HOW SUPPLIED

For easy and convenient treatment, C712.0 FOR CATS is available in one convenient size.

Contains 3 - 0.017 fl. oz. (0.50 mL) (pipettes) (applicators)

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:

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

[MADE IN GERMANY]

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[Text for Back of Blister Pack]

Pictogram with scissors and cut-line (see photo above)

Keep Out of Reach of Children

Read directions before use.

CAUTION

Only for Cats & Kittens 8 weeks or older and 1.5 lbs or greater

C712.0 for Cats

Fipronil 9.7%

EPA Reg. No. 88052-9

Lot No.

0.017 fl. oz.

[Text for Back of Pipette]

Keep Out of Reach of Children

Read directions before use.

CAUTION

Only for Cats & Kittens 8 weeks or older and 1.5 lbs or greater

C712.0 for Cats

Fipronil 9.7%

EPA Reg. No. 88052-9

Lot No.

0.017 fl. oz.

[Optional advertising claims: care card/reminder stickers]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply C712.0 for Cats to your cat.]

[Remove the adhesive backing and attach to your refrigerator [door].]

[Reminder]

[Care Card]

[Reminder sticker for Month 1, Date of Application]

[Reminder sticker for Month 2], Date of Application

[Reminder sticker for Month 3, Date of Application]

[Cat's name; lbs.]