



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 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Subject: Label Amendment – Adding general pet spot-on mitigation language  
Product Name: C712.0 for Dogs  
EPA Registration Number: 88052-8  
Application Date: August 8, 2013  
Decision Number: 478001

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.

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](mailto:chao.julie@epa.gov).

Sincerely,

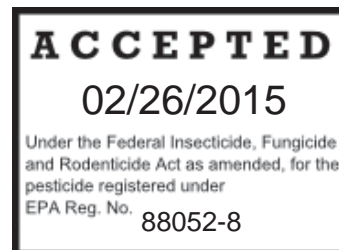
A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a hand-drawn oval.

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

Enclosure

- [Label Directions and Container (Carton) and Package Insert for 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)]
- [Label Directions and Container (Carton) and Package Insert for 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)]
- [Label Directions for Container (Carton) and Package Insert for 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)]
- [Label Directions and Container (Carton) and Package Insert for 0.136 fl. oz. (4.02 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 DOGS

Optional Marketing Claims [Fleas, Ticks, Chewing Lice]

[Distributor name]

[[C712.0] FOR DOGS & PUPPIES – Use only on dogs weighing 5-22 lbs. and 8 weeks or older]; [For small dogs and puppies]

[[C712.0] FOR DOGS & PUPPIES – Use only on dogs weighing 23-44 lbs. and 8 weeks or older]; [For medium dogs]

[[C712.0] FOR DOGS & PUPPIES – Use only on dogs weighing 45-88 lbs. and 8 weeks or older]; [For large dogs]

[[C712.0] FOR DOGS & PUPPIES – Use only on dogs weighing 89-132 lbs. and 8 weeks or older]; [For extra-large dogs]

- [Fast-acting, long-lasting, convenient spot treatment for control of fleas, ticks and chewing lice]
- [Waterproof]
- **[C712.0 FOR DOGS** provides convenient and effective flea, tick, and chewing lice control for dogs and puppies.]
- [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]]
- [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],
- Kills Fleas, [Chewing] Lice]

- [Controls infestations with chewing lice]
- [Controls chewing lice infestations]
- [Aids in control of sarcoptic mange mite infestations]
- [Can be used on breeding, pregnant and lactating bitches]
- [Waterproof (water resistant)]
- [Prevents infestation]
- [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, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, and anaplasmosis]
- [(Easy,) (fast,)(effective) control of fleas, ticks and lice]
- [Kills fleas [ticks] [lice] [chewing lice] [mites]]
- [Kills adult fleas that may cause flea bite anemia]
- [Optional graphics: Picture of Flea]
- [Optional graphics: Picture of tick]
- [Optional graphics: Picture of louse]
- [Contains the active ingredient fipronil]
- [Contains the same active ingredient, fipronil, found in FIPAIRA for Dogs]
- [Convenient to use]
- [Long lasting]
- [Fast acting]
- [Controls infestations with chewing lice]
- [Controls and prevents re-infestation]
- [Kills all stages of deer ticks]
- [Prevents infestations of adult fleas and adult ticks.]
- [Apply monthly]
- [Controls mites that may cause sarcoptic mange]
- [Best results when used monthly (year round)]
- [Apply monthly for year-round protection]
- [Kills newly emerged fleas before they lay eggs]
- [Calendar stickers inside]
- [3 Doses [Inside]]
- [Contains] [3 Month Supply]
- [Contains] [3 Pipettes [Applicators]]
- [9.7% Fipronil]
- [Fipronil 9.7%]
- [Controls flea re-infestation for up to one month (4 weeks)]
- [Contains (Fipronil) the same active ingredient used in FIPAIRA™ for Dogs]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial Limited.]
- [FIPAIRA™ is a trademark of Merial Limited.]
- [Contains Fipronil (the same active ingredient used in FIPAIRA™ for Dogs)]
- [C712.0 FOR DOGS is not manufactured by or distributed by Merial. FIPAIRA is a trademark of Merial]
- [pictogram of [pipette(s)] [applicator(s)]]

[CARTON – 3 x 0.023 FL. OZ. PACKAGE]  
[CARTON – 3 x 0.045 FL. OZ. PACKAGE]  
[CARTON – 3 x 0.091 FL. OZ. PACKAGE]  
[CARTON – 3 x 0.136 FL. OZ. PACKAGE]

EPA Reg. No. 88052-8  
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: [0.069 fl. oz.] [0.135 fl. oz.] [0.273 fl. oz.] [0.408 fl oz.]

[Three (3) 0.023 fl. oz. [0.67 mL] (applicators) (pipettes)]

[Three (3) 0.045 fl. oz. [1.34 mL] (applicators) (pipettes)]

[Three (3) 0.091 fl. oz. [2.68 mL] (applicators) (pipettes)]

[Three (3) 0.136 fl. oz. [4.02 mL] (applicators) (pipettes)]

[CAT PROHIBITION ICON]



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.

Side Effects. Monitor your dog 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. If these or other side effects occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

**C712.0 FOR DOGS 8 weeks or older**

C712.0 FOR DOGS 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 dog, 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 dogs. Do not use on rabbits or on other animals. Use only on dogs and puppies weighing 5 lbs. or more.

[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 dogs and puppies (8 weeks or older) as follows.

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

## **INSTRUCTIONS FOR APPLYING PRODUCT**

To apply C712.0 for Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed. Do not apply more than one applicator for dogs weighing more than 132 lbs.

*OR [Alternate application method]*

*For dogs & puppies weighting 5-22 [23-44] [45-88] [89-132] lbs. Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail. Do not apply more than one applicator for dogs weighing more than 132 lbs.*

*OR [Alternate application method]*

*For dogs & puppies weighting 5-22 [23-44] [45-88] [89-132] lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine). Do not apply more than one applicator for dogs weighing more than 132 lbs.*

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. Multiple monthly treatments are recommended for the elimination of mites.

## **FREQUENCY OF APPLICATION**

When used monthly, C712.0 for Dogs completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 for Dogs kills adult fleas for up to three months. Although C712.0 for Dogs can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 for Dogs kills all life stages of ticks (larvae, nymph, and adult) for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. Applied once a month, C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. C712.0 for Dogs remains effective even after bathing, water immersion, or exposure to sunlight. Do not reapply C712.0 for Dogs for 30 days.

### **Manufactured for:**

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

MADE IN Germany

C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.  
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[LABEL DIRECTIONS FOR PACKAGE INSERT –  
3 x 0.023 FL. OZ. PACKAGE]  
[LABEL DIRECTIONS FOR PACKAGE INSERT –  
3 x 0.045 FL. OZ. PACKAGE]  
[LABEL DIRECTIONS FOR PACKAGE INSERT –  
3 x 0.091 FL. OZ. PACKAGE]  
[LABEL DIRECTIONS FOR PACKAGE INSERT –  
3 x 0.136 FL. OZ. PACKAGE]

### C712.0 FOR DOGS 8 weeks or older

EPA Reg. No. 88052-8

[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 Dogs 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 dog, 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 dogs. Do not use on 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).

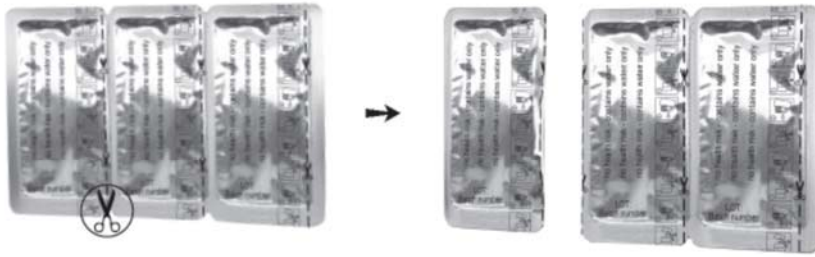
To kill fleas and all stages of **brown dog ticks, American dog ticks, lone star ticks,** and **deer ticks** (which may carry Lyme disease) and chewing lice, apply this product to dogs and puppies (8 weeks or older) as follows.

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 Dogs: Place (applicator) (pipette) tip through dog's hair to the skin level between the shoulder blades. Squeeze (applicator) (pipette), applying entire contents in a single spot to the dog's skin. Avoid superficial application to the dog's hair. Allow area to dry before touching treated area. Only one (applicator) (pipette) per treatment is needed.

*OR [Alternate application method]*

*For dogs & puppies weighting 5-22 [23-44] [45-88] [89-132] lbs. Apply one (applicator) (pipette) from the back of the neck to a point midway between the neck and tail.*

*OR [Alternate application method]*

*For dogs & puppies weighting 5-22 [23-44] [45-88] [89-132] lbs. Apply one (applicator) (pipette) starting at the base of the tail moving in a straight line toward head against the hair along the backbone (spine).*

C712.0 for Dogs can also be used for the treatment and control of flea, tick, and chewing lice infestations on breeding, pregnant, and lactating bitches. C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. Multiple monthly treatments are recommended for the elimination of mites.

### **FREQUENCY OF APPLICATION**

When used monthly, C712.0 FOR DOGS completely controls flea, tick, and chewing lice infestations. Research demonstrates that C712.0 FOR DOGS kills adult fleas for up to three months. Although C712.0 FOR DOGS can control fleas for up to three months, if there is a high risk of re-infestation or if the dog has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. C712.0 FOR DOGS kills all stages of ticks (larvae,



nymph, and adult) for at least one month. A once monthly application is recommended where tick control is needed. A once monthly application is recommended where chewing lice are present. Applied once a month, C712.0 for Dogs aids in the control of sarcoptic mange mite infestations. C712.0 FOR DOGS remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply C712.0 FOR DOGS for 30 days.

[CAT PROHIBITION ICON]

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.

Side Effects. Monitor your dog 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. If these or other side effects occur, consult your veterinarian or the ASPCA Animal Poison Control Center at 1-888-426-4435.

#### **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, doctor or going for treatment. You may 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 puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Dogs 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 dog 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 dogs. Call the ASPCA Animal Poison Control Center at 1-888-426-4435 for assistance.

*[QUESTIONS [OR COMMENTS] ABOUT THIS PRODUCT]*

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

*[GRAPHICS/PICTURES of Appropriate size dog]*

*[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.** Non refillable container. Do not reuse this container. If empty: Place in trash or offer for recycling if available.

### HOW SUPPLIED

C712.0 FOR DOGS is available in convenient sizes for small dogs and puppies 8 weeks or older and 5-22 lbs., medium dogs 23-44 lbs., large dogs 45-88 lbs., and extra-large dogs 89-132 lbs.

5-22 lbs.	Contains 3 - 0.023 fl. oz. (0.67 mL) (applicators) (pipettes)
23-44 lbs.	Contains 3 - 0.045 fl. oz. (1.34 mL) (applicators) (pipettes)
45-88 lbs.	Contains 3 - 0.091 fl. oz. (2.68 mL) (applicators) (pipettes)
89-132 lbs.	Contains 3 - 0.136 fl. oz. (4.02 mL) (applicators) (pipettes)

### 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]

C712.0 FOR DOGS/ trade name is a registered trademark of Horizon Valley Generics, Inc.

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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**

Cat prohibition icon



**DO NOT USE ON CATS**

Use **ONLY** on Puppies 5-22 lbs and 8 weeks or older

0.023 fl. oz.

Use **ONLY** on Dogs 23-44 lbs and 8 weeks or older

0.045 fl. oz.

Use **ONLY** on Dogs 45-88 lbs and 8 weeks or older

0.091 fl. oz.

Use **ONLY** on Dogs 89-132 lbs and 8 weeks or older

0.136 fl. oz.

C712.0 for Dogs

Fipronil 9.7%

EPA Reg. No. 88052-8

Lot No.

[Text for Back of Pipette]

Keep Out of Reach of Children

Read directions before use.

**CAUTION**

**DO NOT USE ON CATS**

C712.0 for Dogs

Fipronil 9.7%

EPA Reg. No. 88052-8

Lot No.

(Use **ONLY** on Puppies 5-22 lbs and 8 weeks or older

0.023 fl. oz.)

(Use **ONLY** on Dogs 23-44 lbs and 8 weeks or older

0.045 fl. oz.)

**(Use ONLY on Dogs 45-88 lbs and 8 weeks or older**

**0.091 fl. oz.)**

**(Use ONLY on Dogs 89-132 lbs and 8 weeks or older**

**0.136 fl. oz.)**

[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]

[Dog's name; lbs.]