

88052-9

12/13/2012



U S ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Ave NW  
Washington DC 20460

EPA Reg Number

88052-9

Date of Issuance

DEC 13 2012

NOTICE OF PESTICIDE

Registration  
 Reregistration  
(under FIFRA as amended)

Term of Issuance

Conditional

C712 0 FOR CATS

Name and Address of Registrant (include ZIP Code)

**Horizon Valley Generics, Inc**  
**c/o Pyxis Regulatory Consulting, Inc**  
**4110 136<sup>th</sup> Street NW**  
**Gig Harbor, WA 98332**

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant the above named pesticide is hereby registered//reregistered under the Federal Insecticide Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment the Administrator on his motion may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you

- 1 Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under section 4 of FIFRA
- 2 Submit within 12 months of the date of issuance of this Registration Notice, acceptable guideline studies for Storage Stability study (OPPTS GLN 830 6317) and Corrosion Characteristics study (OPTS GLN 830 6320) for this product
- 3 Change the product registration number to "EPA Reg No 88052-9"  
(continued on page 2)

Signature of Approving Official

See page 2

Richard Gebken Product Manager (10)  
Insecticide Branch Registration Division (7505P)

Date

DEC 13 2012

EPA Form 8570 6

**Conditions of acceptance**

- 1 This registration is now time-limited and expires two years from the date of this letter
- 2 Please consider limiting the formulations of this product to one basic confidential statement of formula The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future
- 3 You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2012

Please flag any Confidential Business Information as such Enhanced incident reporting should be submitted to the Product Manager Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn Karlton Keller)

The following is a list of information that must be included in the quarterly reports for each incident

- EPA Registration Number
- Product name (brand name)
- Lot #
- Where purchased internet, store, veterinarian
- Active Ingredient(s)
- Weight range for product
  
- Date on which incident occurred (mm/dd/yyyy)
- State in which the incident occurred (standard 2 letter abbreviation)
- Registrant case #
  
- Species dog, cat, other (specify)
- Breed (as reported by pet owner)
- Age months or years
- Sex M, F, or neutered
- Weight pounds
  
- Primary Route of Exposure dermal, oral, other animal, inhalation, other
- Body System neurological, dermatological, GI, respiratory, ocular, other
- Major signs noted with separate column for each sign, using standard terminology
- Time to Onset (hours, days)
- Treated by veterinarian yes or no
- First time product used yes or no
- Misuse use on incorrect species, overdose, too frequent dosing, other (describe)
- Any known precondition
- EPA Severity Code death, major, moderate, minor
- Outcome died, recovered, still treated, unknown

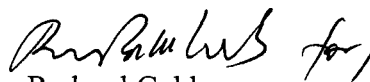
- 4 Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details

- All incidents should be reported including all minor dermal and ocular irritation reports
- Summary table for dogs showing number of incidents of each severity code for each route of exposure Each incident should only be reported once If one incident has several routes of exposure, the order should be ocular > oral > dermal In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e g , multi-pet households)
- A summary table for dogs showing number of incidents for each severity code for these age ranges <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label
- A summary table for dog weight showing number of incidents for each product weight range This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range
- Table showing number of incidents for each dog breed
- Table showing number of incidents in dogs for each clinical sign
- Table showing number of incidents in dogs for each organ system

Report aggregate incidents, but do not combine moderate and minor incidents

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec 6(e) Your release for shipment of the product constitutes acceptance of these conditions If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at Benmhend.driss@epa.gov

Sincerely,



Richard Gebken  
 Product Manager 10,  
 Insecticide Branch  
 Registration Division (7505P)

**Enclosure Label Stamped "with Comments"**

[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]

[CARTON – 3 x 0 017 FL OZ PACKAGE]

**C712 0 FOR CATS  
8 WEEKS AND OLDER**

[Alternate Brand Name

SpringLine (for cats & kittens – use only on cats and kittens 8 weeks or older)

[FOR CATS & KITTENS – use only on cats and kittens 8 weeks or older]

Illustration/Picture of Cat

Optional Marketing Claims [Fleas Ticks Chewing Lice]

[Fleas Ticks Chewing Lice]

- [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 fleas which may cause flea allergy dermatitis]
- [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)]
- [Rapidly eliminates infestations with chewing lice]
- [Can be used on breeding pregnant and lactating queens]
- [Waterproof (water resistant)]
- [Kills fleas that may cause flea allergy dermatitis and flea bite dermatitis]
- [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]
- [Easy fast effective control of fleas ticks and lice]
- [Kills fleas (ticks) (lice)]
- [Kills fleas that may cause anemia]
- [Optional graphics Picture of Flea]
- [Optional graphics Picture of tick]
- [Optional graphics Picture of chewing lice]
- [Contains the proven effective topical fipronil]
- [Contains the proven effective topical fipronil found in Frontline\*]
- [Convenient to use]
- [Long lasting]
- [Fast acting]

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- [Eliminates infestations with chewing lice]
- [Controls and prevents re-infestation]
- [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 adult fleas and ticks for one month
- 3 Doses Inside
- Contains (Fipronil) the active ingredient used in Frontline Top Spot® for Cats
- [C712 0 FOR CATS is not manufactured by or distributed by Merial Frontline is a registered trademark of Merial]
- [(Especially) (specifically) (expressly) formulated for cats and kittens (only) (8 weeks and older)]
- [C712 0 FOR CATS is not manufactured by or distributed by Merial Limited ]
- [Frontline Top Spot® is a registered trademark of Merial Limited ]
- [Contains Fipronil (the active ingredient used in Frontline Top Spot® for Cats)]
- [Compare to Frontline Top Spot® for Cats]

EPA Reg No 88052-O  
 EPA Est 74720-DEU-01

**ACTIVE INGREDIENT**

Fipronil	9.7%
<b>OTHER INGREDIENTS</b>	<u>90.3%</u>
<b>TOTAL</b>	100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

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

**NET CONTENTS**

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**

C712 0 FOR CATS contains the active ingredient fipronil that effectively targets 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 pet 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 rabbits or on other animals

[Precaucion al consumidor si usted no puede leer ingles 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) as follows

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

To apply C712 0 FOR CATS Place (applicator) (pipette) tip through animal s hair to the skin level between the shoulder blades Squeeze (applicator) (pipette) applying entire contents in a single spot to the animal s skin Avoid superficial application to the animal s hair Allow area to dry before touching treated area Only one (applicator) (pipette) per treatment is needed

*[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 completely 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 ticks for at least one month A once monthly application is recommended where tick 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  
1201 Walnut Street Suite 2900  
Kansas City Missouri 64106

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**

EPA Reg No 88052-O

[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 targets 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 rabbits or on other animals.

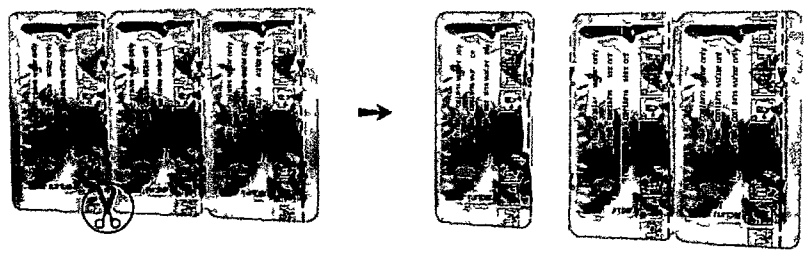
Precaucion al consumidor: si usted no puede leer ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the user: If you cannot speak English, do not use this product until the label has been fully explained to you.)

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) as follows:

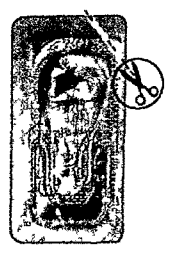
**To remove and open (applicator) (pipette)**

**[ILLUSTRATIONS FOR OPENING PRODUCT]**

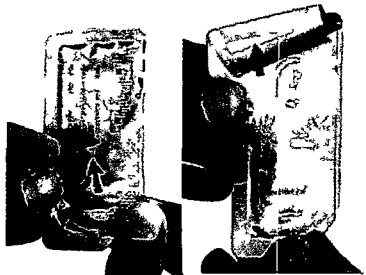
**1** Cut along scissor cut line to separate unit



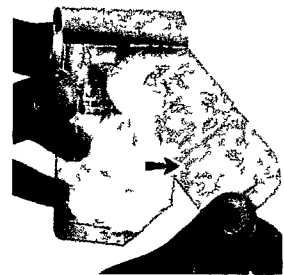
**2** Turn unit over and cut corner at bulb end



**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 completely 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 ticks for at least one month. A once monthly application is recommended where tick 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.



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[LABEL DIRECTIONS FOR PACKAGE INSERT –  
3 x 0.017 FL OZ PACKAGE]

**C712 0 FOR CATS  
8 WEEKS AND OLDER**

**FIRST AID**

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

**IF ON SKIN AND 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.

**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 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 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** Causes moderate eye irritation. Harmful if swallowed. 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. Individual sensitivities while rare, may occur after using any pesticide product. Pets 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 pet 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 animals. 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]

[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** If empty Nonrefillable container Do not reuse this container 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  
1201 Walnut Street Suite 2900  
Kansas City Missouri 64106

[MADE IN GERMANY]

C712 0 FOR CATS/ 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**

**Only for Cats & Kittens 8 weeks or older**

**C712 0 for Cats**

**Fipronil 9.7%**

**EPA Reg No 88052-O**

**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**

**C712 0 for Cats**

**Fipronil 9.7%**

**EPA Reg No 88052-O**

**Lot No**

**0 017 fl oz**