

JUL 05 2006

Nancy Huebl  
Regulatory Specialist  
Wellmark International  
1501 East Woodfield Road  
Suite 200 West  
Schaumburg, Illinois 60173

**Subject:** *Product Name: RF 9804 Topical  
EPA Reg. No: 2724-488 (EPA Submission # 785977)  
Your Application for Notification Dated October 19, 2005*

Dear Ms. Huebl:

The Biopesticides and Pollution Prevention Division (BPPD) is in receipt of the above referenced application submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act as amended.

Because your application proposed changes to the Directions for Use section of the product label, it could not be processed as a notification (see PR Notice 98-10 pg. 8 N-3).

Your application was forwarded to the Biochemical Pesticides Branch's label Amendments Team for review and the actions described in your October 19, 2005 letter are acceptable as follows:

1. Alternate brand name of Zodiac Spot On Flea Control for Cats & Kittens – **Accepted**
2. Additional marketing claims related to new applicator shape - **Accepted**
3. Marketing claim restatement combining claims to include time frame and benefit of IGR killing flea eggs into one claim – **Accepted**
4. Revised trademark statement – **Accepted**
5. Revised Directions for Use in alternate packaging directions A (to add a statement related to new cat head molded applicator advising user to snap off and discard molding end). **(Accepted)**

This acceptance is contingent on Wellmark International completing the following actions:

1. Submit and/or cite all data required for registration of your product under FIFRA section 3(c) (5) when the Agency requires all registrants of similar products to submit such data.							
SYMBOL	▶	BIP					
SURNAME	▶	Cheese					
DATE	▶	6/30/06					

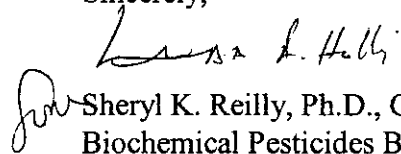
- Submit five (3) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the accepted label is enclosed for your records.

If you have questions, or need additional information about this decision, please contact: Cheryl Greene, 703 308 -0352, Email: [greenec Cheryl@epa.gov](mailto:greenec Cheryl@epa.gov).

Sincerely,



Sheryl K. Reilly, Ph.D., Chief  
 Biochemical Pesticides Branch  
 Biopesticides & Pollution Prevention Division ( 7511P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

( ) Alternate Copy

### RF 9804 TOPICAL

Alternate brand name: ZODIAC® Spot On® Flea Control for Cats & Kittens

(Special formula)(for cats)(Specially formulated for cats)  
 For use on (all) cats and kittens (older than 12 weeks of age)  
 Flea egg treatment  
 (Kills flea eggs), the source of flea infestations  
 (3)(4) month (90 or 120 day) supply, 1<sup>st</sup> dose, 2<sup>nd</sup> dose, 3<sup>rd</sup> dose, 4<sup>th</sup> dose  
 (3 or 4 months)(90 or 120 days) protection – (First month, Second month, Third month, Fourth Month, Month [1/2/3/4])  
 # convenient pre-filled applicators  
 EZ-Squeeze applicator  
 Pet Specifix™ Applicator  
 Accu-Tip Dispenser  
 Unique applicator design helps prevent misapplication  
 Longer applicator tip for easy application to long-haired cats  
 One [tube][applicator] gives 28 days (1 month)(4 weeks) protection  
 Triple pack  
 Advanced (Year-round)(Flea Treatment) Care (Preventative)  
 From ZODIAC®, the originator of IGR technology  
 Contains [With] PRECOR® (vIGRen®), the first insect growth regulator for flea control  
 Plus IGR Kills Flea Eggs  
 This product contains an Insect Growth Regulator  
 Flea control for cats with (PRECOR®)(vIGRen®) Insect Growth Regulator (IGR)  
 Advanced (topical) flea egg treatment that's easy and convenient to use  
 Kills and prevents (flea) eggs from hatching for up to (28 days)(1 month)(4 weeks)  
 Kills (flea) eggs before they hatch  
 Prevents reinfestation for up to (1 month)(28 days)(4 weeks)  
 Kills (hatching) flea eggs for up to (1 month)(28 days)(4 weeks) to prevent reinfestation  
 Interrupts normal flea development  
 Stops the flea life cycle  
 Controls(Kills)(Lasts)(Works)(Protects)(Eliminates) for up to 28 days (1 month)(4 weeks)  
 (Convenient) No mess, (easy)(simple) to (use)(handle)(apply) disposable applicator  
 Apply to one spot for head to tail (total body) flea protection (control)  
 Apply to 1 spot - spreads over the cat's complete body (from head to tail) through the natural motion of the animal  
 Spreads naturally with cat's movement (skin and hair oils)  
 (Satisfaction guaranteed)(Money back guarantee)(Guaranteed to Work)

### KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for ingredients and additional precautionary statements

EPA Reg. No. 2724-488  
Net Contents:

EPA Est. No.

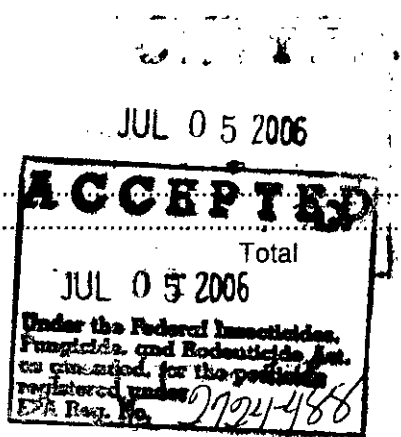
(FRONT OR BACK PANEL)

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS # 65733-16-6) ..... 3.6%

**OTHER INGREDIENTS:** ..... 96.4%

Total 100.00%



( ) = ALTERNATE COPY

**READ ENTIRE LABEL BEFORE USE.**

**USE ONLY ON CATS OR KITTENS OVER 12 WEEKS OF AGE**

(Specially formulated for cats) For use on cats only

**INTRODUCTION:**

RF 9804 (contains) is a topically applied [long-lasting] insect growth regulator (IGR)(product) specifically formulated for cats and kittens to prevent and control flea infestations (kill fleas before they hatch)(which prevents flea eggs from maturing into adults). Its active ingredient, S-Methoprene, an IGR prevents adult female fleas from laying viable eggs. A single application of RF 9804 will last for up to 28 days (1 month)(4 weeks). Each package contains enough product for (three or four)(3 or 4) monthly applications (90 or 120 days of protection). RF 9804 Topical provides relief from flea infestations for one month by controlling and preventing flea eggs on your cat and kitten. Adult fleas can live on your pet while producing vast numbers of eggs which drop off your pet and develop in the surrounding environment. Normal insecticides will not kill the flea eggs, but RF 9804 Topical (is designed to) kill(s) flea eggs, thereby breaking the flea life cycle.

After application, through its natural movement, your cat's skin and hair oils (disperse) carry RF 9804 Topical over the pet's body for protection against flea eggs. Once fleas are evident on your pet, there is already an infestation of their preadult stages in your home. To kill existing adult flea populations, you may need to treat the home, pet's bed, and yard with traditional flea products approved for use on pets, around the home, or in your yard (such as home sprays, foggers, and/or yard and kennel spray). RF 9804 Topical can be used in conjunction with the entire ZODIAC product line for cats. As with all flea products, they are (RF 9804 Topical is) most effective when used as part of a total program aimed at reducing fleas in the cat's environment. Be sure to treat the animal's bedding and surroundings with [Brand Name] flea and tick products registered for these uses, such as the ZODIAC® line.

(ZODIAC products are designed to complement each other in an integrated program for flea and tick management. To assure proper treatment, we recommend use of only ZODIAC products. For complete efficacy, treat all pets in the household.

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product contains (three or four)(3 or 4) monthly doses (one monthly dose), each (1 cc).

**DO NOT USE ON OTHER ANIMALS.** Remove one applicator tube from package. Holding the applicator tube in an upright position, simply press cap down to break the seal of tube. (Hold bottom of tube with one hand. With other hand, snap cap off.) Remove cap carefully. Position the tip of the tube on the cat's back between the shoulder blades and squeeze out the (entire) contents of the tube onto the cat's skin. Repeat every month.

**ALTERNATE PACKAGING DIRECTIONS (A)**

Use ONLY on cats or kittens over 12 weeks of age. [Bend at perforation and tear off 1<sup>st</sup> month's applicator.] Hold applicator and bend numbered area of plastic at perforation, tear off and discard. Hold [applicator] upright and snap tip back, away from face and body. Prior to application of the product, gently lift the cat's (kitten's) haircoat on the back of the neck at the base of the skull, position the tip of the [applicator] tube on the cat's exposed skin and squeeze out the (entire) contents of the [applicator] tube onto the cat's skin. Because of the bitter taste of the product, some cats may salivate if they are able to lick the product when grooming right after application. This effect is temporary and is not harmful. Repeat application once monthly.

**ALTERNATE PACKAGING DIRECTIONS (B)**

Use ONLY on cats or kittens over 12 weeks of age. Remove one applicator tube from package and hold in an upright position. Simply twist (press) cap (down) to break the seal of tube. (Hold bottom of tube with one hand. With other hand, snap cap off.) Remove cap carefully. Prior to application of the product, gently lift the cat's (kitten's) haircoat on the back of the neck at the base of the skull, position the tip of the tube on the cat's exposed skin and squeeze out the (entire) contents of the tube onto the cat's skin. Because of the bitter taste of the product, some cats may salivate if they are able to lick the product when grooming right after application. This effect is temporary and is not harmful. Repeat application once monthly.

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. **Storage:** Store in a cool, dry place. **Disposal: If Empty:** Do not reuse this container. Place in trash or offer for recycling if available. **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.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS - CAUTION:** Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling.

**HAZARDS TO DOMESTIC ANIMALS**

**CAUTION:** Do not use on kittens less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivity may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

<b>FIRST AID</b>	
Call a poison control center or doctor immediately for treatment advice.	
If in eyes	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-[phone number] for emergency medical treatment information.	

[Note: First Aid statement paragraph format may be used if space is limited.]

6/6

(If not completely satisfied, return unused portion for a full refund.)  
Guaranteed to work or your money back.

Be sure to read full directions and precautions on the label. In case of an emergency (help at any step), or for product use information, call (telephone number, time) or visit our Web Site:[URL].

Wellmark international  
Schaumburg, IL 60173  
Made in USA

ZODIAC®, Spot On®, Pet Specifix™, PRECOR® and vIGRen® Insect Growth Regulator are registered trademark(s) of Wellmark International.