

2724-488

05/31/2006

16

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-488	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF9804 Topical	PM # Biopesticides	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No Product Name	
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION
MAY 31 2006

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Revision of a marketing claim for clarity

This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged in:			2. Type of Container		
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic	<input type="checkbox"/> Glass
* Certification must be submitted	If "Yes" Unit Packaging wgt. 1 cc	No. per container 4	If "Yes" Unit Packaging wgt.	<input checked="" type="checkbox"/> Paper	<input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1-4 x 1 cc applicators	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		
			<input checked="" type="checkbox"/> Other Printed cardboard carton & printed foil applicator		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Regulatory Specialist	Telephone No (Include Area Code) (847) 330.5376

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

(Stamped)

2. Signature <i>Nancy Huebl</i>	3. Title Regulatory Specialist
4. Typed Name Nancy Huebl	5. Date 12-May-06

REGULATORY LABEL DATA SHEET

File Name: g:\regulatory\labels\
cahspec\02724488\EPA
notif spoton cats claim 506

Data Sheet Date: May 2006

Product: RF 9804 Topical

EPA Reg #: 2724-488

Approved: Notif submitted 5/06

Supercedes: 12/14/05

OVERVIEW: Per PRN 98-10, §II,N Other Revisions, revise a marketing claim for clarity. No other changes were made to label.

Page #	Description of Major Changes

() Alternate Copy

RF 9804 TOPICAL

NOTIFICATION

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

MAY 31 2006

(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, 1st dose, 2nd dose, 3rd dose, 4th 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 [on dogs]
 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) 0.33%

OTHER INGREDIENTS: 99.67%

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 1st month's applicator.] Hold applicator and bend numbered area of plastic at perforation, tear off and discard. [Hold applicator upright away from face and body and use scissors to cut secure seal applicator tip.] 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. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

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.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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 immediately for treatment advice.
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.]

(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 trademark(s) of Wellmark International.

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Wellmark

May 12, 2006

Document Processing Desk (NOTIF)
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ATTENTION: S. Reilly

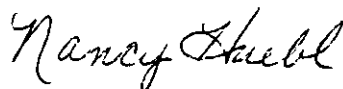
SUBJECT: NOTIFICATION OF LABEL REVISION PER PRN 98-10
RF-9804 TOPICAL/EPA REG. NO. 2724-488

Dear Ms. Reilly:

Enclosed is completed EPA Form 8570-1 and one copy of revised labeling for the above product. I have highlighted added text in red. The label revision involves revising a marketing claim for clarity. This label revision meets the criteria in PRN 98-10, § II-N (Other Revisions). A self-addressed postcard is enclosed for confirmation of notification status.

If you have any questions, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL



Nancy Huebl
Regulatory Specialist
nancy.huebl@wellmarkint.com

enclosure

cc: C. Elmi/J. Flégeau