

2724-504

01/18/2006

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg. Number:

2724-504

Date of Issuance:

01/18/06

Term of Issuance:

Conditional

Name of Pesticide Product:

RF2004 (CCSO)

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Wellmark International  
1501 East Woodfield Road, Suite 200W  
Schaumburg, ILL 60173

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 FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following labeling changes before you release the product for shipment:
  - a. Revise the EPA Registration Number to read: "EPA Registration No. 2724-504"

Signature of Approving Official:

George LaRocca  
Product Manager (RM 13)  
Insecticide Branch  
Registration Division (7505C)

Date:

January 18, 2006

- b. Change the application rate for cats 5lbs and over to *1.8 ml* throughout the labeling. This change is due to the Agency's reliance on your cited companion animal safety study.
  - c. Add the following precautions under Directions for Use:  
***"Do not apply more often than once every month. Do not bathe cat within the first 24 hours after squeeze-on has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried"***.
  - d. Delete the following statements under Alternate Packaging 2 and Hazards to Animals:  
***"Because of the bitter taste . . . temporary and is not harmful"***  
***"Grooming is likely to occur after any topical treatment of cats and is not harmful"***  
These statements are considered implied safety claims, and also conflict with comment 2c above.
  - e. Submit the labeling for the tube applicator.
  - f. Revise the labeling as indicated in the attached "***marked copy***" of the label, relative to the list of claims (e.g., specify the type of ticks as "***deer ticks***", delete "***shield***", "***complete***", change "***eliminate***" and "***rid***" to "***control***", etc.)
3. Submit the labeling for the tube applicator.
  4. Submit to the Agency, data on one year storage stability testing (830.6317), conducted concurrently with the corrosion characteristics study (830-6320) at 0, 3, 6, 9 and 12 months of warehouse storage.

Please note that for the Acute Oral Toxicity, the Agency prefers use of the protocol OECD 425 (Acute Oral Toxicity Up-and-Down Procedure) over OECD 401 (Acute Oral LD50). The latter is no longer acceptable for determining acute oral toxicity.

Submit two (2) copies of the final printed label bearing the above stated revisions prior to releasing this product for sale.

If you fail to comply with the above stated conditions, this 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.

A copy of the stamped label is enclosed for your records. If you have any questions concerning this action, please contact Dr. B. A. Akinlosotu at (703) 605-0653.

Enclosure

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

JAN 18 2006

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
2724-504

[ ] Optional Copy

RF2004 (CCSO)

(General/Protection claims)

1 ml for cats under 5 lbs.; 2 ml for cats 5 lbs. and over  
 For use on cats [under 5 lbs.][5 lbs. and over]  
 Flea & Tick Shield [Protective Shield] for cats [& kittens]  
 Shield [flea & tick] treatment for cats [& kittens]  
 [Special formula for cats/kittens][Superior flea prevention and treatment specially formulated for use on  
 [all] cats and kittens [12 weeks of age and older]  
 Spot On [Topical][Non-systemic] treatment for pets [cats]  
 Flea, Tick, and Mosquito Treatment [Control][Prevention][Relief] for Cats & Kittens  
 Total [Complete] Care  
 4 in 1 Control [Protection][Treatment] (Fleas, Flea Eggs, Ticks, and Mosquitoes)  
 [1 month][monthly][flea, ~~deer~~ tick, & flea egg], protection  
 Monthly treatment [shield] for [fleas, flea eggs, & ~~deer~~ ticks, ]  
 Flea [and tick][and mosquito] control for your pet  
 A smart approach to flea control  
 New and improved flea, tick, and mosquito control  
 Keeps flea, ticks, and mosquitoes under control  
 [Advanced] Spot On [Plus] Insect Control [Treatment and Prevention]  
 A complete flea control program  
 Controls and eliminates flea, tick, and mosquito problems  
 Pet-assured [secure] flea, tick, and mosquito protection  
 Provide your pet with [complete] flea, tick, and mosquito protection, right from the start  
 Provides complete protection  
 Direct on-animal protection from fleas, ticks, and mosquitoes  
 Provides relief [protection] from fleas, ticks, and mosquitoes  
 Once-a-month [topical][Spot On] protection from fleas, ~~and deer~~ ticks, ,  
 Long lasting, complete flea, tick, and mosquito protection

Deleted: mosquito  
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Deleted: and West Nile virus

Deleted: Flea prevention contributes to [good] pet [cat][animal] health [well-being][comfort]!

Deleted: (that may transmit West Nile virus)

Deleted: Kills mosquitoes that may carry West Nile virus and cause heartworm disease!

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(Kills/Repels/Controls claims)

Kills [Controls] [adult] fleas, ~~deer~~ ticks, and flea eggs for [up to][4 weeks][1 month][per application]  
 Kills [and/or Repels] mosquitoes [for up to 18 days]  
 Controls fleas, ticks, and mosquitoes & prevents flea reinfestations [in your home]  
 Kills deer ticks (for up to 1 month [4 weeks]) [per application]  
 Kills ticks

(Disease claims)

Protects your pet [cat][kitten] from fleas, ticks, and mosquitoes (which may transmit heartworm disease )  
 Helps protect [your] pet from disease  
 Flea, tick, and mosquito bites are annoying, and can sometimes carry disease that may cause [illness] sickness and death  
 Effective on fleas, ticks, and mosquitoes that may transmit disease  
 Effectively eliminates fleas, ticks, and mosquitoes  
 Kills [Controls] ~~deer~~ ticks that may transmit [cause][Lyme disease][and Cytauxzoonosis] for up to [1 month][4 weeks]  
 Protect your [cat] pet from [against] ticks that may transmit Lyme disease and Rocky Mountain Spotted Fever  
 Kills [and repels] mosquitoes that may transmit heartworm disease  
 Prevents mosquitoes, from feeding on cats  
 Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation

Preventative treatment for fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation  
Protects your pet [cat] from potential disease and discomfort  
Protect your pet and your family from insect pests [fleas, ticks, mosquitoes] that may transmit dangerous disease  
Control highly irritating (and potentially dangerous) flea, tick, and mosquito [insect] bites

(More general claims)

Keeps fleas, ticks, and mosquitoes away [from your cat]  
Keeps bugs away [at bay][from your cat]  
When it comes to fleas and ticks, there's no room for compromise  
[Zodiac] protecting pets for over 35 years

Deleted: Make life more comfortable for your pet (and your family)!

Deleted: Flea-proof your pet!  
Ensure your pet remains flea-free!

(Flea egg/life cycle claims)

Kills [Controls] flea eggs for up to [30 days][1 month][4 weeks][per application]  
Kills flea eggs, the source of home flea infestations and pet re-infestations, for up to [30 days][1 month][4 weeks]  
Advanced [topical][flea egg treatment] that's easy and convenient to use  
[Kills][Prevents][Keeps] flea eggs from hatching for up to [30 days][1 month][4 weeks]  
Prevents flea eggs from developing into biting adults for up to [30 days][1 month][4 weeks][per application]  
An effective flea topical [A Spot On] product that kills adult fleas and halts the development of flea eggs [immature stages in the flea life cycle]  
Kills [flea] eggs before they hatch into biting adults  
Prevents re-infestation for up to [1 month][30 days][4 weeks]  
Kills hatching [developing] flea eggs  
Interrupts normal flea development [Stops the flea life cycle]  
Interrupts the flea life cycle  
Breaks the flea life cycle for up to [1 month][4 weeks][30 days]  
Controls[Kills][Lasts][Works][Protects][Eliminates] flea infestations for up to [1 month][4 weeks]  
One-two punch gets rid of fleas and flea eggs  
Rids your pet of existing fleas and flea eggs, plus [and][prevents] future flea infestations

(Application claims)

[#] pack [# days'] [#] doses [1/2/3/4/5/6] months supply  
One tube gives [1 month][4 weeks] of protection  
[Pre-measured][Convenient][No mess][easy][simple] to [use][handle][apply] disposable applicator [tube]  
Convenient [and effective], once-a-month [liquid][topical][Spot On] solution  
Practical solution  
Simple choice [powerful][flea & tick control]  
A [One] simple application provides your pet with complete protection for up to [1 month]  
Apply to one spot for head to tail (total body) flea protection [control]  
Apply to 1 spot - spreads over the cat's [entire][complete] body [from head to tail] through natural skin oils  
Spreads naturally with cat's skin oils  
[Plus] Contains a natural coat conditioner  
[Once][One] Monthly Application  
Easy to use [once] monthly application [liquid] prevents [and controls] fleas [& deer ticks, ]  
Reapply [Repeat] [once] monthly  
Repeat [treatment] every month  
Monthly Control [Relief][treatment]

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(Applicator claims)

Unique Applicator {tube} Shape {Design}[helps prevents misuse on dogs][helps prevents misapplication on dogs]  
 Unique shape {for cats & kittens 5 lbs and over}[for cats & kittens under 5 lbs]  
 Pet Specific@ Applicator  
 Accu-Tip Dispenser  
 Easy to apply {identify}[use] applicator {tube}  
 Cat head shape {applicator}[tube] for cats {cat head = cats}  
 The right choice {applicator}[tube] for the right pet  
 Make {Select} the right choice {applicator}[tube][shape]  
 Choice {selection} is simple  
 Easy choice  
 Simple choice delivery system  
 Easy to use applicator {tube} {provides direct on-animal protection}  
 Longer Applicator {tube}[tip] for easy application {to long-haired cats}  
 Longer tube {applicator}[tip] is ideal for long-haired pets {cats}  
 Helps Prevent {misapplication on dogs} misuse on dogs with unique {specially designed} applicator {tube} design  
 Cat head shape prevents misuse {misapplication}[on dogs]  
 Unique tube {applicator} design {pet shape} helps prevent misuse/misapplication {on dogs}  
 EZ-squeeze {Easy squeeze} tube {applicator}[shape]

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(Product Claims)

Odorless  
 Cat friendly {Active Ingredient/Formula}  
 Effective Control {Relief}[Prevention]  
 Fast {Quick} acting {Relief}  
 Quick acting, long lasting {treatment}  
 Long lasting and easy to use {apply}  
 {Flea prevention} Helps stop itching and scratching {from flea bites}

(IGR claims)

From ZODIAC®, the originator of Insect Growth Regulator [IGR] technology  
 {Plus}[Contains][With] PRECOR® [vIGRen®], the first insect growth regulator for flea control  
 Contains {Features} an Insect Growth Regulator (IGR) to stop the development of flea eggs  
 Flea control for cats with {PRECOR®}[vIGRen®] Insect Growth Regulator (IGR)  
 {(S)-Methoprene} Insect Growth Regulator (IGR) interrupts the development of the flea life cycle at the egg stage  
 {(S)-Methoprene} Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas  
 {inhibits the development of flea eggs into adult fleas}  
 Controlling flea reproduction is the first step in controlling flea populations on your pet and in your home  
 {(S)-Methoprene} Insect Growth Regulator (IGR) prevents flea reinfestation on your pet and in your home  
 Flea treatment and preventative with an {insecticide} adulticide and Insect Growth Regulator (IGR)

(Zodiac claims)

We {Zodiac} put(s) your pet(s) first  
 Zodiac...putting (your pet) pets first  
 Right choice = best defense  
 Perfect choice  
 Zodiac - caring & committed  
 Zodiac makes the choice simple  
 {Satisfaction guaranteed}[Money-back guarantee]

Deleted: Promote good pet health with Zodiac pet products!

(Formula claims)

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Worry-free [Carefree][trouble-free] formula  
Etofenprox [a new active ingredient] provides a novel [smart] approach to flea, tick, and mosquito control  
New Active Ingredient (AI)  
Advanced Formula [for cats & kittens]  
Features [Contains] an [insecticide] adulticide to kill [and/or][control] adult fleas [ticks, and mosquitoes]

(Prevention claims)

Preventing fleas and ticks from infesting your pet is much easier than treating an existing problem  
Flea prevention has never been easier  
Prevent the possibility of serious health problems by preventing/controlling fleas up front (so they never become a problem)  
An excellent preventative, offering complete protection against fleas  
Prevents flea, tick, and mosquito infestations  
Prevents flea recurrence  
Control flea infestations by preventing them  
Flea prevention is the best flea control strategy  
Quick and sure flea, tick, and mosquito prevention  
A quick and sure way to avert a flea problem is to [prevent it] use a preventative  
It is far easier to prevent fleas than to get rid of them  
Total flea control involves [requires] preventative measures [for your pet][and][for your home]  
[New][Year-round][Flea Treatment][Preventative]  
Use a flea preventative year-round (to prevent painful bites, itching and scratching, discomfort, and potential illness/disease/secondary infection)  
Fleas are annoying and uncomfortable, but they can also endanger your pet's health by spreading disease

(FRONT OR BACK PANEL)

**ACTIVE INGREDIENTS:**

(S)-Methoprene (CAS # 65733-16-6) .....	3.6%
Etofenprox (CAS # 80844-07-1) .....	40.0%
<b>OTHER INGREDIENTS:</b> .....	<b>56.4%</b>
<b>Total</b>	<b>100.0%</b>

**KEEP OUT OF REACH OF CHILDREN**

See back panel for ingredients and additional Precautionary Statements

EPA Reg. No. 2724-504  
EPA Est. No.

Net Contents:

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**READ ENTIRE LABEL BEFORE USE  
USE ONLY ON CATS OR KITTENS 12 WEEKS OF AGE AND OLDER**

[Specially formulated for cats][For use on cats only][Do not use on other animals]

**INTRODUCTION:**

RF2004CCSO is a topically applied [long-lasting] product specifically formulated for cats and kittens with [containing] an insect growth regulator (IGR) [to prevent and control flea infestations][to kill fleas before they hatch][which prevents flea eggs from maturing into biting adults]. It also contains the highly effective flea, tick, and mosquito killing agent [Etofenprox][Brand Name], which kills biting adult fleas, ticks, and mosquitoes your cat may acquire from its surroundings. A single application of RF2004 (CCSO) will provide egg hatch inhibition for up to 30 days [1 month][4 weeks]. Each package contains enough product for xx monthly applications (xx days of protection [control]). RF2004 (CCSO) provides relief from flea infestations for up to 1 month [4 weeks] by killing adult fleas on your cat or kitten and flea eggs in your home. 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 RF2004 (CCSO) [is designed to] kill(s) adult fleas and flea eggs, breaking the flea life cycle and providing your cat relief from flea bites at the same time.

Deleted: for up to 4 weeks [1 month]

After application, your cat's natural skin oils [disperse] carry RF2004 (CCSO) over your cat's body for protection against biting adult fleas and the development of flea eggs. Once adult fleas are evident on your cat, there is likely an infestation of flea eggs and flea larvae in your home. To completely kill the existing flea population, you may need to treat your home and your pet's bedding (home sprays, foggers), as well as your yard (yard spray/outdoor fogger) with traditional flea products approved for use on pets, around the home, or in your yard. RF2004 (CCSO) can be used in conjunction with all other [Brand Name] premise products. As with all flea products, they are [RF2004 (CCSO) is] most effective when used as part of a total program aimed at reducing all stages of fleas in the cat's environment. [Brand Name] products are designed to complement each other in an integrated program for flea, tick, and mosquito management. To assure proper treatment, we recommend use of [Brand Name] products as directed to treat all pets in the household, as well as the indoor and outdoor home environments.

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

This product contains xx monthly dosages [one monthly dose], each (xx and xx ml [cc]).

**USE ONLY ON CATS AND KITTENS 12 WEEKS OF AGE AND OLDER.**  
Do not get this product in your cat's eyes or mouth.

- 1 ml [cc] dose for use on cats and kittens under 5 lbs.
- 2 ml [cc] dose for use on cats and kittens 5 lbs. and over (Same size applicators with different fill amounts)

[Bend at perforation and tear off 1<sup>st</sup> month's applicator.] Hold [applicator] upright and snap tip back, away from face and body. Prior to application of the product, gently lift the cat's or kitten's hair coat 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.

tear at perforation and tear off 12 month's applicator. Hold applicator upright 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. Prior to application of the product, gently lift the cat's or kitten's hair coat 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 2**

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Hold bottom of tube with one hand. With other hand, snap cap off. Prior to application of the product, gently lift the cat's or kitten's hair coat 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.

**STORAGE AND DISPOSAL:** Storage: Store in a cool, dry place. Do not store unused applicators [tubes] separately from their packaging. Container Disposal: If empty: Do not reuse empty applicator [tube]. 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 AND DOMESTIC ANIMALS**

**HAZARDS TO HUMANS:** Repeated exposure to etofenprox can cause skin irritation.  
**HAZARDS TO ANIMALS:** For External Use on Cats Only. Do not use on kittens less than 12 weeks old. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Grooming is likely to occur after any topical treatment of cats and is not harmful. Sensitivities 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.

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

In case of an emergency or for product use information, call [phone number] or visit our Web site: [URL]

Wellmark International  
Schaumburg, IL 60173  
Made in USA

PRECOR® Insect Growth Regulator, vIGRen® Insect Growth Regulator, and ZODIAC® are registered trademarks of Wellmark International.

Adding a Dose Reminder section to appear as follows on the back panel:  
First Monthly Application: Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_  
Second Monthly Application: Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_  
Third Monthly Application: Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_  
[Fourth Monthly Application: Month \_\_\_\_\_ Day \_\_\_\_\_ Year \_\_\_\_\_]

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