

2724-504

12/8/2011

1 of 9



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Dr. James McFadden  
Senior Regulatory Project Manager  
Wellmark International  
1501 East Woodfield Road, Suite 200 West  
Schaumburg, IL 60173

DEC - 8 2011

Subject: Label Amendment (R340)  
RF2004 (CCSO)  
EPA Reg. No. 2724-504  
Submission dated August 4, 2011

Dear Dr. McFadden,

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable provided you:

1. Remove "Kills more than 80% of fleas in 4 hours" from the label

A stamped copy of the label and a DER are enclosed for your record. If you have any questions, please call Kevin Sweeney at (703) 305-5063.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

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

Enclosure

[ ] Optional Copy

### RF2004 (CCSO)

Alternate brand names: ZODIAC® Spot On® Plus Flea & Tick Control for Cats 5 lbs. and Over  
ZODIAC® Spot On® Plus Flea & Tick Control for Cats & Kittens Under 5 lbs.  
ZODIAC® Multi-Cat Spot On® Plus Flea & Tick Control for Cats 5 lbs. and Over

(General/Protection claims)

1 ml [cc] for cats [kittens] under 5 lbs.; 1.8 ml [cc] for cats 5 lbs. and over  
 For use on cats [under 5 lbs.][5 lbs. and over] For cats weighing [5 lbs and over][< 5 lbs][Under 5 lbs]  
 Flea & Deer Tick [Protective] for cats [& kittens]  
 [Flea & deer 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, Deer Tick, and Mosquito Treatment [Control][Prevention][Relief] for Cats & Kittens  
 4 in 1 Control [Protection][Treatment] (Fleas, Flea Eggs, Deer Ticks, and Mosquitoes)  
 [1 month][monthly][flea, deer tick, & flea egg][ protection  
 Monthly treatment for [fleas, flea eggs, & deer ticks]  
 Flea [and deer tick][and mosquito] control for your pet  
 A smart approach to flea control  
 Improved flea, deer tick, and mosquito control  
 Keeps fleas, deer ticks, and mosquitoes under control  
 [Advanced] Spot On [Plus] Insect Control [Treatment and Prevention]  
 A flea control program  
 Controls flea, deer tick, and mosquito problems  
 Pet-assured [secure] flea, deer tick, and mosquito protection  
 Provide your pet with flea, deer tick, and mosquito protection, right from the start  
 Provides protection  
 Direct on-animal protection from fleas, deer ticks, and mosquitoes  
 Provides relief [protection] from fleas, deer ticks, and mosquitoes  
 Once-a-month [topical][Spot On] protection from fleas, and deer ticks,  
 Long lasting, flea, deer tick, and mosquito protection

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
**DEC - 8 2011**  
 Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act,  
 as amended, for the pesticide  
 registered under EPA Reg. No.  
2724-504

(Kills/Repels/Controls claims)

[Actively] Kills [Controls] [adult] fleas, deer ticks, [larvae], and flea eggs for [up to][4 weeks][1 month][per  
 application]  
 [Actively] Kills [fleas][deer ticks][flea eggs][larvae][&][and][mosquitoes][by contact]Kills [and/or Repels]  
 mosquitoes [for up to 18 days][by contact]  
 Controls fleas, deer ticks, and mosquitoes & prevents flea reinfestations [in your home]  
 [Kills deer ticks] (for up to 1 month [4 weeks]) [per application]  
 Starts killing fleas in 15 minutes  
 Kills more than 80% of fleas in 4 hours

Protects your pet [cat][kitten] from fleas, deer ticks, and mosquitoes (which may transmit heartworm  
disease )

Effectively controls fleas, deer ticks, and mosquitoes  
 Kills [Controls] deer ticks that may transmit [][Lyme disease][and Cytosoonosis] for up to [1 month][4  
 weeks]  
 Protect your [cat] pet from [against] deer ticks that may transmit Lyme disease  
 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  
 Control highly irritating flea, deer tick, and mosquito [insect] bites

(More general claims)

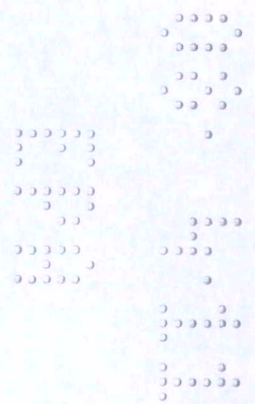
When it comes to fleas and deer ticks, there's no room for compromise  
[Zodiac] protecting pets for over 35 years

(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] flea infestations for up to [1 month][4 weeks]  
One-two punch controls fleas and flea eggs  
Controls existing fleas and flea eggs, plus [and][prevents] future flea infestations  
Plus kills flea eggs and larvae to prevent future 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][and][&][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 [flea & deer tick control]  
A [One] simple application provides your pet with 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] 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]



(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 Specifix® Applicator Accu-Tip Dispenser

[New][X] Pro-cision Flo™ Applicators [tubes]

[New][Exclusive][Pinpoint][Applicator] for [pinpoint][exact][direct][easy][direct to skin] application

Patent pending

For pinpoint accuracy

Direct to your cat's skin

Easily penetrates hair

The [Pro-cision Flo™][exclusive][new] applicator [tube][easily penetrates hair][fur][coat] for [improved][direct] application [directly to your cat's skin]

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]

(Product Claims)

Odorless

Clean fresh scent

Effective Control [Relief][Prevention]

Fast [Quick] acting [Relief]

Starts working by contact

Dual-action for immediate and long-lasting effects

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 inhibit 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<sup>9</sup> [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]

(Formula claims)  
 Etofenprox provides a novel [smart] approach to flea, deer tick, and mosquito control  
 Advanced Formula [for cats & kittens]  
 Features [Contains] an [insecticide] adulticide to kill [and/or][control] adult fleas [deer ticks, and mosquitoes]

(Prevention claims)  
 Preventing fleas and deer ticks from infesting your pet is much easier than treating an existing problem  
 Flea prevention has never been easier  
 An excellent preventative, offering protection against fleas  
 Prevents flea, deer 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, deer 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 control them  
 Flea control involves [requires] preventative measures [for your pet][and][for your home]  
 [[Year-round][Flea Treatment][Preventative]  
 Use a flea preventative year-round (to prevent painful bites, itching and scratching, discomfort)

(FRONT OR BACK PANEL)

**ACTIVE INGREDIENTS:**

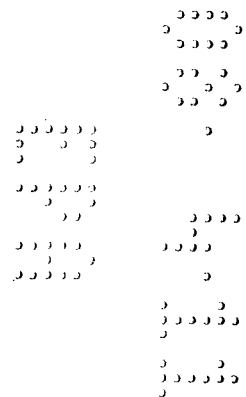
(S)-Methoprene (CAS # 65733-16-6)	3.6%
Etofenprox (CAS # 80844-07-1)	40.0%
<b>OTHER INGREDIENTS:</b>	<b>56.4%</b>
Total	100.0%

**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:



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

[Specially formulated for cats [& kittens]][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] [it also contains] an insect growth regulator (IGR)[S-Methoprene][to prevent and control flea infestations][to kill fleas before they hatch][which prevents flea eggs from maturing into biting adults]. It [This product] also contains the highly effective flea, deer tick, and mosquito killing agent [Etofenprox][Brand Name], which kills biting adult fleas, deer 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.

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. [(product) may stain leather and suede fabrics for (24)(24 to 48) hours after application.] 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 other ZODIAC [HARTZ®] 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. ZODIAC [HARTZ] products [They] are designed to complement each other in an integrated program for flea, deer tick, and mosquito management. To assure proper treatment, we recommend use of ZODIAC [HARTZ] products as directed to treat all pets in the household, as well as the indoor and outdoor home environments.]

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

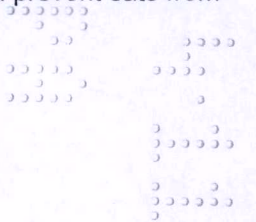
This product contains xx monthly dosages [one monthly dose], each (1 and 1.8 ml [cc]). Do not apply more than once every month.

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

**[APPLICATION METHOD]**

[Bend at perforation and tear off 1<sup>st</sup> month's applicator.] Hold [applicator] upright [and bend 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 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. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.



ALTERNATE PACKAGING DIRECTIONS 1 (CAT-HEAD APPLICATOR)

[Bend at perforation and tear off 1<sup>st</sup> 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. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 2

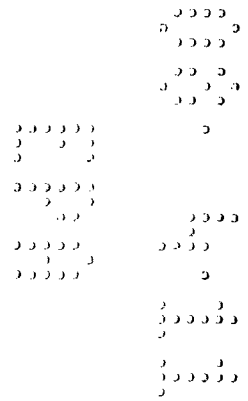
Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Hold bottom of tube with one hand. With other hand, snap cap off. Prior to application of the product, gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, 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. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 3 (for new subregistrant ampoule openings)

1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
2. Twist dispensing tip clockwise about 1/2 turn while pushing down to break the applicator's [tube's] seal. Do not remove the dispensing tip.
3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing 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. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
4. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 4 (for new subregistrant ampoule openings)

1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
2. Twist dispensing tip clockwise about 1/2 turn until you feel it click into place. Do not remove the dispensing tip.
3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing 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. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
4. Repeat application once monthly.



ALTERNATE PACKAGING DIRECTIONS 5 (for new subregistrant ampoule openings)

1. Remove one applicator [tube] from the package and hold in an upright position pointed away from your face.
2. Squeeze the middle of the dispensing tip at the grooved pad to break the inner seal. Do not remove the dispensing tip.
3. Prior to application of the product, using the dispensing tip of the applicator [tube], gently lift the cat's or kitten's hair coat on the back of the neck at the base of the skull, position the dispensing 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. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
4. Repeat application once monthly.

ALTERNATE PACKAGING DIRECTIONS 6

1. Remove one applicator tube from the package and hold in an upright position pointed away from your face.
2. Pull off cap. Turn the cap around and place on top of tube.
3. Simply press cap down to break the seal of tube. Remove cap carefully.
4. 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 tube on the cat's exposed skin and squeeze out the entire contents of the tube onto the cat's skin. Do not bathe cat within the first 24 hours after Spot On [squeeze on] has been applied. Households with more than one cat should prevent cats from grooming each other until solution has dried.
5. Repeat application [once every month][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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

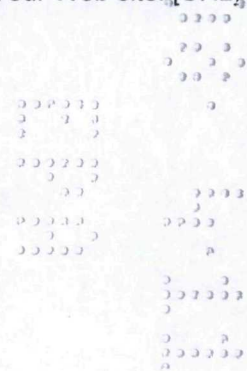
**HAZARDS TO HUMANS:** Repeated exposure to etofenprox can cause skin irritation.

**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. 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  
 1501 East Woodfield Road 200W  
 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 \_\_\_\_\_]

Optional marketing text for subregistrant

[TREATMENT SCHEDULE

Dosage: 1 applicator every 30 days per cat

Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 <sup>st</sup> )	Third Treatment Date (30 Days From 2 <sup>nd</sup> )

NOTES: \_\_\_\_\_

REMINDER: I purchased [Brand Name] \_\_\_\_\_ from \_\_\_\_\_ ]

[All text below represents one label statement with any selected line]

[Protect your family and pet from:]

[When your cat has fleas and ticks, your family and pet may be exposed to:]

- Fleas that may cause:
- Flea allergy dermatitis
- Flea bite anemia
- Tapeworm infestation

- Deer ticks which may carry:
- Lyme disease

To learn more about treating current infestations and preventing future outbreaks, please, visit our website: [URL]

[For more information, call our experts at 1-800-275-1414 (weekdays, 9am – 5 pm EST)]

To learn more, visit [URL]

