


2724-834

04/18/2013

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	<p align="center">U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	<p>EPA Registration No. 2724-834</p>	<p>Date of Issuance: APR 18 2013</p>
<p align="center">NOTICE OF PESTICIDE:</p> <p align="center"> <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration </p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>		<p>Term of Issuance: Conditional Registration Expires April 18, 2015</p> <p>Name of Pesticide Product: RF2185 CSO XM</p>	
<p>Name and Address of Registrant (include ZIP Code): Wellmark International 1501 E. Woodfield Road Suite 200 West Schaumburg, IL 60173</p>			
<p>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.</p>			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>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.</p> <p>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(a) provided that:</p> <ol style="list-style-type: none"> 1. This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing. 2. The basic Confidential Statement of Formula (CSF) dated September 27, 2012 is the CSF of record and supersedes all previously accepted CSFs. 3. Make the following changes to the label: <ol style="list-style-type: none"> a. Revise the EPA Registration Number to read: "EPA Registration No. 2724-834". b. Remove all "long term control" and "long lasting" claims from the label. This product lacks an insect growth regulator. c. Remove the following claims: "[Advanced] Spot-on [Plus] Insect Control [treatment and prevention]" – this is an adulticide product. "A flea control program" – there is no IGR in the formulation. 			

“Long lasting, flea, deer tick, and mosquito protection” – there is no IGR component.
“Flea prevention is the best flea control strategy.”

On page 3 remove all “prevention claims” There is no IGR in the formula.

- 4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2013. The quarterly reports are due two months after the quarter ends. 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: Kaitlin 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

- 5. 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 cats 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 dogs (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 cats 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 cat incidents for each severity code for each pet weight range on the product label (if applicable).
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range (if applicable).
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

6. You must 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, and submit acceptable responses required for reregistration of your product under FIFRA section 4.

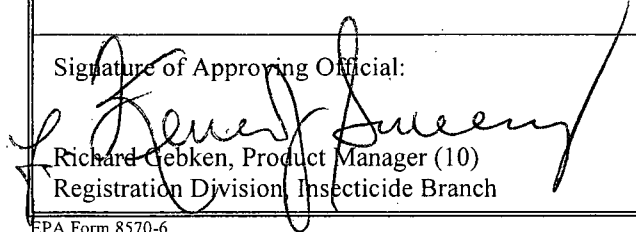
7. The acute toxicity profile for this product is as follows:

Route of Exposure	Toxicity Category
Acute oral toxicity	IV
Acute dermal toxicity	IV
Acute inhalation toxicity	IV - Waived
Primary eye irritation	IV
Primary skin irritation	IV
Dermal sensitization	Non-sensitizer

A stamped copy of the label and copies of the Data Evaluation Records (DERs) are included for your file. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. 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 pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action. If you have any questions concerning this registration, please contact Kevin Sweeney at (703) 305-5063.

Signature of Approving Official:



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

Date:

APR 18 2013

Enclosure

[] Optional Copy

RF2185 CSO XM

Alternate brand names: []

Include "Cat" in product brand name and font size must be 75% of the size of the largest letter in the brand name

[For] use only on cats/kittens [over 2.5 lbs but under 5 lbs.][and weighing][5 lbs. and over] & 12 weeks of age or older

Only For use on cats/kittens weighing [5 lbs and over][> 2.5 lbs but < 5 lbs][over 2.5 lbs but Under 5 lbs] & 12 weeks of age or older

(General/Protection claims)

1 ml [cc] for cats [kittens] over 2.5 lbs but under 5 lbs.; 1.8 ml [cc] for cats 5 lbs. and over

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 cats and kittens [12 weeks of age and older]

Spot On [Topical][Non-systemic] treatment for [cats/kittens]

Flea, Deer Tick, and Mosquito Treatment [Control][Prevention][Relief] for Cats & Kittens

3 in 1 [Protection][Treatment] (Fleas, Deer Ticks, and Mosquitoes)

[1 month][monthly][flea & deer tick,][protection

Monthly treatment for [fleas mosquitoes & deer ticks]

Flea [and deer tick][and mosquito] control for your cat

A smart approach to flea 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

[secure] flea, deer tick, and mosquito protection

Provide your cat with flea, deer tick, and mosquito protection, right from the start

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

(Kills/Repels/Controls claims)

[Actively] Kills [Controls] [adult] fleas, deer ticks, and mosquitoes for [up to][4 weeks][1 month][per application]

[Actively] Kills [fleas][deer ticks][&][and][mosquitoes][by contact] Kills [and/or Repels] mosquitoes [for up to 18 days][by contact]

Controls fleas, deer ticks, and mosquitoes & [in your home]

[Kills deer ticks] (for up to 1 month [4 weeks]) [per application]

Starts killing fleas in 15 minutes

Protects your [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 Cyttauzoonosis] for up to [1 month][4 weeks]

Protect your [cat] 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

[Brand] protecting pets for over 35 years

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

APR 18 2013
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

2724-834

(Application claims)

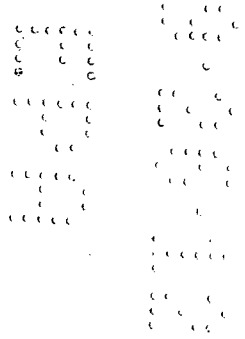
[#] pack [# days'] [#] doses [1/2/3/4/5/6] months supply
 One tube gives [1 month][4 weeks] of protection
 [Pre-measured][Convenient][and][&][No mess][easy][simple] to [use][handle][apply] disposable applicator [tube]
 Convenient [and effective], once-a-month [liquid][topical][Spot On] solution
 Practical solution
 Simple choice [flea & deer tick control]
 A [One] simple application provides your cat 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 [only for cats & kittens 5 lbs and over][only for cats & kittens over 2.5 lbs but under 5 lbs]
 Pet Specific® Applicator Accu-Tip Dispenser
 [New][X] Pro-cision Flo™ Applicators [tubes]
 [New][Exclusive][Pinpoint][Applicator] for [pinpoint][exact][direct][easy][direct to skin] application
 For pinpoint accuracy
 Direct to your cat's skin
 Easily penetrates hair.
 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 [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 (cat shape) helps prevent misuse/misapplication [on dogs]
 EZ-squeeze [Easy squeeze] tube [applicator][shape]

(Product Claims)

Odorless
 Effective Control [Relief][Prevention]
 Fast [Quick] acting [Relief]
 Starts working by contact
 Quick acting [treatment]
 easy to use [apply]
 [Flea prevention] Helps stop itching and scratching [from flea bites]



(Brand claims)

We () [Brand] put(s) your pet(s) first
Brand ... putting (your pet) pets first
Right choice = best defense
Perfect choice
Brand – caring & committed
Brand 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 cat 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 cat][and][for your home]
[[Year-round][Flea Treatment][Preventative]
Use a flea preventative year-round (to prevent painful bites, itching and scratching, discomfort

(FRONT PANEL)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 40.0%

OTHER INGREDIENTS:..... 60.0%

Total 100.0%

KEEP OUT OF REACH OF CHILDREN

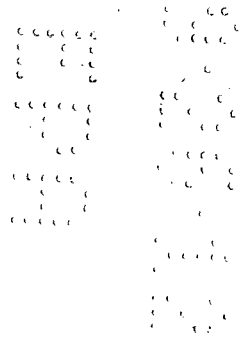
See back panel for additional Precautionary Statements

EPA Reg. No. 2724-XXX

EPA Est. No.

Batch/Lot 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:

[RF2185 CSO XM is a topically applied [long-lasting] product specifically formulated for cats and kittens. It [This product] 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. Each package contains enough product for xx monthly applications (xx days of protection [control]). RF2185 CSO XM provides relief from flea infestations for up to 1 month [4 weeks] by killing adult fleas on your cat or kitten.

After application, your cat's skin oils [disperse] carry RF2185 CSO XM over your cat's body for protection against biting adult fleas. [(product) may stain leather and suede fabrics for (24)(24 to 48) hours after application.] To completely kill the existing flea population, you may need to treat your home and your cat's bedding (home sprays, foggers), as well as your yard (yard spray/outdoor fogger) with traditional flea products approved for use on cats, around the home, or in your yard. RF2185 CSO XM can be used in conjunction with other [Brand] premise products. As with all flea products, they are [RF2185 CSO XM is] most effective when used as part of a total program aimed at reducing all stages of fleas in the cat's environment. [BRAND] 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 [Brand] 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.

USE ONLY ON CATS AND KITTENS 12 WEEKS OF AGE AND OLDER. (on the 2.5 - < 5 lb product – Do not apply to cats weighing less than 2.5 lbs.)[Do not apply to cats weighing less than 5 lbs.] Do not get this product in your cat's eyes or allow your cat to ingest this product. Do not use more than one applicator per cat and do not apply more than once every month.

[This product contains xx monthly dosages [one monthly dose], each [0.034 fl oz and][0.054 oz] (1 and 1.6 ml [cc]).

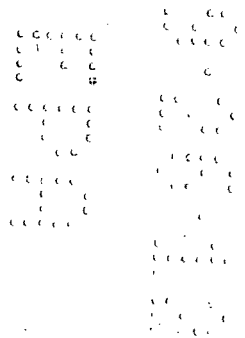
[1 ml [cc] [0.034 fl oz] dose for use only on cats and kittens over 2.5 lbs but under 5 lbs.

1.6 ml [cc]][0.054 oz] dose for use only on cats and kittens 5 lbs. and over (Same size applicators with different fill amounts)]

[APPLICATION METHOD]

[Bend at perforation and tear off 1st 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.



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ALTERNATE PACKAGING DIRECTIONS 1 (CAT-HEAD APPLICATOR)

[Bend at perforation and tear off 1st 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

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.

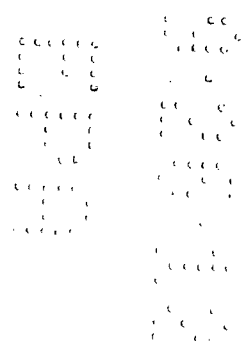
PRECAUTIONARY STATEMENTS

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 cat/kitten with mild soap and rinse with large amounts of water. If signs continue, [please call 1-phone number or] consult a veterinarian immediately. Be careful not to get any product in the cat's mouth during application. For multiple cat households, prevent the cats from grooming each other until the product has dried.



WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

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

SIDE EFFECTS: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [Brand at 1-800-number]

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

Cat's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2nd)

NOTES: _____

REMINDER: I purchased [Brand Name] _____ from _____

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

[Protect your family and cat from:]

[When your cat has fleas and ticks, your family and cat 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]

