

2724-835

04/18/2013

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

2724-835

Date of Issuance:

April 18, 2013

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

RF2184 DSO XM

Name and Address of Registrant (include ZIP Code):

Wellmark International
1501 E. Woodfield Rd. Suite 200 West
Schaumburg, IL 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.

(continued on page 2)

Signature of Approving Official:

Refer to Page 4

Richard J. Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7505P)

Date:

April 18, 2013

Make the following change to the label:

- a. Per the Efficacy Review DER dated April 2, 2013, Remove the following:
 - 1. **“Kills Brown Dog ticks (for)(28 days)(30 days)(1 month)(4 weeks)”**
 - 2. **Kills deer ticks (that may carry Lyme disease) (for)(28 days)(30 days)(1 month)(4 weeks)(on dogs)”**
 - 3. **Remove the word “naturally” from the statement “Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog.....” found on page 3.**

- 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. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.

- 3. You must submit the following data within the timeframes described below:

Acceptable Storage Stability and Corrosion Characteristics data must be provided to the agency within 16 months of the date of this Notice of Registration.

- 4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on April 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: Kimberly Nesci).

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 dogs 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 cats (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 dogs 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 dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each dog breed.

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- Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs 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. You revise the EPA Registration Number to read: "EPA Registration No. 2724-835" on page 1 of the label.

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.

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. A copy of your label stamped "Accepted with Comments" is enclosed for your records.

If you have any questions concerning this action, please contact Richard Gebken @ (703)-305-6701 or gebken.richard@epa.gov].

1. Submit one copy of the revised final printed label for the record before the product is released for shipment.

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 constitutes acceptance of these conditions.

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



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

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RF2184 DSO XM

Font size for word "Dog" in product name must be at least 75% the height of the largest letter in the primary brand name

Front Panel: For Use only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), and Extra Large (81 lbs. and over) Dogs/Puppies & 10 weeks of age or older

[Flea & Tick [& Mosquito][Treatment] [and] Control only for Dogs and Puppies 10 weeks of age or older]

([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment] [Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes]

~~Kills Brown Dog Ticks (for) (28 days) (30 days) (1 month) (4 weeks)~~

~~Kills Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)~~

[Aids in Control of Ticks for up to 30 days]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills fleas, ticks, and mosquitoes,] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads with dog's/puppy's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

[Fresh][Clean][[Scent][Smell]

[Reapply monthly] [Suitable for year-round use][[Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

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:

2774-835

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(Front panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1).....30.0

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS:65.0

TOTAL 100.0%

*(butyl carbityl) (6-propylpiperonyl ether) and related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

NET CONTENTS:

One: 0.05 fl oz (1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube]

(Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube] (Medium Dogs)/0.20 fl oz (6.0 cc)

Applicator [tube] (Large Dogs)/0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)/

EPA Reg. No. 2724-XXX

EPA Est. No.

Batch/Lot No.



**DO NOT USE
ON CATS**

(Minimum size 1.5 cm X 1.5 cm)

[RF2184 DSO XM kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.][RF2184 DSO XM] treats fleas, ticks, and mosquitoes for up to one month.

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

IMPORTANT! READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES 10 WEEKS OF AGE OR OLDER. DO NOT USE ON OTHER ANIMALS!

USE RESTRICTIONS:

For indoor use only.

Do not apply this product to puppies less than 10 weeks of age.

Do not apply to dogs/puppies weighing less than 6 lbs. (for smallest size dog package only).

Do not allow your dog/puppy to ingest this product.

Do not reapply this product for 30 days unless retreatment is required, but not sooner than 8 days after the initial treatment. Do not use more than one applicator/tube per dog/puppy and do not retreat more than 1 time per month.

RF2184 DSO XM works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth.

[(Note: Application now assumes one applicator per dog/puppy per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

ONLY FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

1. Bend at perforation and tear off first applicator [tube].
2. [Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to [two spots](toy dogs)[three spots](small or medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2184 DSO XM by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin.
5. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

ONLY FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

RF2184 DSO XM is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2184 DSO XM rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2184 DSO XM from: _____

NOTES: _____

Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: **Pesticide Storage:** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals. **Container Disposal: If empty:** Do not reuse container [tube];[applicator]. Place in trash or offer for recycling if available. **If partially 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 - CAUTION

DO NOT USE ON PUPPIES LESS THAN 10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your dog/puppy with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs/puppies may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-xxx-xxxx.

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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 first 5 minutes, then continue rinsing • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-XXX-XXXX, 24 hrs/day, 7 days/wk.	

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 emergency or for product information, call 1-800-xxx-xxxx.

Side Effects: Monitor your dog 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.



DO NOT USE ON CATS
Keep cats away from treated dogs/puppies for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173
[URL]
Made in USA

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TEXT FOR INDIVIDUAL APPLICATOR

Product name

Etofenprox 30%, Piperonyl Butoxide 5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

[READ DIRECTIONS BEFORE USING] (If space permits)

EPA Reg. No.

Net Contents



**DO NOT USE
ON CATS**

For use only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.), Large (56-80 lbs.), and Extra Large (81 lbs. and over) Dogs/Puppies & 10 weeks of age or older