

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

NOTICE OF PESTICIDE:

X Registration

Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

2724-842

11/23/15

Term of Issuance:

Conditional, Time-Limited

Expires: 11/23/2017

Name of Pesticide Product:

RF2236 CDSO-N1 FOR DOGS

Name and Address of Registrant (include ZIP Code):

Veronica Semetis Lawless Regulatory Affairs Specialist Wellmark International 1501 E. Woodfield Rd., Suite 200W 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 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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Date:

11/23/15

Jennifer Saunders, Ph.D., Product Manager 04

Invertebrate & Vertebrate Branch 1

Registration Division (7505P)

Office of Pesticide Programs

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EPA Form 8570-6

- 2. This registration is time-limited and expires 11/23/2017.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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
- 4. 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 cats and table for dogs 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, as applicable.
- 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, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- 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.

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.

- 5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
 - a. Ethofenprox GDCI-128965-954
 - b. Ethofenprox GDCI-128965-1041
 - c. Piperonyl Butoxide GDCI-067501-1063
 - d. MGK 264 GDCI-057001-1224
 - e. MGK 264 GDCI-057001-26616
 - f. MGK 264 EDSP-057001-250

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

- 6. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 7. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 2724-842."

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8. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under 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.

Please note that the record for this product currently contains the following CSFs:

Basic CSF dated 09/23/2015

If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or via email at fertich.elizabeth@epa.gov.

RF2236 CDSO-N1for Dogs

(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

ACTIVE INGREDIENTS:

Etofenprox	55.0%
*Piperonyl Butoxide (PBO)	10.0%
**n-octyl bicycloheptene dicarboximide (MGK 264)	
Pyriproxyfen (Nylar)	0.5%
OTHER INGREDIENTS.	33.5%
TOTAL	

^{*(}butylcarbityl)(6-propylpiperonyl) ether and related compounds

NYLAR, MGK®- Registered Trademarks of McGlaughlin Gormley King Company

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENT: Contains (*number*) tubes, each fl. oz. (ml)

For use ONLY on Dogs and	Net Contents (Each tube)
Puppies 12 weeks and older	
Weighing:	
5 to 14 lbs.	0.031 fl. oz. (0.91 ml.)
15 to 30 lbs.	0.066 fl. oz. (1.95 ml.)
31 to 60 lbs.	0.132 fl. oz. (3.90 ml.)
61 to-150 lbs.	0.220 fl. oz. (6.50 ml.)

EPA Reg. No. 2724-xx

EPA Est. No.

Batch/Lot No.

Cat Warning Icon: A cat prohibition icon will appear on the front panel lower right corner area. Icon is 1.5 cm x 1.5 cm black image a yellow background



Nov 23, 2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 2724-842



^{**}MGK ® 264, Insecticide Synergist

(BACK/SIDE PANELS)

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. -

HAZARDS TO DOMESTIC ANIMALS

DO NOT USE ON OTHER ANIMALS. Do not use on dogs or puppies less than 12 weeks of age. Do not use on dogs or puppies weighing less than 5 [or 15 or 31 or 61] lbs. -Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or on animals known to be sensitive to pesticide products without first consulting a veterinarian. Sensitivity, such as slight transitory redness of the skin at the site of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap, rinse with large amounts of water, and consult a veterinarian immediately.

ENVIRONMENTAL HAZARDS

This product is toxic to fish.

FIRST AID

If in eyes •Hold eye open and rinse slowly and gently with water for 15-20 minutes.

•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice. **If on skin:** Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice. **HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center, doctor or veterinarian, or going for treatment. **For additional information on this pesticide product (including** human and veterinary **health concerns, medical emergencies or pesticide incidents), you may call** 1-800—950-4783 [1-800-766-7661/1-800-234-2269 or a Poison Control Center], twenty-four (24) hours per day, seven (7) days per week.

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.

FOR_USE ONLY ON DOGS OR PUPPIES (12 WEEKS OF AGE OR OLDER).

DO NOT USE ON DOGS OR PUPPIES WEIGHING LESS THAN 5 [or

15 or 31 or 61] LBS.

DO NOT ALLOW YOUR DOG/PUPPY TO INGEST THIS PRODUCT.

DO NOT EXCEED LABELED-DOSAGE AMOUNT FOR DOGS.

DO NOT APPLY MORE THAN ONE TUBE PER TREATMENT.

DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY.

DO NOT USE ON OTHER ANIMALS

DO NOT DOUBLE-DOSE OR APPLY MORE THAN ONE APPLICATOR TO DOGS HEAVIER THAN 150 LBS. Must be added to the 61-150 lb label.

[Option 1]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades. Use the tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail. Repeat every month. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

[Option 2]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you (move) (glide) from the shoulder blades along the dog's back to the base of the tail. Repeat every month. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

[Option 3]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the dog's back at the base of the dog's tail. Use the tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the base of the tail along the dog's back to the shoulder blades. Repeat every month. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

[Option 4]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the dog's back at the base of the dog's tail. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you (move) (glide) from the base of the tail along the dog's back to the shoulder blades. Repeat every month. (Do not bathe your dog 48 hours prior to application.) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied.

(Side Effects to be placed above or adjacent to "Directions for Use" section.)

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 call 1-800—950-4783.

Cat Warning Icon: A cat prohibition icon will appear on the back panel Icon is 1.5 cm x 1.5 cm black image with a yellow background

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

STORAGE AND DISPOSAL

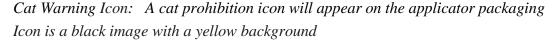
PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* 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.

For more information call our (flea and tick) experts at 1-800—950-4783 (weekdays, 9 am - 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT





Insert "Product Name "or ABN

(Product name will be followed by one of the following minimum dog weight treated statements)

For use **ONLY** on dogs 12 weeks and older, Weighing 5 to 14 lbs.

For use **ONLY** on dogs 12 weeks and older, Weighing 15 to 30 lbs

For use **ONLY** on dogs 12 weeks and older, Weighing 31 to 60 lbs

For use **ONLY** on dogs 12 weeks and older, Weighing 61 to 150 lbs

[Active Ingredients:]

Etofenprox 55.0%, PBO10.0%, MGK 264 1.0%, Nylar 0.5%

Keep Out of Reach of Children

CAUTION

Read accompanying label before use

Range of volumes from 0.031 fl. oz. (.91 ml) to 0.220 fl. oz (6.5 ml) depending upon weight of dog EPA Reg. No. 2724-xx EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Weighing 5 to 14 lbs. Weighing 15 to 30 lbs. Weighing 31 to 60 lbs. Weighing 61to150 lbs.

(S) Only (for) Dogs & Puppies 5-14 lbs (Small)
(M) Only (for) Dogs 15-30 lbs (Medium)
(L) Only (for) Dogs 31-60 lbs (Large)
(XL) Only (for) Dogs 61-150 lbs (Extra Large)

(S) Only (for) (Small) (Dogs) (&) Puppies 5-14 lbs.

(M) Only (for) (Medium) Dogs 15-30 lbs.

(L) Only (for) (Large) Dogs 31-60 lbs.

(XL) Only (for) (Extra Large) Dogs 60-150 lbs.

(Rapidly) (Quickly) eliminates fleas

Kills [(and) (&) Repels] Mosquitoes, Prevent re-infestation(s) for (28 days) (30 days) (1 month) (4 weeks)

Kills [(and) (&) Repels] Mosquitoes (before they bite) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Mosquitoes (for) (28 days) (30 days) (1 month) (4 weeks)

After the applied treatment has spread over the dog's body, this product will kill newly infesting fleas within 15 minutes.

Within 24 hours of application, this product will kill fleas by contact within 15 minutes.

When fully protected by full coverage of this product, infesting fleas will be killed within 15 minutes.

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae)(after contact)(through contact), Kills [(and)(&)Repels] Mosquitoes, Prevents re-infestation(s) (for)(28 days)(30 day)(1 month)(4 weeks)

Kills Fleas, Brown Dog (Ticks) (and) Deer Ticks, Flea Eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog (Ticks) (and) Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog (Ticks) (and) Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (through contact)

Kills [(and) (&) Repels] Mosquitoes, Prevent re-infestation(s) (for) (28 days) (30 days) (1 month) (4weeks)

Kills [(and) (&) Repels] Mosquitoes (before they bite) (for) (28 days) (30 days) (1 month) (4weeks)

Kills Mosquitoes (for) (28 days) (30 days) (1 month) (4weeks)

Fast Acting

(Rapidly)(Quickly) eliminates fleas

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills fleas that may cause flea allergy dermatitis (and flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills Brown Dog Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

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)

Kills all biting stages of Brown Dog Ticks and Deer Ticks

Kills adult Brown Dog Ticks and Deer Ticks, nymphs and larvae

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea (and) (Brown Dog Tick) (and) (Deer Tick) infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent re-infestation of fleas (and) (Brown Dog Tick) (and) (Deer Tick) (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea (and) (Brown Dog Tick) (and) (Deer Tick) re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Repels Mosquitoes (before they bite) (for) (28 days) (1 month) (4 weeks)

Repels (and controls) Mosquitoes (for) (28 days) (1 month) (4 weeks)

Controls mosquitoes (for) (28 days) (1 month) (4 weeks).

Repels Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)

Repels Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)

Once-a month Flea (and Brown Dog Tick, and Deer Tick)(Prevention) (Treatment) (Control) (Solution)

Monthly Flea (and Brown Dog Tick, and Deer Tick)(Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 weeks)Flea (and Brown Dog Tick, and Deer Tick) (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks) Gentle protection for dogs (and puppies)

Quick drying formula

Quick dry	ing
-	nd doesn't rub off
•	rith dog's natural skin oils
	ing fleas within 15 minutes
	ing fleas within 15 minutes and lasts for 30 days (1 month) (4 weeks)
	for 30 days (1 month) (4 weeks)
	e-infestation(s) (for) (30 days) (1 month) (4 weeks)
	and controls re-infestation(s) Long lasting
	and convenient topical treatment
	s (and Brown Dog, Deer Ticks) through (after) contact
	tented applicator
	tent pending applicator
	on topical applicator
	of control of flea eggs (and larvae)
-	s before they have a chance to lay eggs
	rying) (Formula)
` _	
	STICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT
1 st dose,	2 nd dose, 3 rd dose (X th dose)
First mor	th, second month, third month (Xth month)
X-pack	
X-tubes	
X month	supply
X month	y treatment(s)
Erograna	froe
Fragrance Unscente	
	ent) (fragrance)
	scent) (fragrance)
	scent) (fragrance)
	esh Scent
(Conveni	ent)(easy to use) applicator
After apr	lication, the treated area may appear wet (or) (oily) for up to 24 hours
	bathe your dog 48 hours after application
	emind you when you last applied treatment, simply write in the date when each dose is
applied:	
First Dos	
	ose
Third Do	e
Vth Doso	
VIII DOVE	

Dries quickly

Schaumburg, IL 60173

Made in the USA