

2724-796

10/31/2013

1/8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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

OCT 31 2013

Subject: RF2042 (CDSO) EPA Reg. No. 2724-796
Amendment dated 4/4/2012 to incorporate pet spot-on mitigation label language
EPA Decision Nos. 469108

Dear Mr. McFadden,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels incorporating these changes to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action. The time-limited registration for this product is extended two years from the date of this letter. If a registration extension request is not received prior to that date, the registration of this product will expire. If a review of the previously submitted enhanced incident data indicates that there is a concern with this product, EPA may choose to take further regulatory action at that time.

Per the additional requirements of September 30, 2011 letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. 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 attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

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

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.
- 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.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Labels stamped "Accepted"

RF2042 [CDSO]

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.), or 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) [weighing more than 6] lbs. (only required on smallest size dog packaging)

- Effective on indoor and outdoor dogs/puppies
- ([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]
- [Aids in Control of Ticks for up to 30 days]
- Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]
- [Starts Killing Fleas and Ticks within 15 minutes]
- [Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]
- [Dual Action kills adult fleas and prevents flea development]
- [Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]
- [Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]
- [Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [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)
- [With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]
- Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]
- Spreads naturally 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
 OCT 31 2013
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 Registered under
 EPA Reg. No. 2724-796

5/8

(Front panel)

ACTIVE INGREDIENTS:

| | |
|-------------------------------------|---------------|
| Etofenprox (CAS # 80844-07-1) | 30.0% |
| S-Methoprene (CAS # 65733-16-6) | 3.6% |
| Piperonyl Butoxide (CAS # 51-03-6)* | 5.0% |
| OTHER INGREDIENTS: | 61.4% |
| 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. 2724-796

EPA Est. No.



**DO NOT USE
ON CATS**

(Minimum size 1.5 cm X 1.5 cm)

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.][RF2042 [CDSO] treats fleas, ticks, and mosquitoes for up to one month and prevents flea eggs from developing for up to 2.5 months.]

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. (only required for smallest size dog packaging)
- 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.

RF2042 [CDSO] 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 RF2042 [CDSO] 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.

RF2042 [CDSO] 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 RF2042 [CDSO] 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 RF2042 [CDSO] 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.

| | |
|---|--|
| 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**

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

TEXT FOR INDIVIDUAL APPLICATOR

Product name
Etofenprox 30%, S-methoprene 3.6%, 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.), or Extra Large (81 lbs. and over) Dogs/Puppies & 10 weeks of age or older