

2724-497

10/31/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 31, 2012

Mr. James J. McFadden, Ph.D.
Regulatory Project Manager
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, IL 60173-5417

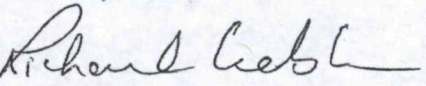
**Subject: Amending Labeling; Response to EPA Letter Dated September 30, 2011
RF9908 SPOT ON, EPA Reg. No. 2724-497
Your Submission Dated April 2, 2012**

Dear Mr. McFadden

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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 section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists 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 be 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted" is enclosed for your records. If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely Yours,

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

Enclosure: Label stamped "Accepted," dated October 31, 2012
002724-00497 D468359

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RF9908 SPOT ON

Alternate Brand Names: ZODIAC[®] Groomers' Spot ON[®] Pack
 ZODIAC[®] Spot On[®] Flea & Tick Control for Small Dogs 16-30 lbs.
 ZODIAC[®] Spot On[®] Flea & Tick Control for Medium Dogs 31-60 lbs.
 ZODIAC[®] Spot On[®] Flea & Tick Control for Large Dogs Over 60 lbs.
 ZODIAC[®] Spot On[®] Flea & Tick Control for Puppies, Toys, & Miniatures Under 15 lbs.
 Font size for word "Dog" in product name must be at least 75% the height of the largest letter in the primary brand name

For Use Only on Dogs and Puppies 7-15 lbs [puppies, toys, & miniatures]/16-30 lbs [small dogs]/31-60 lbs [medium dogs]/over 60 lbs [large dogs] & 6 Months of Age or Older

Topical Flea and Tick Treatment only for Dogs and Puppies six months and older
 Contains [With] Precor[®], Vigren[®], [Insect Growth Regulator (IGR)], or FGR[®] (Flea Growth Regulator)
 Prevents Flea Eggs from Developing into Biting Adults for up to 30 Days [3 Months]
 Each applicator] Kills and Repels Fleas, Ticks and Mosquitoes for up to 30 Days
 Kills Fleas Before they Lay Eggs
 Contains Insect Growth Regulator (IGR)] to [Kill(s) Flea Eggs] [to][and] Prevent Reinfestation
 [Number] Convenient, Pre-filled Applicators
 Easy and Convenient to Use
 3 [Number] Month Supply [1 applicator = 1 month treatment]
 3 [Number] month Flea & Tick Treatment
 Four [Number] Monthly Treatments
 Once a Month Flea, Tick and Mosquito Treatment
 3 [Number] Month treatment
 Month 1 Month 2 Month 3 Month [#]
 Unique applicator design [shape] helps prevent misapplication on cats
 Helps prevent misapplication on cats with unique applicator
 Longer applicator tip for easy application to long-haired dogs
 Accu-Tip Dispenser
 Pet Specifix[™] Applicator
 EZ-Squeeze Applicator

ACTIVE INGREDIENTS:	
Permethrin [CAS #52645-53-1].....	45%
(S)-Methoprene [CAS #65733-16-6].....	3%
OTHER INGREDIENTS:	52%
Total	100%

**KEEP OUT OF REACH OF CHILDREN
 CAUTION**

See back panel for additional precautionary statements

Net Contents: 3 – 0.022 fl oz (.65 ml) applicators (dogs 7-15 lbs)
 [Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

EPA Reg. No. 2724-497
 EPA Est. No.

ACCEPTED
October 31, 2012
**Under the Federal Insecticide, Fungicide,
 and Rodenticide Act, as amended, for the
 pesticide registered under:**



(Minimum size 1.5 cm X 1.5 cm)

EPA. Reg. No: 2724-497

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READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES 6 MONTHS OF AGE OR OLDER. DO NOT USE ON CATS!

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS - CAUTION:

Humans: Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling.
Domestic Animals: Do not use on puppies less than six months of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your dog/puppy with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian IMMEDIATELY. In the event of an emergency, contact 1-800-950-4783.

FIRST AID

If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • [Call a poison control center or doctor for treatment advice.] (if space available)
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-950-4783 [1-800-766-7661 or a Poison Control Center] for emergency medical treatment.</p>	

[First Aid statement paragraph format may be used if space is limited]

ENVIRONMENTAL HAZARDS: This product is toxic to fish.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

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

Reminder: I purchased RF9908 Spot On from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

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

This product [or product name] prevents eggs from developing into adult fleas for up to 30 days [3 months]. This product [or product name] also kills and repels ticks and mosquitoes for up to 30 days.

USE RESTRICTIONS: Do not apply to dogs/puppies weighing less than 7 lbs (for smallest size dog package only). Do not use more than one tube per dog/puppy and do not retreat more than once per month. Do not allow your dog/puppy to ingest this product.

[Graphics for Each Step]

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[Alternate applicator sizes permitted as long as dosage/ratios are maintained the same. See end of label for examples*]

Remove pre-filled applicator(s) from package and hold in an upright position.

1. Gently press cap to break the seal of the applicator. [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
2. [Carefully remove the cap.] Position the tip of the applicator on the dog's back between the shoulder blades. Apply half of the contents of the tube (0.5 cc) and proceed with steps 3 and 4.
3. Invert the applicator to an upright position and move to the dog's hindquarters. Position the tip of the applicator at the base of the tail and apply the remaining contents of the tube (0.5 cc).
4. Do not reapply product for 30 days.

[Alternate Packaging Directions 1][Application Method]

Bend at perforation and tear off first month's applicator.

Hold applicator [and bend area of plastic at perforation, tear off and discard]. [Hold applicator] upright and snap tip back, away from face and body.

[Alternate Packaging Directions 2]

Bend at perforation and tear off first month's applicator.

Hold applicator 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.

Note: DO NOT APPLY this product [or product name] to cats. These flea drops are intended for dogs only!

Although this product [or product name] is applied only between the shoulder blades and at the base of the tail [and in the middle of the back (over 60 lbs)], the dog's skin and hair oils carry the product over the entire body for protection against fleas, ticks, and flea eggs. This product [or product name] is most effective when used as part of a total flea and tick management program. Use other [Zodiac][Wellmark] products registered for residential area control of these pests in conjunction with this treatment. [For additional control of fleas in and around the home, use [product names]

STORAGE AND DISPOSAL

Storage: Store in a cool, dry area in a location out of reach of children and pets.

Disposal: If Empty: Do not reuse this container [empty applicator]. 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.

Copy: _____

Product Code: _____

Made in USA

Wellmark International
1501 East Woodfield Road Suite 200W
Schaumburg, Illinois 60173
[Web site URL]

Questions? Call (1-800-xxx-xxxx) Monday through Friday, [time]

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

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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- phone number.



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

TEXT FOR TUBE/APPLICATOR

Product Name
Permethrin 45%, S-methoprene 3%
KEEP OUT OF REACH OF CHILDREN
CAUTION
[READ DIRECTIONS BEFORE USING] (if space permits)
EPA Reg No. 2724-497
Net Contents:



For Use Only on Dogs and Puppies 7-15 lbs [puppies, toys, & miniatures]/16-30 lbs [small dogs]/31-60 lbs [medium dogs]/over 60 lbs [large dogs] & 6 Months of Age or Older

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[Alternate Language for dogs Over 60 lbs][W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same.

4 Month Supply [1 applicator = 1 month treatment]

Net Contents: 4 - 3 cc applicators

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break the seal of the applicator.][Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
3. Position the tip of the applicator at the base of the dog's neck. Apply 1/3 of the contents of the applicator.
4. Invert the applicator to an upright position and move to the middle of the dog's back. Apply 1/2 of the remaining contents of the applicator.
5. Invert the applicator to an upright position and move to the base of the dog's tail. Apply the remaining 1/3 of the contents of the applicator.
6. Do not reapply product for 30 days.

[Alternate Packaging Directions 1]

1. Bend at perforation and tear off first month's applicator.
2. Hold applicator and bend area of plastic at perforation, tear off and discard.
3. Hold applicator upright and snap tip back, away from face and body.

[Alternate Packaging Directions 2]

Bend at perforation and tear off first month's applicator.

Hold applicator 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.

[Alternate Language for dogs of all sizes][W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

Net Contents: 50 - 1 cc applicators

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break the seal of the applicator.][Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube. [Carefully remove the cap.]
3. Apply as directed below.
4. Do not reapply product for 30 days.

[Alternate Packaging Directions 1]

Bend at perforation and tear off first month's applicator.

Hold applicator upright and snap tip back, away from face and body.

[Alternate Packaging Directions 2]

Bend at perforation and tear off first month's applicator.

Hold applicator 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.

MONTHLY [product name] APPLICATION

Application by Weight	# of 1 cc Tubes [applicators]	Where to Apply
Dogs 16 - 29 pounds	One tube [applicator]	1/2 tube [applicator] at base of neck 1/2 tube [applicator] at base of tail
Dogs 30 to 59 pounds	Two tubes [applicator]	1 tube [applicator] at base of neck 1 tube [applicator] at base of tail
Dogs 60 pounds +	Three tubes [applicator]	1 tube [applicator] at base of neck 1 tube [applicator] in middle of back 1 tube [applicator] at base of tail

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[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. Examples]

DOG WEIGHT	SIZE	WHERE TO APPLY
7-15 lbs	0.022 fl oz (0.65 cc)	½ at neck, ½ at tail
16-30 lbs	0.034 fl oz (1 cc)	½ at neck, ½ at tail
31-60 lbs.	0.068 fl oz (2 cc)	½ at neck, ½ at tail
Greater than 60 lbs.	0.101 fl oz (3 cc)	1/3 at neck, 1/3 at mid-back, 1/3 at tail