

2724-497

10/9/2012

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OCT 9 2012

Mr. James McFadden
Wellmark International
1501 East Woodfiel Road, Suite 200W
Schaumburg, Illinois 60173

Subject: Amended Reregistration Label
Product Name: RF9908 Spot On
EPA Registration Number: 2724-497
EPA Decision Number(s): 413634

Dear Mr. McFadden:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Permethrin RED(s), and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated [February 24, 2011]

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Dani Daniel at (703)305-5409 or via e-mail at daniel.dani@epa.gov

Sincerely,



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

*Enclosures: Label stamped "Accepted," dated OCT 9 2012
Acute Toxicity Review, dated (August 19, 2010)
Product Chemistry Review, dated (May 25, 2012)*

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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.

Topical Flea and Tick Treatment 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]

IMPORTANT! [Intended] For Use on Dogs and Puppies 6 Months of Age or Older:

For [Use on] Dogs and Puppies Under 30 lbs. [0.03 fl oz (1 cc) applicator]
[For] [Puppies, Toys, Miniatures][Large][Medium][Small] size dogs
[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 for dogs under 30 pounds
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

(Front or Back)

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 [Ingredients and] additional precautionary statements

DO NOT USE ON CATS!

No Cat Graphic-CAT SLASH ICON

Net Contents: 3 – 0.03 fl oz (1 cc) applicators [dogs/puppies under 30 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
OCT 09 2012**
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 2724-497

**READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES.
DO NOT USE ON CATS!**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS - CAUTION:

Humans: Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before use.

Domestic Animals:

DO NOT USE ON CATS!
May be toxic and potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

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 pet 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-[phone number].

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)
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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—[phone number [1-800-phone number or a Poison Control Center] for emergency medical treatment

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

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			
Pet'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.

[Graphics for Each Step]

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[Alternate applicator sizes permissible 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

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

Pesticide Disposal and Container Handling: 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.

[Disposal: Do not reuse this container [empty applicator]. Place in trash or offer for recycling if available. Never place unused product down any indoor or outdoor drain.]

Copy: _____

Product Code: _____

Made in USA

Wellmark International
1501 East Woodfield Road 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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[Alternate Language for dogs Over 30 lbs][E]

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

For [Use on] Dogs and Puppies Over 30 lbs. [0.03 fl oz (1 cc) applicator]

3 Month treatment for dogs Over 30 pounds

3 Month Supply [2 applicators = 1 month treatment]

Net Contents: 6 – 0.03 fl oz (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.
3. [Carefully remove the cap.] Position the tip of the applicator on the dog's back between the shoulder blades. Apply the entire contents of the tube (1 cc) and proceed with steps 4 and 5.
4. Open another applicator (following directions provided in steps 1 and 2 above). Position the tip of the applicator at the base of the tail and apply the entire contents of the tube (1 cc).
5. Do not reapply product for 30 days.

[Alternate Packaging Directions]

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

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

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

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 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 up to 60 lbs][W]

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

4 Month Supply [1 applicator = 1 month treatment]

Net Contents: 4 - 2 cc applicators [dogs/puppies 31-60 lb]

Net Contents: 4 - 1 cc applicators [dogs/puppies less than 30 lb]

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 on the the dog's back between the shoulder blades. Apply 1/2 of the contents of the applicator.
4. 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 applicator.
5. 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 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][E]

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

For [Use on] Dogs of All Sizes [0.03 fl oz. (1 cc) applicator]

6 Month treatment for dogs Under 30 pounds [1 applicator = 1 month treatment]

3 Month treatment for dogs 30 to 59 pounds [2 applicators = 1 month treatment]

2 Month treatment for dogs over 60 pounds [3 applicators = 1 month treatment]

Drop 1 Drop 2 Drop 3 Drop 4 Drop 5 Drop 6

Net Contents: 6 - 0.03 fl. oz. (1 cc) applicators

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

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

For [Use on] Dogs of All Sizes [0.03 fl oz. (1 cc) applicator]

3 Month treatment for dogs Under 30 pounds [1 applicator = 1 month treatment]

1.5 Month treatment for dogs 30 to 59 pounds [2 applicators = 1 month treatment]

1 Month treatment for dogs over 60 pounds [3 applicators = 1 month treatment]

Drop 1 Drop 2 Drop 3

Net Contents: 3 - 0.03 fl. oz. (1 cc) applicators

[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 up to 29 pounds	One tube [applicator]	½ tube [applicator] at base of neck ½ 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

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

DOG WEIGHT	SIZE	WHERE TO APPLY
Less than 15 lbs.	1 cc	½ at neck, ½ at tail
16-30 lbs	1 cc	½ at neck, ½ at tail
31-60 lbs.	2 cc	½ at neck, ½ at tail
Greater than 60 lbs.	3 cc	1/3 at neck, 1/3 at mid-back, 1/3 at tail