

2724-497

1/30/2004

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave. N.W.
Washington, D.C. 20004

EPA Reg. Number:

2724-497

Date of Issuance:

JAN 30 2004

Term of Issuance: Conditional

Name of Pesticide Product:

RF9908 Spot On

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Wellmark International
1100 E. Woodfield Rd. #500
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.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A), subject to the following provisions:

1. You must submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of you product under FIFRA section 4.
2. You must make the following label changes:
 - a. Revise the EPA Registration Number to read "EPA Reg. No. 2724-497"
 - b. Under "Physical or Chemical Hazards", include the word "Combustible" as required text, rather than optional text. It is required based on the product's flash point.
 - c. In step 2 at the top of the third page, revise the end of the second sentence to read "... and proceed with steps 3 and 4." [not "4 and 5"]

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 bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Submit two copies of your final printed label before you release the product for shipment.

Signature of Approving Official:

Date:

Susan L. Stanton for George T. LaRocca

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If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosures

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RF9908 SPOT ON

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: Do not use on Cats!

No Cat Graphic

For [Use on] Dogs and Puppies Under 30 lbs. [0.03 fl oz (1 cc) applicator]
Kills and Repels Fleas, Ticks and Mosquitoes for up to 30 Days
Kills Fleas Before they Lay Eggs
Kills Flea Eggs to Prevent Reinfestation
[Number] Convenient, Pre-filled Applicators
Easy and Convenient to Use
3 Month Supply [1 applicator = 1 month treatment]
3 month Flea & Tick Treatment
Once a Month Flea, Tick and Mosquito Treatment
3 Month treatment for dogs under 30 pounds
Month 1 Month 2 Month 3

(Front or Back)

ACTIVE INGREDIENTS:

Permethrin [CAS #52645-53-1].....	45%
Methoprene [CAS #65733-16-6]	3%
OTHER INGREDIENTS:	<u>52%</u>

Total	100%
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**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See back panel for [Ingredients and] additional precautionary statements

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-XXX

EPA Est.

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

JAN 30 2004

**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: 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 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 1-800-950-4783.

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)
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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 1-800-950-4783 [1-800-766-7661 or a Poison Control Center] for emergency medical treatment, Monday – Friday [time]

[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			
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: _____

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.

DO NOT USE ON CATS!

May be toxic and potentially fatal if applied to or ingested by cats. Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effects.

[Graphics for Each Step]

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

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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 4 and 5.
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]

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

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

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 or 1-800-CLEANUP 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
500 East Woodfield Road Suite 500
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)]

w/g

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

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

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