

2724-497

10-16-2006

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Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-497	2. EPA Product Manager G. LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF9908 Spot On	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____	

Check if this is a new address

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION OCT 16 2006
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Submission of optional alternate directions for use statement to reflect method of opening additional applicator style. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged In:				2. Type of Container			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic	<input type="checkbox"/> Glass	<input checked="" type="checkbox"/> Paper
* Certification must be submitted	If "Yes" Unit Packaging wgt. 1-3 cc	No. per container 1-50	If "Yes" Unit Packaging wgt.	Other (Specify) _____			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1-3 cc, 1-50/container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input checked="" type="checkbox"/> Other outer printed cardboard carton			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Regulatory Specialist	Telephone No. (Include Area Code) (847) 330-5376
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Regulatory Specialist	
4. Typed Name Nancy Huebl	5. Date 21-Sep-06	

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REGULATORY LABEL DATA SHEET

File Name: G:\regulatory\labels\cahspec\epa notif farnam table 906
Data Sheet Date: September 2006

Product: RF9908 Spot On
EPA Reg #: 2724-497

Approved: Notification submitted 9/21/06
Supercedes: 5/8/06

OVERVIEW: Per PRN 98-10, §II, E. Changes in Packaging and Related Labeling Statements, a different style of applicator is being used by a subregistrant and this notification reflects the way the applicator is opened.

Page #	Description of Major Changes
1	Added marketing claim to reflect varying dog size packages (for puppies, toys, miniatures, large, medium, small dogs)
2	Treatment Table – can be expanded for varying size (monthly) packages (3/6 months), added area for consumer to add “notes”
3	A different style of applicator is being used by a subregistrant and this notification reflects the way the applicator is opened (optional text).
4	Corrected for dogs over 60 lbs, should be neck not back

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NOTIFICATION

OCT 16 2006

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: Do not use on Cats!

No Cat Graphic

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

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.

**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: _____

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.

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]

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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

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)

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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 backneck. 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.

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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]

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

Wellmark

September 21, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: G. LaRocca

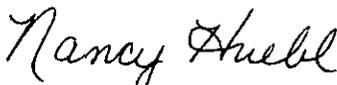
SUBJECT: NOTIFICATION OF LABEL REVISION PER PRN 98-10
RF9908 SPOT ON/EPA REG. NO. 2724-497

Dear Mr. LaRocca:

Enclosed is a completed EPA Form 8570-1 and one copy of revised highlighted labeling (red is new text) for the above product. Per PRN 98-10, §II E, Changes in Packaging and Related Labeling Statements, the revision involves the addition of an optional statement in the Directions For Use, (to advise the user to snap off the molded plastic header piece). This is being submitted due to a different type of applicator being used by a subregistrant. All of the criteria for §II E are met. I have enclosed a self-addressed postcard for notification confirmation.

If you have any questions, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL



Nancy Huebl
Regulatory Specialist
nhuebl@central.com

enclosure

cc: C. Elmi/J. Flegeau
C. Purcell, Central Life Sciences