

43576-11

10-19-2010

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

October 19, 2010

Ms. Kim Davis,  
Consultant/Agent for GPS Group  
c/o RegWest Company, LLC  
8203 West 20<sup>th</sup> Street, Suite A  
Greeley, CO 80634-4696

**Subject: Label Notification(s); Pesticide Registration Notifications (PRNs) 98-10 & 2007-4  
Flea & Tick Killer, EPA Reg. No. 43576-11  
Your Submission Dated August 17, 2010**

Dear Ms. Davis:

The Agency is in receipt of your application for Pesticide Notification under Pesticide Registration Notifications (PRNs) 98-10 & 2007-4, dated August 17, 2010, for the referenced product. The Registration Division has conducted a review of this request for its applicability under PRNs 98-10 & 2007-4, and finds that the action(s) requested fall within the scope of PRNs 98-10 & 2007-4.

Please be reminded that 40 CFR §156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-Notification/PRN 98-10) or durably marked on the container itself.

The label submitted with this application has been time-stamped "Notification," and will be placed within the administrative file for this product. If you have any questions, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

Sincerely yours,

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

 <p>United States <b>Environmental Protection Agency</b> 401 M Street, S.W. Washington, DC 20460-0001</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number  <b>Notification</b>
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**Application for Pesticide – Section I**

1. Company/Product Number <b>43576-11</b>	2. EPA Product Manager <b>Richard Gebken</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Flea &amp; Tick Killer</b>	PM # <b>10</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>GPS Group c/o RegWest Company, LLC 8203 West 20<sup>th</sup> St., Suite A Greeley, CO 80631-4696</b> <input checked="" type="checkbox"/> Check if this is a new address		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. <b>NOTIFICATION</b>  Product Name <b>OCT 19 2010</b>

**Section – II**

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

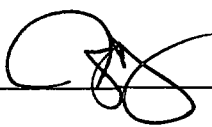
**Submit label revision notification per PR Notices 98-10 and 2007-4:  
Refer to the Reference Label for an illustration of all revisions.**

*This notification is consistent with the provisions of PR Notices 98-10 and 2007-4 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 the EPA. I further understand that if this notification is not consistent with the terms of PR Notices 98-10 and 2007-4 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging Wt.	No. Per Container	If "Yes" Packaging Wt.	No. Per Container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <b>2 fl. oz. through 1 gallon</b>		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Other Self-adhesive					

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name <b>Kim Davis</b>	Title <b>Consultant/Agent</b>	Telephone No. (Include Area Code) <b>970.353.0611 kim@regwest.com</b>
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 statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <b>(Stamped)</b>
2. Signature 	3. Title <b>Consultant/Agent</b>	
4. Typed Name <b>Kim Davis</b>	5. Date <b>August 17, 2010</b>	

Non-PRIA Label Revision Notification



August 17, 2010

Mr. Richard Gebken, Product Manager 10  
Document Processing Desk – NOTIF  
Office of Pesticide Programs – 7504P  
U.S. Environmental Protection Agency  
One Potomac Yard (South Building), Room S-4900  
2777 South Crystal Drive  
Arlington, VA 22202

NOTIFICATION

OCT 19 2010

Dear Mr. Gebken:

Subject: GPS Group  
Flea & Tick Killer  
EPA Reg. No. 43576-11

On behalf of **GPS Group**, RegWest Company, LLC is submitting the attached materials as a notification of label revisions per PR Notices 98-10 and 2007-4. RegWest will act as sole agent in this endeavor.

Attached are the following:

- 1. Application for Pesticide: Notification
- 2. One **Reference Label** (illustrating the label revisions)
- 3. Two **New Labels** (incorporating the revisions)

In addition to the PR Notices changes we are deleting the web address and moving optional marketing claims to the end of the label. Please refer to the *Reference Label* for an illustration of all revisions.

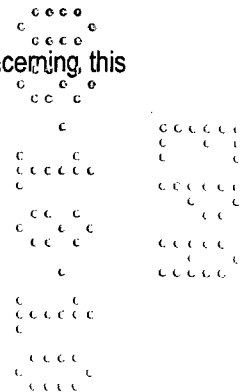
Please contact me at 970.353.0611 or kim@regwest.com if you have any questions or comments concerning this submission.

Regards,  
RegWest Company, LLC

Kim Davis,  
Consultant/Agent

Attachments

cc: GPS – Lucius, D.



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# Flea & Tick Killer

{ABN: R-7M Ear Mite Treatment}  
{ABN: R-7 Ear Care for Dogs & Cats}

**NOTIFICATION**

[[Select marketing claims from "Marketing Claims" section]]

**OCT 19 2010**

**Active Ingredients:**

Pyrethrins (CAS No. 8003-34-7) .....	0.15%
*Piperonyl Butoxide, Technical (CAS No. 51-03-6) .....	1.50%

**Other Ingredients** ..... 98.35%

**Total** ..... 100.00%

\*Equivalent to max. 1.2% (butylcarbityl)(6-propylpiperonyl) ether and min. 0.3% related compounds.

**Keep Out of Reach of Children**  
**CAUTION**  
**See back panel for additional Precautionary Statements.**

Net Contents: \_\_\_\_ fl. oz. ( \_\_\_\_ ml)

{Back Panel}

**READ ENTIRE LABEL BEFORE EACH USE**  
**USE ONLY ON DOGS AND CATS, HORSES AND PONIES**

Temporarily repels gnats, mosquitoes and biting flies. Contains a grooming agent to ease combing and brushing to remove dead fleas, ticks and lice.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Use only in a well ventilated area. Shake well before using. When used indoors as a space spray remove birds and cover aquariums before spraying. Do not use on puppies or kittens under 12 weeks of age. Consult a veterinarian before using this product on debilitated, medicated, aged, pregnant or nursing animals.

Cover animal's eyes with hand and with a firm fast stroke, to get a proper spray mist, spray head, ears and chest until damp. Spray fingertips then rub onto animal's face around mouth, nose and eyes. Spray neck, middle and hindquarters, finishing legs last. For best penetration of spray to the skin, direct spray against the natural lay of the hair. On long-haired dogs and cats, rub your hand against the lay of the hair, spraying the ruffled hair directly behind the hand. Make sure spray thoroughly wets ticks. Do not repeat treatment for 3 to 5 days.

**Puppies and Kittens:** Spray only along back or on your fingertips and rub into coat.

**Pet Sleeping Quarters:** Thoroughly spray infested areas, pet beds, resting quarters, around baseboards, windows, door frames, wall cracks and local areas of floors. Repeat as needed. Put fresh bedding in animal's quarters following treatment. Concurrent treatment of animals is recommended.

**Horses and Ponies:** To control stable flies, horse flies, deer flies and face flies, apply to face, neck, legs, flanks, topline and other body areas commonly attacked by these flies. Repeat treatment as needed.

**To Control Spinose Ear Ticks and Ear Mites,** apply 10 drops of this product to each ear making sure it penetrates the wax down to surrounding tissues. Repeat treatment once or twice at 2-3 day intervals.

[Free Bonus Ear Cleaner Enclosed. Ear Care for Dogs and Cats. Helps to clean the ears, reduce ear odors and dry the ears.]

Two Simple Steps to Reduce Ear Problems:

- 1) First, use Ear Cleaner to clean and help reduce ear odors. [Ear Cleaner helps reduce ear odors.] Use two or three times a week [to keep the ears clean and reduce ear odors]. Use before and after bathing, swimming or hunting. Also available in 4 oz., 8 oz., 16 oz. and gallons. Fill the ear canal with Ear Lotion. Gently massage the base of the ears. Use facial tissue or cotton to clean the ears.
- 2) Next, use Drying Ear Creme and Flea & Tick Killer to keep the ears dry and control any ear mites or ear ticks present. Use after the ears are cleaned with Ear Cleaner. This unique liquid and dry phase crème will dry to a powder to help keep the ears dry and keep Ear Mites and Ear Ticks out of the ears. Also available in 1 oz. and 4 oz. size. To control ear ticks and ear mites, apply 10 drops of this product to each ear making sure it penetrates the wax down to surrounding tissues. Repeat treatment one or twice at 2-3 day intervals.

The ears of dogs and cats are a frequent source of problems. The long ear canal (see diagram below) allows dirt and wax to build up.

[Diagram of Ear, Head, Ear Canal and Ear Drum]

The heavy drooping ear of some dogs closes off the opening of the ear canal. This prevents proper air circulation and results in a moist odorous ear.

**Ear Mites:** These are small parasites that crawl in the ear canal of dogs and cats. They chew on the ear and cause scratching, head-shaking, pain and infection. A crusty brownish black material will occur in the ear when mites are present.

#### **Storage and Disposal**

Do not contaminate water, food or feed by storage or disposal

**Pesticide Storage:** Store in original container in a cool, dry place (preferably locked) inaccessible to children and pets and away from heat or open flame. Protect from freezing. **Pesticide/Container Disposal:** Non-refillable container; do not reuse or refill this container. **If empty:** Offer for recycling, if available; otherwise, discard in trash. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

*{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}*

#### **PRECAUTIONARY STATEMENTS**

##### **Hazards to Humans & Domestic Animals**

**CAUTION: Humans:** Harmful if swallowed or inhaled. Avoid breathing spray mist. Avoid contact with skin, eyes or clothing. Wash skin with soap and water after using. Avoid spraying food or foodstuffs. **Animals:** Avoid contact with animal's eyes. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

**First Aid**

<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Immediately call a poison control center or doctor for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Immediately rinse skin with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor or going for treatment. [You may also call 1-800-755-7056 for emergency medical treatment advice.]	

(Note: The first aid statements' grid format will be used if market label space allows; otherwise a paragraph format will be used.)

**Environmental Hazards**

This product is toxic to aquatic organisms. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

[In case of questions or emergencies, call 800-755-7056.]

To the extent permitted by applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herewith.

Product No. \_\_\_\_\_

EPA Reg. No. 43576-11      EPA Est. 43576-GA-1

[Manufactured by]

**GPS Group**

4280 Northeast Expressway

Atlanta, GA 30340

800-755-7056

© \_\_\_\_\_

{The following verbiage will appear on the labeling when the product is sold as a "kit" containing this product and a non-regulated ear cleaner product}  
 {Front panel}

**FLEA & TICK KILLER EAR CARE**

**For Dogs and Cats**

**An Ear Care Kit Containing Flea & Tick Killer and R-7™ Ear Cleaner**

Cleans Ears • Helps Reduce Ear Odors • Controls Ear Mites & Ticks

Two Simple Steps: 1) Use R-7™ Ear Cleaner to clean and help reduce ear odors.

2) Use Flea & Tick Killer to control Ear Mites and Ear Ticks

Made in the U.S.A.

{Back panel}

### An Ear Care Kit Containing Flea & Tick Killer and R-7™ Ear Cleaner

The ears of dogs and cats are a frequent source of problems. The long ear canal allows dirt and wax to build up. The heavy drooping ear of some dogs closes off the opening of the ear canal. This prevents proper air circulation and results in a moist, odorous ear.

**Ear Mites:** These are small parasites that crawl in the ear canal of dogs and cats. They chew on the ear and cause scratching, head-shaking, pain and infection. A crusty brownish black material will occur in the ear when mites are present.

<p style="text-align: center;"><b>READ ENTIRE LABEL BEFORE EACH USE</b> <b>Use Only on Dogs and Cats</b> <b>Flea &amp; Tick Killer</b></p> <p style="text-align: center;"><b>DIRECTIONS FOR USE</b></p> <p>It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Use only in a well ventilated area. Shake well before using. Do not use on puppies or kittens under 12 weeks of age. Consult a veterinarian before using this product on debilitated, medicated, aged, pregnant or nursing animals.</p> <p>To Control Spinose Ear Ticks and Ear Mites, apply 10 drops to each ear making sure it penetrates the wax down to surrounding tissues. Repeat treatment once or twice at 2-3 day intervals.</p> <p style="text-align: center;"><b>Storage and Disposal</b></p> <p>Do not contaminate water, food or feed by storage or disposal</p> <p><b>Pesticide Storage:</b> Store in original container in a cool, dry place (preferably locked) inaccessible to children and pets and away from heat or open flame. Protect from freezing.</p> <p><b>Pesticide/Container Disposal:</b> Non-refillable container; do not reuse or refill this container. If empty: Offer for recycling, if available; otherwise, discard in trash. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.</p> <p style="text-align: center;"><i>(Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.)</i></p> <p style="text-align: center;"><b>PRECAUTIONARY STATEMENTS</b> <b>Hazards to Humans &amp; Domestic Animals</b></p> <p><b>CAUTION: Humans:</b> Harmful if swallowed or inhaled. Avoid breathing spray mist. Avoid contact with skin, eyes or clothing. Wash skin with soap and water after using. Avoid spraying food or foodstuffs. <b>Animals:</b> Avoid contact with animal's eyes. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.</p> <p style="text-align: center;"><b>First Aid</b></p> <p><b>If Swallowed:</b> Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. <b>If Inhaled:</b> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice. <b>If on Skin or Clothing:</b> Take off contaminated clothing. Immediately rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. <b>If in Eyes:</b> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.</p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. [You may also call 1-800-755-7056 for emergency medical treatment advice.]</p> <p style="text-align: center;"><b>Environmental Hazards</b></p> <p>This product is toxic to aquatic organisms. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.</p> <p style="text-align: center;">EPA Reg. No. 43576-11      EPA Est. 43576-GA-1 [In case of questions or emergencies call 800-755-7056]</p>	<p style="text-align: center;"><b>R-7™ Ear Cleaner</b> <b>Two Simple Steps to Reduce Ear Problems</b></p> <p><b>Directions:</b></p> <ol style="list-style-type: none"><li>1. R-7™ Ear Cleaner - Use two or three times a week to keep the ears clean and reduce ear odors. Use before and after bathing, swimming or hunting. Fill the ear canal with R-7™ Ear Cleaner. Gently massage the base of the ears. Use facial tissue or cotton to clean the ears.</li><li>2. R-7™ Drying Ear Creme &amp; Ear Mite Treatment - Use after the ears are cleaned with R-7™ Ear Cleaner. The Drying Ear Creme will dry to a powder to help keep the ears dry and the Ear Mite Treatment keeps ear mites and ear ticks out of the ears.</li></ol> <p><b>CAUTION:</b> Keep out of reach of children. Avoid contact with eyes or mucous membranes. If eyes are contacted, wash with water immediately. <b>Do not use on infected ears, especially if there is an open wound. Contact a veterinarian if irritation develops or if an allergic reaction is suspected.</b> Harmful if swallowed.</p> <p><b>First Aid (Human):</b> Call a physician or poison control center.</p> <p><b>Ingredients:</b> Water, 35% Isopropyl Alcohol, Salicylic Acid, Oil of Eucalyptus, Polysorbate 60, FD&amp;C Yellow No. 5, FD&amp;C Red No. 40, FD&amp;C Blue No. 1</p>
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Product No. \_\_\_\_\_

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**[Manufactured by]**  
**GPS Group**  
4280 Northeast Expressway  
Atlanta, GA 30340  
800-755-7056  
© \_\_\_\_\_

**Made in the U.S.A.**

{Marketing Claims}

**Spray For Dogs and Cats, Puppies and Kittens Over 12 Weeks of Age  
and For Use On Pet Bedding and Carpets  
For the Control of Fleas, Ticks, Ear Mites and Lice  
Controls Spinose Ear Ticks and Ear Mites  
For Dogs and Cats**

**[Money Back Guarantee]**

**[Money Back Guarantee]**

If not satisfied, return unused portion to GPS Group for full refund.]



{End of Marketing Claims}

[ ] Denotes alternate/optional language

{ } Denotes language that does not appear on the market labeling