

43576-11

01-24-2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 24, 2012

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

**Subject: Amending Labeling; Addition of "Quick Response" Codes
Flea & Tick Killer, EPA Reg. No. 43576-11
Your Submission Dated November 4, 2011**

Dear Ms. Davis:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revision provision(s):

Ingredient Statement section comment(s):

1. In order to incorporate required label changes from the RED for piperonyl butoxide, you must:
 - Revise "*Piperonyl Butoxide, Technical (CAS #51-03-6)" to read "*Piperonyl Butoxide (CAS #51-03-6)"
 - Revise the following footnote to read "* (butylcarbityl)(6-propylpiperonyl) ether and related compounds."

Directions for Use section comment(s):

2. Make the following subsection-specific changes on the subject label:
 - Within the "**Horses and Ponies:**" subsection, revise the words "To control stable flies, ..." to read "To kill stable flies, ..."
 - Revise the subsection heading "**To Control Spinose Ear Ticks and Ear Mites:**" to read "**To Kill Spinose Ear Ticks and Ear Mites:**"
 - Within the 1st and 5th sentences of the "Two Simple Steps to Reduce Ear Problems:" subsection, revise the word "control" to read "kill"

First Aid Statement section comment(s):

3. In order to facilitate inclusion of required language per the Agency's Label Review Manual (LRM), revise the 2nd sentence within the "**HOT LINE NUMBER**" subsection to read "For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-755-7056, twenty-four (24) hours per day, seven (7) days per week."

Optional Marketing Claims (FLEA & TICK KILLER EAR CARE KIT) section comment(s), bottom of page 3 of 5:

4. Revise "Use Flea & Tick Killer to control Ear Mites and Ear Ticks" to read "Use Flea & Tick Killer to kill Ear Mites and Ear Ticks"
5. Revise "Controls Ear Mites & Ticks" to read "Kills Ear Mites & Ticks"

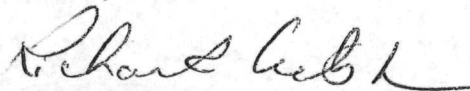
Optional Marketing Claims section comment(s), top of page 5 of 5:

6. Revise the 1st optional marketing claim to read "Kills Spinose Ear Ticks and Ear Mites"
7. Revise the 3rd optional marketing claim to read "To Kill Fleas, Ticks, Ear Mites and Lice"

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia 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: *Copy of label stamped "Accepted with Comments"*
043576-00011 D457649

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Flea & Tick Killer

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

ACCEPTED
With COMMENTS
In EPA Letter Dated:

January 24, 2012

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

43576-11

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

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 man 4.00%~~ (butylcarbityl)(6-propylpiperonyl) ether and ~~0.00%~~ 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.

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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.

5
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First Aid

If Swallowed	<ul style="list-style-type: none">• 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.
If Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none">• 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.
If in Eyes	<ul style="list-style-type: none">• 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.

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.

6
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{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;">READ ENTIRE LABEL BEFORE EACH USE Use Only on Dogs and Cats Flea & Tick Killer DIRECTIONS FOR USE</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;">Storage and Disposal</p> <p>Do not contaminate water, food or feed by storage or disposal</p> <p>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.</p> <p>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.</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;">PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals</p> <p>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.</p> <p style="text-align: center;">First Aid</p> <p>If Swallowed: 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. If Inhaled: 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. If on Skin or Clothing: 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. If in Eyes: 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;">Environmental Hazards</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;">R-7™ Ear Cleaner Two Simple Steps to Reduce Ear Problems</p> <p>Directions:</p> <ol style="list-style-type: none">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.2. R-7™ Drying Ear Creme & 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. <p>CAUTION: Keep out of reach of children. Avoid contact with eyes or mucous membranes. If eyes are contacted, wash with water immediately. 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. Harmful if swallowed.</p> <p>First Aid (Human): Call a physician or poison control center.</p> <p>Ingredients: Water, 35% Isopropyl Alcohol, Salicylic Acid, Oil of Eucalyptus, Polysorbate 60, FD&C Yellow No. 5, FD&C Red No. 40, FD&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}

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

[Money Back Guarantee]

[Money Back Guarantee]

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



{Quick Response code for 4 fluid ounce ear treatment only}



{Quick Response code for 2 fluid ounce ear treatment kit}



{Quick Response code for 1 fluid ounce ear treatment kit}

{End of Marketing Claims}

[] Denotes alternate/optional language

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