

43576-11

11/6/2013

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NOV 6 2013

GPS Group
c/o
Kimberlee Young
RegWest Company, LLC
8203 West 20th St., Suite A
Greeley, CO 80634

Subject: Amended Reregistration Label
Product Name: Flea & Tick Killer
EPA Registration Number: 43576-11
EPA Decision Number: 410459, 411842

Dear Ms. Young:

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 pyrethrins and PBO REDs, 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 be reminded that 40 CFR Part 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 or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statement of Formulation (CSF) listed below. Any CSFs other than those listed below are superseded.

- Basic CSF dated >> 08/10/12


A copy of your label 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).

Please note that, should you wish to add/retain a reference to the company's website on your label, the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12 (a)(1)(E) of FIFRA. 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially different from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially different from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

If you have any questions about this letter, please contact Gene Benbow at 703-347-0235 or benbow.gene@epa.gov.

Sincerely,



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

*Enclosures: Acute Toxicity Review, dated 11/01/10
Product Chemistry Review, dated 10/12/12
Stamped Accepted Label, dated*

3/10

ACCEPTED
NOV 6 2013
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
Registered under
EPA Reg. No. 43576-11

43576-11 Label: Page 1 of 8
10/18/2013 PDCI Amendment

Flea & Tick Killer

{ABNs: R-7M® Ear Mite Treatment, R-7® Ear Care for Dogs & Cats,
HAMILTON no fly zone® plus fly spray for horses, R-7® FLEA & TICK FOR DOGS & CATS,
R-7M® EAR CARE FOR CATS and R-7® EAR CARE}

{{Select marketing claims from "Marketing Claims" section}}

Active Ingredients:

Pyrethrins (CAS No. 8003-34-7)	0.15%
Piperonyl Butoxide* (CAS No. 51-03-6)	1.50%
Other Ingredients	98.35%
Total	100.00%

*(butyl carbityl)(6-propylpiperonyl) ether and related compounds

Keep Out of Reach of Children

[CAUTION]

See back panel for [First Aid and] additional Precautionary Statements.

Net Contents: ____ fl. oz. (____ ml)
{2 fl. oz. through 1 gallon}

{Back Panel}

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS, PUPPIES, CATS, KITTENS, 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 Restrictions: Use only in a well-ventilated area. Do not contaminate food or foodstuffs. Do not use treated articles until spray has dried. Not for use in outdoor residential misting systems. Except when applying directly to pets, do not allow adults, children or pets to enter until sprays have dried and do not apply this product in a way that will contact adults, children or pets, either directly or through drift. **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. 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, immediately consult a veterinarian.

When used indoors as a space spray: do not remain in treated area; immediately exit area and remain outside the treated area until vapors and/or mists have dispersed; do not allow adults, children or pets to enter until sprays have dried; do not allow adults, children or pets to enter until vapors, mists and aerosols have dispersed and the treated area has been thoroughly ventilated; remove or cover exposed food and drinking water before application; remove or

cover dishes, utensils, food processing equipment and food preparation surfaces, or wash them before use; and remove pets/birds and cover fish aquariums before spraying.

Dogs and Cats: 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, but not to the point of saturation or run-off, 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.

[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 fl. oz., 8 fl. oz., pints 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 fl. oz. and 4 fl. oz. sizes. 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 once 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.

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.

Storage and Disposal
Do not contaminate water, food or feed by storage or disposal.
Pesticide Storage: Store in original container in a cool, dry (preferably locked) place inaccessible to children and pets and away from heat or sunlight. Pesticide Disposal: Wastes resulting from the use of

this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Non-refillable container; do not reuse or refill 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.}

[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 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 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 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.
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. [For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-755-7056 24 hours per day, 7 days per week.]</p>	

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

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

[CAUTION:] Thoroughly wash with soap and water after using and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Environmental Hazards

This pesticide is toxic to aquatic organisms including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run-off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Do not make applications during rain. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

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

To the extent not prohibited 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. _____

REV{MMYY}

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

[Manufactured by:]
GPS Group
2425 W. Dorothy Lane
Dayton, OH 45439
800-755-7056
© {Year}

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

{Front panel}

{Kit Product Name}

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

**An Ear Care Kit Containing Flea & Tick Killer {or other additional brand name} (__ fl oz)
and R-7™ Ear Cleaner {or other brand name} (__ fl oz)**

Active Ingredients:

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

Other Ingredients	98.35%
Total	100.00%

*(butyl carbityl)(6-propylpiperonyl) ether and related compounds

Keep Out of Reach of Children
[CAUTION]
See back [side] panel for [First Aid and] additional Precautionary Statements.

Net Contents: {Number} __ fl. oz. (__ ml) bottles

{Back [Side] Panel(s)}

**An Ear Care Kit Containing Flea & Tick Killer {or other additional brand name}
and R-7™ Ear Cleaner {or other brand name}**

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.

READ ENTIRE LABEL BEFORE EACH USE

Use Only on Dogs and Cats

Flea & Tick Killer

DIRECTIONS FOR USE

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

Use Restrictions: Use only in a well-ventilated area. Do not contaminate food or foodstuffs. Not for use in outdoor residential misting systems. **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. 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, immediately consult a veterinarian.

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.

Storage and Disposal

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

Pesticide Storage: Store in original container in a cool, dry (preferably locked) place inaccessible to children and pets and away from heat or sunlight. Protect from freezing. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **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.

[First Aid

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 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 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 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. Have the product container or label with you when calling a poison control center or doctor or going for treatment. [For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-755-7056 24 hours per day, 7 days per week.]

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

[CAUTION:] Thoroughly wash with soap and water after using and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

EPA Reg. No. 43576-11

EPA Est. 43576-GA-1

REV{MMYY}

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

R-7™ Ear Cleaner

Two Simple Steps to Reduce Ear Problems

Directions:

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-7M™ 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.

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.

First Aid (Human): Call a physician or poison control center.

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

Product No. _____

[Manufactured by:]

GPS Group

2425 W. Dorothy Lane

Dayton, OH 45439

800-755-7056

© {Year}

(Marketing Claims)

Kills Spinose Ear Ticks and Ear Mites
 For Dogs and Cats
 To Kill 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
 Fly Spray for Horses
 Money Back Guarantee
 If not satisfied, return unused portion to GPS Group for full refund.
 Flea & Tick Spray
 With citronella fragrance
 Ear Mite Treatment Kit
 For Dogs and Cats
 Kills Ear Mites & Ticks

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.

(End of Marketing Claims)

(Graphics)





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



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



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



{Quick Response code for 32 fluid ounce fly spray for horses}



{Quick Response code for 8 fluid ounce dog and cat spray}



{Quick Response code for 1 fluid ounce cat ear mite treatment}



{Quick Response code for 2 fluid ounce R-7 Ear Care}

{End of Graphics}

- [] Denotes alternate/optional language*
- { } Denotes language that does not appear on the market labeling*