

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 3, 2021

Kim Davis Consultant/Agent GPS Group c/o RegWest Company, LLC 8209 West 20th Street, Suite B Greeley, CO 80634-4699

Subject: Label Amendment – Deleted use directions for ear cleaner and added alternate

brand names, marketing claims, and graphics

Product Name: Flea and Tick Killer EPA Registration Number: 43576-11

Application Date: 12/23/2020 Decision Number: 579225

Dear Ms. Davis:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

The alternate brand names R-7 Ear Mite Treatment for Cats, R-7 Ear Mite Treatment for Dogs, R-7 Ear Mite Treatment Kit for Cats, and R-7 Ear Mite Treatment Kit for Dogs have been added to the product record.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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 FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list 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 substantially differ 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

Page 2 of 2 EPA Reg. No. 43576-11 Decision No. 579225

or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Kaitlin Saunders by phone at 202-566-2890, or via email at Saunders.Kaitlin@epa.gov.

Sincerely,

Elizabeth Fertich Product Manager 4 Invertebrate-Vertebrate Branch 1 Registration Division Office of Pesticide Programs

Enclosure

ACCEPTED

12/03/2021

Under the Federal Insecticide, Fungicide

and Rodenticide Act as amended, for the

43576-11

pesticide registered under

EPA Reg. No.

Flea & Tick Killer

{ABNs: HAMILTON No Fly Zone® Plus Fly Spray for Horses;

R-7[®] Ear Care;

R-7[®] Ear Care Ear Care Kit:

R-7[®] Ear Care for Dogs & Cats;

R-7[®] Ear Mite Treatment for Cats;

R-7[®] Ear Mite Treatment for Dogs;

R-7[®] Ear Mite Treatment Kit for Cats;

R-7[®] Ear Mite Treatment Kit for Dogs;

R-7M_™ Ear Care Ear Mite Treatment Kit

R-7M_™ Ear Care for Cats;

R-7M_{TM} Ear Care for Cats Ear Mite Treatment Kit; and

 $R-7M_{TM}$ Ear Mite Treatment; $R-7^{\circ}$ Flea & Tick for Dogs & Cats }

{SubLabel A: Spray bottle (container) label;

SubLabel B: Spray bottle with non-regulated ear cleaner product (copack) outer box label.}

Active	Ingredients:
,	

Pyrethrins (CAS No. 8003-34-7)	. 0.15%
Piperonyl Butoxide* (CAS No. 51-03-6)	. 1.50%
Other Ingredients	
Total	
*(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. (____ m {1 fl oz through 1 gallon} {SubLabel A: Spray bottle (container) label}

Flea & Tick Killer

{Select marketing claims and graphics from "Marketing Claims" and "Graphics" sections}

Active Ingredients:		
Pyrethrins (CAS No. 8003-34-7)	0.15	5%
Piperonyl Butoxide* (CAS No. 51-03-6))%
Other Ingredients	<u>98.35</u>	<u>5%</u>
Total	100.00)%
*(butyl carbityl)(6-propylpiperonyl) ether and	I related compounds	
	·	
Kee	p Out of Reach of Children	
	[CAUTION]	
See back panel for [Fire	st Aid and] additional Precautionary Statements.	
Not	Contents: fl. oz. (ml)	
Net	{1 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 guarters 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 {for dogs} [3 {for cats}] 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 Handling: 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:	 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	Take off contaminated clothing.
or 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 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.
I lava tha sasahvat	

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222. For general information on this product call 1-800-635-2044 or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM Pacific time or at http://npic.orst.edu.

{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, call 800-635-2044.]

To the extent consistent with 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. 89798-OH-1

[Manufactured [Made] in [the] U.S.A. [USA] for:]

GPS Group

2425 W. Dorothy Lane
Dayton, OH 45439

800-635-2044
[© {Year}]

{SubLabel B: Spray bottle with non-regulated ear cleaner product (copack) outer box label}

{Box Front panel}

{Kit Product Name}

{Select marketing claims and graphics from "Marketing Claims" and "Graphics" sections}

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)

Two Step Kit Contains Flea & Tick Killer {or other additional brand name} & R-7™ Ear Cleaner {or other brand name}

Active Ingredients:

Pyrethrins (CAS No. 8003-34-7)	0.15%
Piperonyl Butoxide* (CAS No. 51-03-6)	1.50%
Other Ingredients	
Total	
*(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} bottles - ____ fl. oz. (____ ml) each

{Box 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}

[This Kit Contains:

1 fl. oz. bottle of Flea & Tick Killer {or other additional brand name} & 2 fl.oz. bottle of 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 {for dogs} [3 {for cats}] 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 Handling: 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 medical emergencies, call the poison control center at 1-800-222-1222. For general information on this product call 1-800-635-2044 or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM Pacific time or at http://npic.orst.edu.]

R-7™ Ear Cleaner {or other product name}

Directions for Use:

Use two or three times a week to keep the ears clean and reduce ear odors. Use before and after bathing. Fill the ear canal with R-7™ Ear Cleaner {or other product name}. Gently massage the base of the ears. Use facial tissue or cotton to clean 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

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.

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

EPA Reg. No. 43576-11

EPA Est. 89798-OH-1

REV{MMYY}

[In case of questions call 800-635-2044]

Product No.

[Manufactured [Made] in [the] U.S.A. [USA] for:]

GPS Group

2425 W. Dorothy Lane Dayton, OH 45439 800-635-2044 [© {Year}]

{Marketing Claims}

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 (Used only with Citronella oil-containing formulations)

Ear Mite Treatment Kit

Kills Ear Mites & Ticks

Cleans Ears • Helps Reduce Ear Odors • Controls Ear Mites & Ticks
Free Bonus Ear Cleaner Enclosed. Helps to clean the ears, reduce ear odors and dry the ears.

Made in the U.S.A. [USA]

{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