2517-114

8/21/2009



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

August 21, 2009

Ms. Susan Kane, Regulatory Specialist Sergeant's Pet Care Products, Inc. 2625 South 158th Plaza, Suite 100 Omaha, NE 68130-1770

Subject: Amended Labeling, Addition of Label Claims and ABNs, Updated Warranty Statement and **Response to PR Notice 2007-4** Sergeant's® Pyrethrin-Pyriproxyfen Residual Ovisterilant Shampoo #1, EPA Reg. No. 2517-114 Your Submission Dated May 13, 2009

Dear Ms. Kane:

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

General Comments:

- 1. Delete all text throughout the label marked with "strikethrough."
- 2. Either correct the primary brand name by replacing "Pyrethrin" with "Pyrethrins" and striking out the word "Ovisterilant" so that it reads "Pyrethrins-Pyriproxyfen Residual Shampoo #1" or replace with another new, acceptable primary brand name.

Alternate Brand Name (ABN) section comment(s):

- Add a bolded asterisk "*" immediately following ABNs #3 and #4 and add a corresponding 3. footnote to the label which reads "*Do not apply to puppies less than 11 weeks old."
- 4. Add double bolded asterisks "**" immediately following ABN #5 and add a corresponding footnote to the label which reads "**Do not apply to kittens less than 6 months old."

Optional Marketing Statements section comment(s):

- 5. Revise optional marketing statement #2 to read "[Flea and tick shampoo with residual properties for use on dogs, cats, puppies (over 11 weeks of age) and kittens (over 6 months of age)]"
- Revise optional marketing statement #3 to read "[Nylar® IGR kills fleas and their eggs for 4 weeks]" 6.
- 7. Revise new optional marketing statement #8 to read "[Kills fleas and their eggs for up to [30 days] [One] [1] [Month] [4 weeks]]"

Ingredient Statement section comment(s):

8. Remove the brackets surrounding the asterisks (*) for piperonyl butoxide and its footnote, since the referenced footnote is not optional text. Replace the single bolded asterisk "*" for piperonyl butoxide and its corresponding footnote with triple bolded asterisks "***"

Precautionary Statements, Hazards to Humans and Domestic Animals subsection comment(s):

9. Revise this subsection to read:

"HAZARDS TO HUMANS: Harmful if swallowed or absorbed through the skin. Avoid breathing vapors. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse."

HAZARDS TO DOMESTIC ANIMALS: FOR USE ON [CATS] [AND] [KITTENS (OVER 6 MONTHS OF AGE)], [DOGS] [AND] [PUPPIES (OVER 11 WEEKS OF AGE)]. Do not treat nursing puppies and kittens. Do not apply to (use on) puppies less than eleven (11) weeks old and kittens less than six (6) months of age. Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant or nursing dogs (or cats). 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."

Directions for Use section comment(s):

10. To facilitate inclusion of language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist, add the following new subsection in its own text box immediately following the statement "It is a violation of Federal law ..." as follows:

GENERAL PRECAUTIONS & USE RESTRICTIONS

- Apply this product only as specified on this label.
- Do not contaminate of food or feedstuffs.
- Do not apply to puppies less than 11 weeks old.
- Do not apply to kittens less than 6 months old.
- Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant or nursing animals.
- 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.
- Remove birds and cover fish aquariums before spraying.
- 11. In the paragraph immediately following the new subsection added as part of Item #_ above, incorporate the following comments:
 - Insert the following text as a new 1st sentence: "FOR USE ON [CATS] [AND] [KITTENS (OVER 6 MONTHS OF AGE)], [DOGS] [AND] [PUPPIES (OVER 11 WEEKS OF AGE)] TO KILL FLEAS AND TICKS."
 - Replace the existing 3rd, 4th and 5th sentences with "Pyriproxyfen is absorbed onto, and sticks tightly to hair and skin, even after complete rinsing. This insect growth regulator (a synthetic flea hormone) kills fleas and their eggs for 1 month and breaks the flea's life cycle by preventing the development of new fleas in the pet's environment and the build-up of reinfestation pressure."

Storage and Disposal section comment(s):

12. Replace this section with:

"STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **PESTICIDE STPRAGE:** Do not store near heat or open flame. Store in original container in a cool, dry area away that is inaccessible to children or pets.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain."

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 J. Rodia, Jr. at (703) 306-0327 or via e-mail at *Rodia.Carmen@epa.gov*.

Sincerely Yours,

anen J. Poli, fr.

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments" 002517-00114 D414734

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12 May 2009AMEND ABNS, claims, warranty, storage, disposal PHASE 2EPA ReInformation in [] is optional.Page 1 of 3EPA SA

EPA Reg. No. 2517-114 EPA SAL 23 Oct 2008

FRONT PANED Pyrethrin-Pyriproxyfen Residual Ovisterilant Shampoo #1

Pyriproxyfen, pyrethrins, piperonyl butoxide, N-Octyl bicycloheptene dicarboximide [Optional text appears in brackets – the final label may include some or all of the optional text on front, back or side label panels]

Pyrethrin-Pyriproxyfen Residual Ovisterilant Shampoo #1

- {ABN: Sergeant's Gold Flea and Tick Shampoo for Dogs}
- {ABN: Sergeant's Gold Flea and Tick Shampoo for Cats} "
- ABN: SentryPro Flea and Tick Shampoo for Dogs and Puppies}
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- Martin & Constant of the and Martin and Ma
 - [Dual synergized Pyrethrins kill fleas and ticks]
 - [Flea and tick shampoo with residual ovisterilant properties for use on dogs, cats, puppies and kittens]
 - 3 [Nylar® IGR sterilizes all new fleas and kills their eggs for 4 weeks]
 - [Fast action immediately kills adult fleas and ticks]
 - [Residual action kills flea eggs for one month]
 - [Baby powder scent]
 - [Faster Action * Breaks Flea Life Cycle * Longer Lasting] (Circular bullet)

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ACTIVE INGREDIENTS:

Pyriproxyfen	0.01%
Pyrethrins	0.15%
Piperonyl Butoxide technical [*]	1.50%
N-Octyl bicycloheptene dicarboximide	0.50%
OTHER INGREDIENTS:	
[TOTAL	100.00%]

[* equivalent to 1.2% (butylcarbityl) (6-propylpiperonyl) ether and 0.03% related compounds.]

KEEP OUT OF REACH OF CHILDREN CAUTION See [Back][or][Side] Panel[s] for Additional Precautionary Statements. NET [WEIGHT] [CONTENTS] XXX oz (XXX mL)

ACCEPTED With COMMENTS In EPA Letter Dated: August 21, 2009Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

Sergeant's Master Laber

12 May 2009 AMEND ABNS, claims, warranty, storage, disposal PHASE 2

Information in [] is optional.

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SIDE/BACK PANEL

Pyrethrin-Pyriproxyfen Residual Ovisterilant Shampoo #1

Pyriproxyfen, pyrethrins, piperonyl butoxide, N-Octyl bicyclohepfene dicrboximide

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON [DOGS] [AND] [CATS]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS **CAUTION**

Do not treat nursing puppies or kittens. Do not use on puppies under 11 weeks of age and on kittens under 6 months of age. Consult a veterinarian before treating pregnant, nursing, sick, aged, debilitated, or medicated dogs [or cats]. Sensitivities may occur after using any pesticide product on pets. If signs of sensitivity occur, bathe pet with mild soap or a non-pesticidal shampoo and rinse with large quantities of water. If signs continue consult a veterinarian immediately. Wash hands with soap and water after using.

BOX OPTIONAL}

	FIRST AID
IF ON SKIN OR CLOTHING:	 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 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 further treatment advice.
IF SWALLOWED	 Call a poison control center or doctor immediately 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.
	HOT LINE NUMBER
	ontainer or label with you when calling a poison control center or doctor, or going for y also contact 1-800-781-4738 for emergency medical treatment information. exets is optional)

DIRECTIONS FOR USE

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

The dual synergistic pyrethrins provide immediate killing of fleas and ticks on the pet. Pyriproxyfen, in this special formulation*, is absorbed onto, and sticks tightly to hair and skin, even after complete rinsing. This insect growth regulator (a synthetic flea hormone) sterilizes all fleas that jump onto the pet (even new fleas before they start laying eggs) and therefore kills all flea eggs. This action persists for 1 month and breaks the flea's life cycle by preventing the development of new fleas in the pet's environment and the build-up of reinfestation pressure. Shake well before using. Wet the pet thoroughly with warm water. Apply product onto its lack at the rate of approximately 1 tablespoon for each 5 lb. bodyweight (7.5g per kg) for dogs and puppies and 1¹/₄ tablespoonful (8.5g per kg) for cats and kittens. Massage well into the skin to obtain good lathering over the entire body. Allow lather to remain in contact for at least 10 minutes then rinse off. Allow pet to air dry or blow day. To maintain effective flea life cycle control (through IGR flea egg killing) repeat treatment at least once every month. Under conditions of flea reinfestation pressure from the environment, repeat treatment when new parasites are seen on the pet, but not more frequently than once weekly on dogs and twice monthly on cats.

Sergeant's Master Label

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SIDE/BACK PANEL Pyrethrin-Pyriproxyfen Residual Ovisterilant Shampoo #1 Pyriproxyfen, pyrethrins, piperonyl butoxide, N-Octyl bicyclohepfene dicrboximide

STORAGE AND DISPOSAL DIRECTIONS

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In Case of Emergency, call: 1-800-781-4738 Non-Emergency call 1-800-224-PETS (7387) [Made in USA]

Distributed by: Sergeant's Pet Care Products, Inc. P.O. Box 540399 Omaha, NE 68154-0399 {END - BACK / SIDE PANEL}

EPA Reg. No. 2517-114 EPA Est. No. XXXXX-XX-XX

[lot, date & label code] [UPC CODE]