2517-117 3/11/2014 (Page 186

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



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MAR 1 1 2014

Sergeant's Pet Care Products, Inc. c/o Mr. John F. Wright Product and Regulatory Associates, LLC P.O. Box 1683 Voorhees, NJ 08043-9998

Subject:

Amended Reregistration Label

Product Name: Zema Ear Miticide for Dogs & Cats

EPA Registration Number: 2517-117 EPA Decision Numbers: 411006, 412244

Dear Mr. Wright,

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 Piperonyl Butoxide 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 Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated May 26, 2011

A copy of your label stamped "Accepted" 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).

If you have any questions about this letter, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,

Richard J. Gebken Product Manager (10) Insecticide Branch

mell for

Registration Division (7504P)

Enclosures:

Label stamped "Accepted"

Acute Toxicity Review, dated October 25, 2010

Product Chemistry Reviews, dated May 31, 2011 and August 29, 2013

Sergeant's Pet Care Products

Master Label

11March2014 re-registration Information in [] is optional.

Page 1 of 4

EPA Reg. No. 2517-117 EPA SAL

Front panel

ZEMA EAR MITICIDE FOR DOGS & CATS

- WITH SYNERGIZED PYRETHRINS
- FOR DOGS AND CATS
- CONTAINS LANOLIN

ACTIVE INGREDIENTS:

Pyrethrins*	0.05%
	0.50%
OTHER INGREDIENTS: ***	<u>99.45%</u>
TOTAL	100.00%

^{*}CAS # 8003-34-7

Keep Out of Reach of Children

CAUTION

See back panel for additional Precautionary Statements

Net Contents: 4 fl. Oz. (118 ml)

Side/Back panel

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND CATS
PREACUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS: CAUTION: Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash 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.

ACCEPTED MAR 1 1 2014

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 2517-117

^{**}CAS # 51-03-6

^{** (}butylcarbityl) (6-propylpiperonyl) ether and related compounds.

^{***} Contains petroleum distillates.

Sergeant's Pet Care Products

Master Label

11March2014 re-registration Information in [] is optional.

Page 2 of 4

EPA Reg. No. 2517-117 EPA SAL

-HAZARDS-TO-DOMESTIC ANIMALS:-FOR USE ON-DOGS AND PUPPIES, CATS &

KITTENS: Do not use on puppies and kittens under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing dogs and cats. Sensitivities may occur after using ANY pesticide product for dogs and cats. 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	
IF SWALLOWED:	 Immediately call a poison control center or doctor for treatment advice. Do not give any liquid to the person.
	 Do not induce vomiting unless told to do so by poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR	Take off contaminated clothing.
CLOTHING:	 Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICL pneumonia.	AN: Contains petroleum distillates. Vomiting may cause aspiration
Have the product conta	ainer or label with you when calling a poison control center or doctor, or
•	ou may also contact 1-800-781-4738 for emergency medical treatment

DIRECTIONS FOR USE

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

USE RESTRICTIONS

Do not apply to dogs and cats less than 12 weeks old.

Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing dogs and cats.

Sensitivities may occur after using any pesticide product for dogs and cats. If signs of sensitivity occur bathe your dog or cat with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

To be used as an aid in eliminating mites and ticks in the ears of [dogs] [cats] or [dogs or cats] and for relief from itching caused by such conditions. Apply 5 drops into ears twice daily until ticks and mites are eliminated. Do not allow children to apply this product. Use other EPA approved products for treatment of mites and ticks outside the ear.

5 26

Sergeant's Pet Care Products

Master Label

11March2014 re-registration Information in [] is optional.

Page 3 of 4

EPA Reg. No. 2517-117 EPA SAL

INDICATIONS: Ear mites normally cause dry, dark brown waxy exudates with crusts in the ears of dogs and cats. Mites are easily observed by placing some of the ear wax on a dark surface and watching closely for moving white specks. Do not injure the delicate tissue of the ear. Inflamed, watery or blocked ear canals indicate a more serious condition which requires services of a veterinarian.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in original container in a cool, dry area away that is inaccessible to children or pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or 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.

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. [[The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks inherently associated with the use of this product. Unintended consequences may result because of such factors as weather conditions, presence or absence of other materials, or the manner of application, all of which are beyond the control of Sergeant's.] Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller disclaims any liability whatsoever for special, incidental, or consequential damages resulting from the use of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: Sergeant's Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 Non-Emergency call: 1-800-224-PETS (7387) [Made in USA] EPA Reg. No. 2517-117 EPA Est. No. XXXXX-XX-XX [lot, date & label code] [UPC CODE] Sergeant's Pet Care Products
11March2014 re-registration

Master Label

Information in [] is optional.

Page 4 of 4

EPA Reg. No. 2517-117 EPA SAL

Manufactured by [for]: [Distributed-by:]——Sergeant's Pet Care Products, Inc. P.O. Box 540399 Omaha, NE 68154-0399