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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES. AND TOXIC SUBSTANCES

SEP 2 3 2008

Sergeant's Pet Care Products, Inc. c/o RegGuide Sharon M. Johnston 509 Tower Valley Drive Hillsboro, MO 63050

Dear Ms. Johnston:

Subject:

Label amendment in response to propoxur RED and efficacy DCI

Sergeant's Dual Action Flea & Tick Collar

EPA Registration No. 2517-61 Submission Date: March 11, 2008

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided you make the following changes before you release the product for shipment bearing the amended labeling:

- Correct the spelling of "scent."
- Under the Precautionary Statements, delete the word "intended" in the eight sentence so it reads, "Collar is for external use only."
- Delete the following claims:
  - "Long Lasting Protection"
  - "Long Lasting Protection 6 months"
  - "Gentle"
  - "Kills The Ticks That Carry Lyme Disease [Rocky Mountain Spotted Fever] [Ehrlichiosis]"
  - "Thus, collar has the effect of simultaneous usage of a spray and powder in the control of fleas and ticks, including ticks that may carry [Rocky Mountain Spotted Fever] [Lyme disease] [Ehrlichiosis]."
  - "Wetting collar will not impair collar's effectiveness."
  - "It is not necessary to remove collar if pets go swimming or are out in the rain."

#### Revise the following:

- "Fast-Acting" and "Quick Kill" to "Works in as little as twenty-four hours."
- "Kills Fleas and Ticks for 6 months" to Kills fleas and aids in tick control on dogs for up to four months." "Kills fleas and aids in tick control on cats for up to three months."
- Revise "This collar kills fleas and ticks for 6 months" to This collar kills fleas and aids in tick control on dogs for up to four months." "This collar Kills fleas and aids in tick control on cats for up to three months."
- "Collar is a double-layer sustained-release system containing three active ingredients combining the insecticidal actions of vapors and powders, working in [two][three] ways to provide fast acting quick kill and long-lasting head to tail protection" to "Collar is a double-layer sustained-release system containing three active ingredients combining the insecticidal actions of vapors and powders.
- "Thus, collar has the effect of simultaneous usage of a spray and powder in the control of fleas and ticks, including ticks that may carry [Rocky Mountain Spotted Fever] [Lyme disease] [Ehrlichiosis]." to "Thus, collar has the effect of simultaneous usage of a spray and powder."
- "Replace every 6 months" to "Replace every three months for cats and four months for dogs."
- "Under conditions of severe infestation and where continued rapid kill is desired, collar may be replaced more often" to "Replace every three months for cats and four months for dogs. Under conditions of severe infestation, collar may be replaced more often."
- NOTE: Should you wish to add/retain a reference to the company's website on your label, the website then 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 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 Assurance.

Approval of this labeling amendment does not constitute approval of your application for reregistration of this product. Product reregistration is currently pending and future labeling amendments and/or additional data may be required.

You must submit one (1) copy of the final printed label before you release the product for shipment. Products shipped after 12 months from the date of this Notice or the next printing of the label whichever occurs first, must bear the new revised label. A stamped copy of the label is enclosed for your records. Should you have any questions, please contact Julie Chao at 703-308-8735 or <a href="mailto:chao.julie@epa.gov">chao.julie@epa.gov</a>.

Sincerely,

John Hebert

Insecticide-Rodenticide Branch Registration Division (7505P)

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**Enclosure** 

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## Sergeant's Master Label

11 March 2008 propoxur DCI Information in [ ] is optional.

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DRONT PANDLE

rage 1 01 3

DOG COLLAR Propoxur, Phenothrin, MGK 264

Editors Note: [Optional proposed text appears in brackets - the final label may include some or all of the optional text]

### Sergeant's Dual Action Flea & Tick Collar (with d-phenothrin)

{ABN} [Bansect Flea & Tick Collar for Dogs]

[Pet ID Collar info and logo]

{ABN} [Bansect Flea & Tick Collar for Cats]

{ABN} [Sergeant's Triple Protection Flea & Tick Collar]

{ABN} [Sergeant's Dual Action Flea & Tick Collar for Cats]

[ABN] [Sergeant's Dual Action Flea & Tick Collar for Small Dogs & Puppies]

{ABN} [Sergeant's Dual Action Flea & Tick Collar for Dogs]

{ABN} [Sergeant's Dual Action Flea & Tick Collar for Large Dogs]

{ABN} [Sentry PurrScriptions Dual Action Flea & Tick Collar for Cats]

{ABN} [Sentry Dual Action Flea & Tick Collar for Small Dogs & Puppies]

{ABN} [Sentry Dual Action Flea & Tick Collar for Dogs]

{ABN} [Sentry Dual Action Flea & Tick Collar for Large Dogs]



• For [Dogs], [Large Dogs], [Medium Dogs] [Small Dogs & [Puppies] [small breeds], [Cats]

• [Fast Acting]

• [Quick Kill]

• [Kills [Fleas & Ticks] for 6 months]

• [Deodorizes]

• [Deodorizing]

• [Long Lasting Protection]

• [Long Lasting Protection 6 months]

• [Gentle]

• [[Fresh] [Powdery] [Clean] Sent]

ACCEPTED
With COMMENTS
In EPA Letter Dated:

SEP 2.3 2008 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

2517-61

- [Kills The Ticks That Carry [Lyme Disease] [Rocky Mountain Spotted Fever] [Ehrlichiosis]
- Fits Neck to [12.5"] [14"] [20"] [26"]
- Fits Neck to [specific inch size]

{Ingredient Statement may be on front or back label}

#### **ACTIVE INGREDIENTS:**

Propoxur	. 9.00%
d-(cis,trans) phenothrin*	
n-Octyl bicycloheptene dicarboximide	
OTHER INGREDIENTS:	
TOTAL	100.00%

<sup>\*</sup>cis/trans isomer ratio": Max. 25% (+/-) cis Min. 75% (+/-) trans

## DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR CAUTION

See [Back][or][Side] Label [Panel(s)] for Additional Precautions
[See Additional Precautions on Back]
Net Weight: XX

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## Sergeant's Master Label

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BACK PANEL

SECTO BILL

DOG GODLAR Propoxur, Phenothrin, MGK 264

### {Product Name}

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON [DOGS] [MEDIUM DOGS] [SMALL BREEDS] [PUPPIES] [CATS] [KITTENS]

#### [IMPORTANT CONSUMER INFORMATION]

[[[Product Name] [This collar] kills fleas and ticks for 6 months. Collar is a [double layer] sustained-release system [containing three active agents] combining the insecticidal actions of vapors and powders, working in [two] [three] ways to provide fast acting [quick kill] and long lasting head-to-tail protection. Thus, collar has the effect of simultaneous usage of a spray and powder in the control of fleas and ticks, including ticks that may carry [Rocky Mountain Spotted Fever] [Lyme disease] [Ehrlichiosis]. Wetting collar will not impair collar's effectiveness. It is not necessary to remove collar if pets go swimming or are out in the rain. Use [Product Name] year round for most effective control. [Replace every 6 months.]]

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Do not open until ready to use. Dust will form on collar during storage. Do not get dust in mouth or eyes. Harmful if swallowed. If in eyes will cause eye irritation. In case of contact, flush eyes with water. If irritation persists, get medical attention. Collar is intended for external use only, not to be taken internally. Some animals may become irritated by any collar. If this occurs, remove collar. If condition persists, consult a veterinarian. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Do not use on pets under 12 weeks of age. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur remove collar and bathe your pet with mild soap and rinse with large amounts of water. Notice: This product contains a chemical (o-Isopropoxyphenyl methylcarbamate) known to the State of California to cause cancer.

FIRST AID	
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice.
	Have person sip of glass of water if able to swallow.
'	Do not induce vomiting unless told to do so by the poison control
	center or doctor.
_	Do no 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 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.
IF ON SKIN OR	Take off contaminated clothing.
<b>CLOTHING:</b>	• Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product co	ontainer or label with you when calling a poison control center or doctor, or
going for treatment	You may contact 1-800-781-4738 for emergency medical treatment

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information.

#### NOTE TO PHYSICIAN/VETERINARIAN:

Dust release by this collar is a cholinesterease inhibitor. Atropine is antidotal. Do not use this product on animals simultaneously or within 30 days or after treatment with or exposure to cholinesterease inhibiting drugs, pesticides or chemicals. However, flea and tick collars may be immediately replaced.

#### **DIRECTIONS FOR USE**

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

Place collar around pet's neck, adjust for fit, and buckle in place. The collar must be worn loosely to allow for growth of the pet and to permit the collar to move about the neck. Generally, a properly fitted collar is one that when fastened, will snugly slide over pet's head. Leave 2 or 3 inches for extra adjustment. Cut off and dispose of excess length. Wash hands after installing collar on pet. Under normal conditions, replace collar every 6 months. Under conditions of severe infestation and where continued rapid kill is desired, collar may be replaced more often.

#### [(INSERT DIAGRAM THAT DEPICTS DOUBLE LAYER PROTECTION OF PRODUCT)]

#### STORAGE AND DISPOSAL

STORAGE: Store unopened collar in a cool, dry place. Protect from freezing.

**DISPOSAL:** Dispose of empty pouch and expired collar in trash.

[NOTICE OF WARRANTY: To the extent consistent with applicable law, Sergeant's Pet Care Products, Inc. makes no warranty of merchantability, fitness for any particular purpose, or otherwise expressed or implied concerning this product or its uses which extend beyond the use of the product under normal conditions in accordance with the statements made on this label.]

Sergeant's Pet Care Products, Inc. is committed to providing high quality products. 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)

[For more information] [Visit us at:] <u>www.sergeants.com</u> [Made in USA]

Distributed by: Sergeant's Pet Care Products, Inc. Omaha, NE 68130 {END - BACK / SIDE PANEL} EPA Reg. No. 2517-61 EPA Est. No. XXXXXXX {date & label code}