

2517-78

06-08-2011

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



JUN 08 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Sergeant's Pet Care Products, Inc.
c/o Deborah Chadbourne
Deborah Chadbourne LLC Attorney-at-Law
592 Bierys Bridge Road
Bethlehem, PA 18017

Dear Ms. Chadbourne:

Subject: Amendment reconsider label changes required by Re-registration letter dated 9/23/08 concerning efficacy claims by re-examining previously submitted data Sergeant's Sendran Flea & Tick Collar EPA Registration No. 2517-78 Your Submissions Dated January 13, 2011

The efficacy review attached dated 6/8/11 supersedes the review previously emailed to you dated 5/31/11. It seems as though the data supporting a 10% collar continue to be allowed to be bridged to your 9% collar and the new memo revises any statements that didn't allow or review data on 10% collars. Please refer to this memo for further details and clarifications.

Most of the conditions outlined in the reregistration letter dated 9/23/08 are still applicable. The claims that will now be allowable to be added onto your label include:

- Controls fleas on cats for up to 5 months.
- Kills [adult] fleas which may cause flea bite anemia
- Kills [adult] fleas which may cause flea allergy dermatitis
- Kills [adult] fleas which may transmit tapeworms

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable provided you make the following changes as required in the reregistration letter (unless otherwise noted):

Delete the following claims:

1. "Fast-Acting"
2. "Quick Kill"
3. "Kills the Ticks that Carry Lyme Disease [Rocky Mountain Spotted Fever][Ehrlichiosis]"

- 4. "Thus, collar controls fleas and tick, including ticks that may carry [Rocky Mountain Spotted Fever][Ehrlichiosis]"
- 5. "Wetting collar will not impair collar's effectiveness"
- 6. "It is not necessary to remove collar if pets go swimming or are out in the rain"

Revise the following claims:

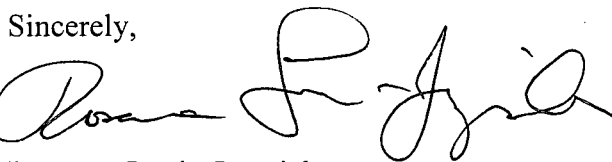
- 1. Kills Fleas and Ticks for (3)(4)(5) months [(90)(120)(150)days]" to read "controls fleas for up to five months (140 days) on cats and four months on dogs. Aids in the control of ticks on dogs for up to four months" *
- 2. "This collar kills fleas and ticks for (3)(4)(5) months" to read "controls fleas for up to 5 months on cats and four months on dogs. Aids in control of ticks on dogs for up to 4 months."
- 3. "collar is a double layer sustained-release system working to provide fast acting [quick kill] and long-lasting head-to-tail protection" to read "Collar is a double layer sustained-release system."
- 4. "Under normal conditions, replace collar ever (3)(4)(5) months. Under conditions of severe infestation and where rapid kill is desired, collar may be replaced more often" to read "Replace every 4 months. Under conditions of severe infestation, collar may be replaced more often." *

Other required changes:

Revise the claim that says "[For [Dogs], [Large Dogs], [Small Dogs & [Puppies], [Cats]" to read "[For [Dogs], [Large Dogs], [Small Dogs & [Puppies over 12 weeks of age], [Cats over 12 weeks of age]" unless Companion Animal Safety data can be provided for animals younger than this age restriction.

***denotes was revised per this amendment**

A stamped copy of the labeling is enclosed for your records. Please submit one final printed copy of the labeling before releasing the product for shipment. If you have any questions regarding this label, please contact Autumn Metzger at (703) 305-5314.

Sincerely,


Rosanna Louie-Juzwiak
 Acting Product Manager 7
 Insecticide-Rodenticide Branch
 Registration Division (7505P)

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FRONT PANEL	DOG-COLLAR Propoxur
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Editors Note: [Optional proposed text appears in brackets – the final label may include some or all of the optional text]

Sergeant's Sendran Flea & Tick Collar

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

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

- [Fits Neck to [12.5"] [14"] [20"] [26"] inches]
- [For [Dogs], [Large Dogs], [Small Dogs & [Puppies], [Cats]
- [Fast Acting]
- [Quick Kill]
- [Kills [Fleas & Ticks] for (3) (4) (5) months] [(90) (120) (150) days]
- [Fresh] [Clean] [Scent]
- [Kills The Ticks That May Carry [Lyme Disease] [Rocky Mountain Spotted Fever]
- [Kills [adult] fleas which may cause flea bite anemia.]
- [Kills [adult] fleas which may cause flea allergy dermatitis.]
- [Kills [adult] fleas which may transmit tapeworms.]

{Ingredient Statement may be on front or back label}

ACTIVE INGREDIENTS:

Propoxur [o-Isopropoxyphenyl methylcarbamate] [CAS #114-26-1]	9.00%
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OTHER INGREDIENTS:	91.00%
[TOTAL]	100.00%

**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

ACCEPTED

With COMMENTS

In EPA Letter Dated:

JUN 08 2011

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

2517-78

Sergeant's Master Label

AMEND 13JAN2011 CLEAN
Information in [] is optional.

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EPA SAL 23 Sep 2008

BACK PANEL

DOG COLLAR
Propoxur

{Product Name}

READ ENTIRE LABEL BEFORE EACH USE.

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

IMPORTANT CONSUMER INFORMATION

[[**Product Name**] [This collar] kills fleas and ticks for (3)(4)(5) months. Collar is a [double layer] sustained-release system, working to provide fast acting [quick kill] and long lasting head-to-tail protection. Thus, collar controls fleas and ticks, including ticks that may carry [Rocky Mountain Spotted Fever] [Lyme disease]. Wetting collar temporarily will not impair collar's effectiveness. Use [**Product Name**] year round for most effective control. [Replace every three (3) (4) (5) months.]]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HAZARDS TO HUMANS: 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.

HAZARDS TO DOMESTIC ANIMALS: 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. If signs continue, consult a veterinarian immediately. [Notice: This product contains a chemical (o-Isopropoxyphenyl methylcarbamate) (Propoxur) 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 not give anything by mouth to an unconscious person.

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.

HOT LINE NUMBER

Have the product container 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 information.

NOTE TO PHYSICIAN/VETERINARIAN:

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

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Information in [] is optional.

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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 three (3) (4) (5) 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

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

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. Dispose of expired collar in trash.

[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 adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer.]] 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 shall not be liable for indirect, special, incidental or consequential damages. 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 [Product coupons]

Non-Emergency call 1-800-224-PETS (7387) [Made in USA] {lot, date & label code}

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68130-0399

[BAR CODE AREA]
EPA Reg. No. 2517-78
EPA Est. No. XXXXXXXX

{END - BACK / SIDE PANEL}