

68086-9

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 23, 2012

Mr. Kevin R. Kutcel
Authorized Agent for Synergy Labs
c/o KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256-6345

**Subject: Amended Labeling; Response to Rejection of Notification for PR Notice 98-10
Groomers Blend Flea & Tick Shampoo, EPA Reg. No. 68086-9
Your Submission Dated July 26, 2012**

Dear Mr. Kutcel:

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

General Comment(s):

1. The newly added/proposed alternate brand name (ABN) "**Clinical Care Flea & Tick Shampoo**" is not acceptable since it implies heightened performance and is also considered false and misleading to the consumer; therefore, you must delete the listing of the proposed ABN and replace it with the active name for this product to read "**Groomers Blend Flea & Tick Shampoo.**"

Front Panel section comment(s):

2. In order to incorporate required additional label changes from pages 104 & 128-129 of the revised RED for permethrin (May 2009), you must revise the statement "**USE ONLY ON DOGS AND CATS**" that is currently listed on the front panel of the subject product packaging to read "**USE ONLY ON DOGS AND PUPPIES (OLDER THAN 12 WEEKS OF AGE). DO NOT USE ON CATS OR KITTENS.**"

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

3. In order to incorporate required additional label changes from pages 104 & 128-129 of the revised RED for permethrin (May 2009), you must make the following changes:
 - Revise the 4th sentence within this subsection to read "Do not use on puppies less than 12 weeks of age."
 - All cat warning labels must have language placed within a shaded text box within the precautionary statements. The coloring of the box and text will be such to provide a contrasting color to other label text. In addition, each label must include at least one (1) cat slash icon which may be in the shaded box or in other areas on the subject label. The shaded box must contain the following:

DO NOT USE ON CATS OR KITTENS. May be toxic or potentially fatal if applied to or ingested by cats.
Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

Please note that these statements are being required on ALL permethrin pet products, including spot-on products, because permethrin is known to be very toxic to cats.

Directions for Use section comment(s):

4. In order to incorporate required additional label changes from the REDs for pyrethrins and piperonyl butoxide (updated label table for pyrethrins/piperonyl butoxide combo products) and the revised RED for permethrin (May 2009), you must revise the existing 7th sentence within this section to read "Do not use on nursing puppies under 12 weeks of age. **DO NOT USE ON CATS OR KITTENS. Do not treat cats or their bedding. This product may be toxic or potentially fatal if applied to or ingested by cats or kittens.**"

Please note that these statements are being required on ALL permethrin pet products, including spot-on products, because permethrin is known to be very toxic to cats.

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

Sincerely yours,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND CATS**

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Harmful if swallowed. Avoid contact with eyes. Do not use on puppies or kittens under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, or nursing animals or animals on medication. 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.

FIRST AID	
IF SWALLOWED	Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
IF IN EYES	Causes moderate eye irritation. Avoid contact with eyes or clothing. 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.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Clinical Care Flea & Tick Shampoo

With Aloe & Lanolin
Controls Fleas & Ticks on Contact

CLEANS, DEODORIZES & CONDITIONS COAT & SKIN

ACTIVE INGREDIENTS:

Permethrin ((3-Phenoxyphenyl) methyl (+/-) cis/trans-3 (2,2-dichloroethenyl) - dimethyl cyclopropanecarboxylate).....0.25%
INERT INGREDIENTS:.....99.75%

**Gently cleanses and exfoliates skin & coat.
Leaves the coat soft and lustrous.**

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panels for Additional Precautionary Statements

MANUFACTURED BY:
SYNERGY LABS
3333 SE 14th Ave.
Ft. Lauderdale, FL 33316

EPA Registration No. 68086-9
EPA Establishment No. 68086-FL-01

Net Contents _____ oz.

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

When shampooing animal, avoid eyes. Use cloth or sponge to shampoo around animal's eyes. Wear rubber gloves (mitts) when applying this product. Thoroughly wet the entire hair-coat with warm water and then apply enough shampoo to make a lather and work thoroughly into the hair-coat. For maximum parasite control allow lather to remain in contact with skin for five to minutes before rinsing. Do not reapply product for 7 days. Do not use on nursing puppies or kittens under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals, or animals on medication.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place.
DISPOSAL: If empty: Do not reuse this container. 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.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of emergency, call the National Pesticide Information Center at 800-858-7378.

**ACCEPTED
With COMMENTS
In EPA Letter Dated:
October 23, 2012**
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

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