



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 27, 2017

Sharon M. Johnston
Regulatory Consultant
Bio-Derm Laboratories, Inc. c/o RegGuide
509 Tower Valley Drive
Hillsboro, MO 63050

Subject: Amended Reregistration Label
Product Name: Bio-Groom Ear Mite Treatment
EPA Registration Number: 15297-19
Decision Number: 410353, 412515

Dear Ms. Johnston:

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 Pyrethins/Piperonyl Butoxide RED, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

NOTE: This product is **not** yet being reregistered under section 4(g) of FIFRA.

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 Any previously dated CSFs are superseded.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 11/04/2014
- Alternate CSF 1, dated 11/04/2014

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website 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.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment or the next printing of the label, whichever occurs first, must bear the

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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 section 6.

If you have any questions about this letter, please contact Tim Ciarlo by phone at 703-347-8082, or via email at Ciarlo.Timothy@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gene Benbow".

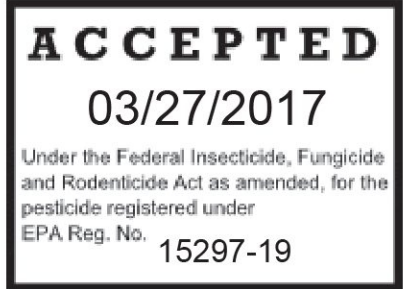
Gene Benbow, Acting Product Manager 4
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

BIO-GROOM®
Ear Mite Treatment

WITH ALOE VERA
FOR DOGS, PUPPIES, CATS, KITTENS, RABBITS

Kills Ear Mites and Ear Ticks

Aids in Ear Wax Removal
Plastic Applicator Bottle
Non-Sticky/Non-Oily



ACTIVE INGREDIENTS:

Pyrethrins..... 0.15%
Piperonyl Butoxide*..... 1.50%

OTHER INGREDIENTS:..... 98.35%
TOTAL 100.00%

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

See side/back panel(s) for additional precautions.

EPA Reg. No. 15297-19

EPA Est. No.

Manufactured By:
Bio-Derm Laboratories, Inc.
PO Box 8070
Longview, TX 75607
Telephone: 800-762-0232
www.biogroom.com

Net Contents:

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS, CATS & RABBITS**

Kills Ear Mites and Ear Ticks, Aids in Ear Wax Removal, Contains Aloe Vera

DIRECTIONS FOR USE

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

USE RESTRICTIONS:

- Apply this product only as specified on this label.
- Do not contaminate animal feed or water during application.
- Do not allow the product to enter any drain during or after application
- Not for use in outdoor residential misting systems.
- Do not apply to pets less than 12 weeks 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.

To control spinose ear ticks and ear mites and to remove ear wax, apply 10 drops to each ear. Massage base of ear a few minutes to assist penetration of the ear wax by the solutions. Allow pet to shake its head. Wipe excess solution from the ear with cotton. Repeat every 2 days until condition has cleared up or as directed by your veterinarian. As a preventative treatment, apply this solution every 15 days to reduce ear mite and ear tick infestation and ear wax accumulation.

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool, dry place in an area that is inaccessible to children and animals. Store in original, sealed container away from food or feed.

Pesticide Disposal and Container Handling: Non-refillable 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.

FIRST AID

- | | |
|--------------------|---|
| If in eyes: | <ul style="list-style-type: none">• 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. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-222-1222.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution: 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.

PHYSICAL AND CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

NOTICE: To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herewith.

Product Batch Code No. _____

BOTTLE LABEL – 1 fl. oz.
FRONT

**BIO-GROOM
EAR MITE TREATMENT**

With Aloe Vera
For Dogs, Puppies,
Cats, Kittens, Rabbits

Kills Ear Mites and Ear Ticks

ACTIVE INGREDIENTS:

Pyrethrins 0.15%

Piperonyl Butoxide* 1.50%

OTHER INGREDIENTS: 98.35%

TOTAL 100.00%

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

**KEEP OUT OF REACH OF CHILDREN
CAUTION**
See carton/box/outer packaging for additional precautions.

Net Contents: 1 fl. oz.

BOTTLE LABEL – 1 fl. oz.
BACK

See carton/box/outer packaging for complete precautionary statements and directions for use.

Manufactured By:
Bio-Derm Laboratories, Inc.
PO Box 8070
Longview, TX 75607
Telephone: 800-762-0232
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