

15297-19

3/1/2010

1 of 8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 1 2010

Ms. Marla K. Jackson
Bio-Derm Laboratories, Inc.
P.O. Box 8070
Longview, TX 75607

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Ms. Jackson:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 2007-4 dated January 28, 2010 for the following product(s):

Bio-Groom Ear Mite Treatment; EPA Reg. No. 15297-19

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

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 nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Regina Foushee'-Smith at 703-605-0780.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken".

Richard J. Gebken
Product Manager
Insecticide Branch
Registration Division (7505P)

2008



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 15297-19	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bio-Groom Ear Mite Treatment	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Bio-Derm Laboratories, Inc. P.O. Box 8070 Longview, TX 75607 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar in composition and labeling to: EPA Reg. No. <u>MAR 1 2010</u> Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application.

Notification - Explain below. Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR 156.10, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

~~1. Material This Product Will Be Packaged In:~~

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt

~~3. Location of Net Contents Information
 Label Container~~

~~4. Size(s) Retail Container~~

~~5. Location of Label Directions~~

~~6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled Other _____~~

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Marla K. Jackson	Title Agent for Bio-Derm Laboratories, Inc.	Telephone No. (Include Area Code) 972-939-8390
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.

6. Date Application Received (Stamped)

2. Signature 	3. Title Agent for Bio-Derm Laboratories, Inc.
4. Typed Name Marla K. Jackson	5. Date 01/28/2010

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Brazos Associates, Inc.®

1806 Auburn Drive • Carrollton, TX 75007-1451
Phone: 972-939-8390 • Facsimile: 972-939-8370

By Courier Delivery

January 28, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Richard Gebken
Product Manager 10

Dear Mr. Gebken:

Subject: Notification
Bio-Groom Ear Mite Treatment
EPA Reg. No. 15297-19

This submission is being made on behalf of our client, Bio-Derm Laboratories, Inc. We are providing the attached Notification to revise labeling as requested in PR-Notice 2007-4. One (1) copy of draft labeling is enclosed with the changes underscored.

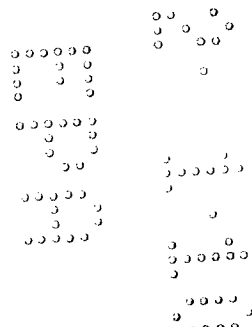
Should you have any questions or require additional information please do not hesitate to contact us.

Sincerely,

Marla K. Jackson
Agent for Bio-Derm Laboratories, Inc.

cc: Frank Pohl - Bio-Derm Laboratories, Inc.

Attachments as noted



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[BIO-GROOM EAR MITE TREATMENT 1 FL.OZ. CARTON LABELING - FRONT PANEL(21.875 sq.in. front panel area). *NOTE: The minimum type size for all text on this label will be at least six point unless otherwise specified*]

BIO-GROOM®

NOTIFICATION

MAR 1 2010

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, technical 1.50%

INERT INGREDIENTS: 98.35%
100.00%

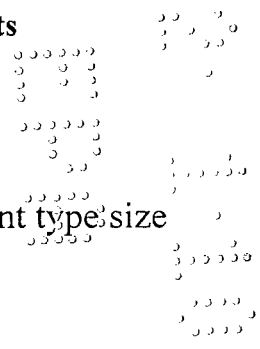
*Equivalent to 1.2% (butylcarbityl)(6-propylpiperonyl) ether and min. 0.3% related compounds.

KEEP OUT OF REACH OF CHILDREN [minimum 10 point type size]

CAUTION [minimum 14 point type size]

See back panel for additional precautionary statements

NET CONTENTS 1 FL.OZ. (29.6 mL) [minimum 10 point type size recommended]



5 of 8

[BIO-GROOM EAR MITE TREATMENT 1 FL.OZ. CARTON LABELING - BACK PANEL]

BIO-GROOM[®] EAR MITE TREATMENT

FOR DOGS, PUPPIES, CATS, KITTENS, RABBITS

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

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

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. 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 solution. 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. Do Not Use on Dogs, Cats or Rabbits Under 12 Weeks of Age. Consult a veterinarian before using this product on debilitated, medicated, aged, pregnant or nursing animals.

STORAGE AND DISPOSAL [minimum 10 point type size]

Pesticide Storage: Store in a cool, dry area. Always store pesticides in the original container. Store away from food and pet food.

Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. **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 or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or inhaled. Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after using. Do not contaminate food or foodstuffs with this solution. Avoid contact with animal's eyes. 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

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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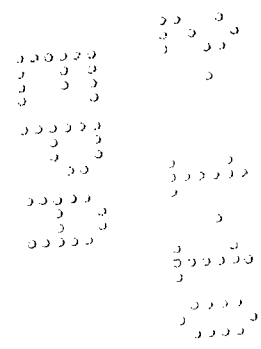
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none">• 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 on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
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.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

EPA Reg. No. 15297-19
EPA Est. No. 15297-TX-1

[Bar Code Placement]

Manufactured by
BIO-DERM[®] LABORATORIES, INC.
P.O. BOX 8070
LONGVIEW, TX 75607 USA
Telephone: 800-762-0232



7028

[BIO-GROOM EAR MITE TREATMENT 1 FL.OZ. BOTTLE LABELING - FRONT PANEL(1.53 sq.in. front panel area). *NOTE: The minimum type size for all text on this label will be at least six point unless otherwise specified*]

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, technical	1.50%

INERT INGREDIENTS:	<u>98.35%</u>
	100.00%

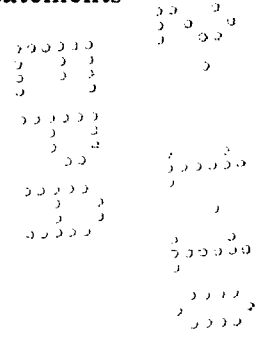
*Equivalent to 1.2% (butylcarbityl)(6-propylpiperonyl) ether and min. 0.3% related compounds.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See accompanying carton label for additional precautionary statements

NET CONTENTS 1 FL.OZ. (29.6 mL)



8 of 8

[BIO-GROOM EAR MITE TREATMENT 1 FL.OZ. BOTTLE LABELING - BACK/SIDE PANEL]

**For Complete Precautionary Statements and Directions for Use
See Accompanying Carton Label**

Manufactured by
BIO-DERM[®] LABORATORIES, INC.
P.O. BOX 8070
LONGVIEW, TX 75607 USA
Telephone: 800-762-0232

EPA Reg. No. 15297-19
EPA Est. No. 15297-TX-1

REVISED: 01-25-10
S:\MAIN\BIO-DERM LABORATORIES\LABELS\BIO-GROOM EAR MITE 1 FL OZ LABEL

