

15297-19

2/12/2002

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Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 15297-19	2. EPA Product Manager Marion Johnson	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 2(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION FEB 12 2002
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 "Notification of label change relative to PR Notice 2001-6. This notification is consistent with the guidance in PR Notice 2001-6 and the requirements of EPA's regulations at 40 CFR 156.10 and 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of 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 notification is not consistent with the guidance of PR Notice 2001-6 and the requirements of 40 CFR 156.10 and 40 CFR 152.46, 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:				2. Type of Container	
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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> 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) 972-323-9840
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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 or 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 12/21/2001		

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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®

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

NOTIFICATION

FEB 12 2002

ACTIVE INGREDIENTS:

Pyrethrins 0.15%

*Piperonyl butoxide, technical 1.50%

INERT INGREDIENTS: 98.35%

100.00%

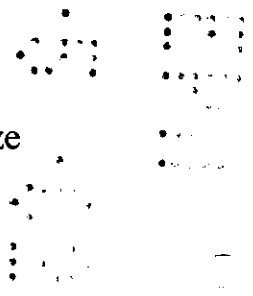
*Equivalent to 1.2% (butylcarbityl)(6-propylpiperonyl) ether and min. 0.3% related compounds.

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]



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[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]

Storage: Store in original, closed container 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 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 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

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[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)

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**[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**

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