

152 97-9



04-15-2010
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Bio-Dem Laboratories, Inc.
c/o Ms. Marla K. Jackson
Brazos Associates, Inc.
1806 Auburn Drive
Carrollton, TX 75007

APR 15 2010

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

Dear Jackson:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated for March 30, 2010

EPA Registration Number: 15297-9 Bio-Groom Repel-35 Insect Control Spray

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 non-refillable 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 Melody Banks on 703 305-5413.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard Gebken".

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



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 15297-9	2. EPA Product Manager George LaRocca	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bio-Groom Repel-35 Insect Control Spray	PM# 13	
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 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 _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION

APR 15 2010

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:				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	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
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) 972-939-8390
<p align="center">Certification</p> <p>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.</p>		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Bio-Derm Laboratories, Inc.	
4. Typed Name Marla K. Jackson	5. Date 03/30/2010	

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[CONTAINER LABEL - FRONT PANEL]

NOTIFICATION

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BIO-GROOM

LASTING RESIDUAL ACTION

Repel - 35

Insect Control Spray

- [• For Horses]
- [• For Horses and Dogs]
- [• Controls Fleas and Ticks on Dogs for 35 Days]
- [• Water Base Formula] [with Lanolin and Aloe]

[] - Denotes optional language

ACTIVE INGREDIENT:

*Permethrin..... 0.50%

OTHER INGREDIENTS:..... 99.50%

TOTAL: 100.00%

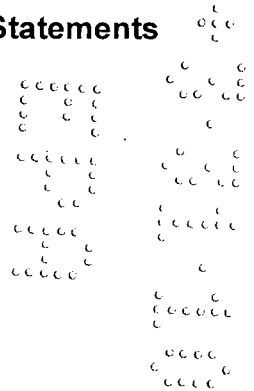
* (3-Phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl)2,2-dimethylcyclopropanecarboxylate.
Cis/trans ratio: min. 35%(+/-) cis and max.65%(+/-) trans.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back/Side Label Panel for Additional Precautionary Statements

Net Contents _____



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[Back/Side Label Panel]

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

Residual action protects horses from Horn flies, Face flies, Horse flies, Mosquitoes and Gnats. Kills Lice and Louse eggs, Ticks and Fleas (adults and larvae) on Dogs.

DIRECTIONS FOR USE

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

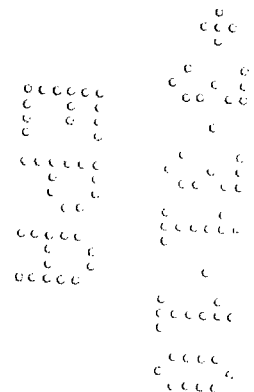
SHAKE WELL BEFORE USING. ON HORSES: Apply REPEL-35 to a clean coat. Brush animal thoroughly to remove loose dirt and dust or bathe the animal with BIO-GROOM GOLDEN SHEEN Conditioning Shampoo. Allow Coat to dry before applying REPEL-35. For protection from flies, mosquitoes and gnats: Apply at a rate of 2 Fl. Oz. per adult animal, sufficient to wet the hair thoroughly. Avoid spraying into eyes, wipe-on or around eyes. Repeat every four weeks if required, as prescribed by a veterinarian. Reapply after animal has been washed or soaked by rain.

ON DOGS: To control fleas, ticks and lice: Start spraying at the tail, moving the dispenser rapidly and making sure the animal's entire body is covered, including the legs and underbody. While spraying, fluff the hair so that the spray will penetrate to the skin. Make sure spray wets thoroughly. Do not spray into eyes or face. Avoid contact with genitalia. Repeat every 35 days, if needed. Do not use on puppies under 12 weeks. Do not use on cats or kittens. Consult a veterinarian before using on debilitated, medicated, aged, pregnant or nursing animals.

STORAGE AND DISPOSAL

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 for disposal instructions. Never place unused product down any indoor or outdoor drain.



[Back/Side Label Panel]

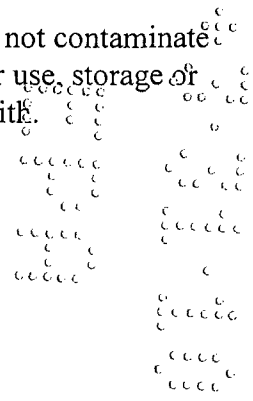
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with eyes, skin or clothing. In case of contact, flush with plenty of water. Call a physician if irritation persists. Wash thoroughly after handling and before smoking or eating. Avoid contamination of food or foodstuff. Do not use in any area where food or feed is stored, prepared or consumed. Do not use on humans. Sensitivities may occur after using ANY pesticide product for pets. If mild signs of sensitivity occur bathe your pets 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. You may also contact 1-800-858-7378 for emergency medical treatment information.	
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 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 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 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.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not apply directly to any body of water. Do not contaminate water when disposing of equipment washwaters. Buyer assumes all risks for use, storage or handling of this product not in strict accordance with directions given herewith.



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[Back/Side Label Panel]

EPA Reg. No. 15297-9
EPA Est. No. 15297-TX-1

Manufactured by
BIO-DERM® LABORATORIES, INC.
P.O. Box 8070
Longview, TX 75607 USA
Telephone: 800-762-0232
www.biogroom.com

[bar code]

Revised: 03/17/10
S:\Main\Bio-Derm Laboratories\Repel 35 label.wpd

