

82810-1

4-4-2007

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 4 2007

Timothy H. Dickens, Ph.D.
Registered Agent
Coulston's Products Inc. c/o Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, Maryland 20853

RE: Add the Marketing Statement, "30% DEET in a Liposome Base"
EPA Registration Number: 82810-1
Date of Submission: November 8, 2006

Dear Dr. Dickens:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated November 8, 2006, for the product DermAegis LipoDEET Insect Repellent 302. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



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 82810-1	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DermAegis LipoDEET Insect Repellent 302	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) DermAegis, Inc. c/o Scientific Coordination, Inc. 4629 Cherry Valley Dr. Rockville, MD 20853	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 checked="" 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 checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION

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

"Notification to add the marketing statement, 30% DEET in a liposome base, per PR Notice 98-10." "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 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 terms of PR Notice 98-10 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 checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" 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
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 4, 4.5, 6, 8 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled	<input checked="" type="checkbox"/> Other Shrink Wrap	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Timothy H. Dickens, Ph.D.	Title Registered Agent	Telephone No. (Include Area Code) 301-570-4390
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 Registered Agent	
4. Typed Name Timothy H. Dickens, Ph.D.	5. Date 08 November 2006	

Scientific Coordination, Inc.

Helping Technology Transfer
4629 Cherry Valley Drive
Rockville, MD 20853
November 8, 2006

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: Mr. Richard Gebken, Product Manager (10)

Subject: DermAegis LipoDEET Insect Repellent 302
EPA File Symbol: 82810-1
NOTIFICATION

Dear Mr. Gebken:

By notification, our Client, DermAegis, Inc. is adding the following marketing statement to the subject label:

“30% DEET in a liposome base”

Enclosed, please find the following:

- 1. Application for Pesticide (Other), EPA Form 8570-1
- 2. One copy of a reference label illustrating the label revision.
- 3. Two copies of the final label.

We would appreciate receiving a copy of the label stamped approved – notification.

If you have any questions or comments regarding this submission, please do not hesitate to contact me at (301) 570-4390 or by e-mail at dickensth@aol.com.

Sincerely,



Timothy H. Dickens, Ph.D.
Registered Agent
encl./as listed

DermAegis LipoDEET Insect Repellent 302

Provides Protection Against Mosquitoes for Up to 4 Hours

30% DEET ● 30% DEET in a liposome base

Insect Repellent ● Lotion ● Repels Mosquitoes

Odorless After Application

Repels biting insects for up to 4 hours

Effective Unscented Protection From Mosquitoes, Gnats, No-See-Ums, Sand Flies, Biting Flies, Deer Flies, Stable Flies, Black, Flies, Ticks, Chiggers, Red Bugs and Fleas

Just the right protection around the home and backyard

Non-greasy ● Non Staining ● Resists Perspiration

ACTIVE INGREDIENTS:

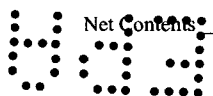
DEET (CAS No. 134-62-3)	30.00%
OTHER INGREDIENTS	<u>70.00%</u>
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

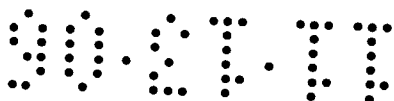
WARNING

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents _____ oz..



Underlined Denotes New Text.



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Avoid contact with eyes. Use of this product may cause skin reactions in rare cases. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash treated clothing before wearing it again. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

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 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, continue rinsing the eye. • Call a poison control center or doctor for treatment advice.
If you suspect a reaction to this product	<ul style="list-style-type: none"> • Discontinue use. • 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.
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. Questions ???: 858-259-5659</p>	

NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label. **SHAKE WELL BEFORE USING.**

Skin application: Squeeze into one hand, rub hands together and apply thoroughly in a thin layer to the forearms. Use additional lotion for upper arms. Repeat for other exposed areas. To apply to face, squeeze lotion into palm of hand and spread on face and neck. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not apply over cuts, wounds or irritated skin. When using on children, apply to your own hands and then put it on the child. Do not allow children to handle this product. Use just enough repellent to cover exposed skin and/or clothing. Wipe excess from hands after applying. Do not use under clothing. Avoid over-application of this product. Frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors wash treated skin with soap and water. May damage certain synthetic fabrics, acetate, spandex and nylon. If you suspect a reaction to this product, discontinue use, wash treated skin, and call your local poison control center. If you go to a doctor, take this product with you.

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool and dry place. Keep out of reach of children. **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.

EPA Reg. No. 82810-1 EPA Est. No. 54287-FL-01
DermAegis, Inc.
4747 Plummer Ct.
San Diego, CA 92130

110706LipoDEETNotifRef-01

NOTIFICATION

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