

82810-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 2, 2008

Mr. Timothy H. Dickens, Ph.D.,
Authorized Agent for DermAegis, Inc.
c/o Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853-0030

**Subject: Label Amendment, Delete Clothing Statements & Support Liposome Patent Claim
DermAegis LipoDEET Insect Repellent 302, EPA Reg. No. 82810-1
Your Rebuttal Dated June 23, 2008**

Dear Mr. Dickens:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following provision(s):

Directions for Use section comment(s):

1. The Agency concurs with your suggestion to delete the referenced clothing statements in your rebuttal dated June 23, 2008.
2. Insert the following statement immediately following the 5th sentence in paragraph 1: "Do not apply this product to the outer surfaces of clothing."

Optional Marketing Claims section comment(s):

3. Revise the 17th optional marketing claim to read: "Patented Liposome Formula provides unique insect repellent formulation technology available only in this product."

DermAegis, Inc. should note that the Agency is in the process of developing and improving the current Efficacy Assessment Guidelines for repellent products. The Agency intends to defer the determination of any related efficacy data requirements supporting the claims that may appear on this label until these Efficacy Assessment Guidelines are complete. When the guidelines are finalized, the Agency expects to issue a Data Call-In to address the revised guidelines to all registrants with registrations for personal repellent products that have not previously submitted efficacy data sufficiently consistent with the revised guidelines.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: Copy of label stamped "Accepted with Comments"

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DermAegis LipoDEET Insect Repellent

~ OPTIONAL MARKETING LANGUAGE: SEE LAST PAGE ~

ACTIVE INGREDIENT:	
DEET	30.00%
OTHER INGREDIENTS	70.00%
TOTAL:	100.00%

<p align="center">Keep Out of Reach of Children WARNING See back panel for additional precautionary statements. [See (inside)(back) panel for precautions.]</p>
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Net [Contents][Weight] _____ [fl.] oz.

[] indicates alternate text.

ACCEPTED
with COMMENTS
In EPA Letter Dated
September 2, 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
82810-1

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
WARNING

Causes substantial but temporary eye injury. Do not get in eyes. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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, continue rinsing the eye. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. [Questions ???: 858-259-5659]	

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. Use Restrictions:** Apply this product only to exposed skin as specified on this label. Do not use it near food. Do not use under clothing. Do not apply near eyes and mouth, and apply sparingly around ears. Never use repellents over cuts, wounds or irritated skin. Do not allow children to handle this product, and do not apply to children's hands. Do not use on infants. Do not apply more than 3 times per day to children ages twelve (12) and under. [Will not damage cotton, wool or nylon.] Do not apply on or near acetate, rayon, Spandex or other synthetic fabrics (other than nylon), furniture, plastics (such as eyeglasses and watch crystals), leather and painted or varnished surfaces (including automobiles). **Use of this product may cause skin reactions in rare cases. 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 repellent product with you.**

Application: Squeeze into one hand, rub hands together and apply thoroughly in a thin layer to all exposed skin areas. To apply to face, squeeze lotion into palm of hand and spread sparingly on face and neck. When using on children, apply to your own hands and then put it on the child. Use just enough repellent to cover exposed skin and/or clothing. Wipe excess from hands after applying. Avoid over-application of this product. Heavy application and saturation is unnecessary for effectiveness. For maximum protection, spread evenly with hand to moisten all exposed skin. If biting insects do not respond to a thin film of repellent, apply a bit more. After returning indoors wash treated skin with soap and water or bathe. This is particularly important when this product is used repeatedly in a day or on consecutive days.

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STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool, dry place inaccessible to children. Pesticide 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 toll free number or website which meets the criteria in paragraph II.E., PR Notice 2007-1] for disposal instructions. Never place unused product down any indoor or outdoor drain.

DermAegis, Inc.
5730 Clarendon Drive.
Rockford, IL 61114

EPA Reg. No. 82810-1

EPA Est. No. 58188-FL-01

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~ OPTIONAL MARKETING LANGUAGE ~

1. Provides Protection against Mosquitoes for 11 hours
2. [Enjoy] 11 hours of protection from mosquitoes
3. Lasts [for] 11 hours [against mosquitoes][that may carry West Nile Virus]
4. [Proven][Effective] protection for 11 hours against mosquitoes
5. Repels mosquitoes that may carry West Nile Virus for 11 hours
6. Repels mosquitoes that may carry St. Louis encephalitis and Western equine encephalitis for 11 hours
7. Repels biting insects for 4 hours
8. 30% DEET
9. Insect Repellent
10. Lotion
11. Repels Mosquitoes
12. Odorless After Application
13. 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
14. Non-greasy
15. Non Staining
16. Resists Perspiration
17. ~~Advanced~~, Patented Liposome Formula, provides unique formulation technology available only in this product.
18. Family•Daytime•Fishing [Formula]