

82810-1

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 4, 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, Data-Supported Duration Claims & Revised Marketing Claims
DermAegis LipoDEET Insect Repellent 302, EPA Reg. No. 82810-1
Your Submission Dated January 14, 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. Replace the 3rd sentence from paragraph 1 with: "Apply this product only to exposed skin as specified on this label."
2. Replace the 7th sentence from paragraph 1 with: "Never use repellents over cuts, wounds or irritated skin."
3. The last 3 sentences from paragraph 1 should be **bolded** in order to increase the prominence of these label statements.
4. At the end of the 1st sentence from paragraph 2, replace the words "the forearm" with the words "all exposed skin areas."
5. Delete the 2nd and 3rd sentences found in paragraph 2.
6. Replace the 9th sentence from paragraph 2 with: "Heavy application and saturation is unnecessary for effectiveness."
7. Insert the following 2 sentences at the end of paragraph 2: "This is particularly important when this product is used repeatedly in a day or on consecutive days. Wash treated clothing before wearing it again."

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Optional Marketing Claims section comment(s):

8. In the 7th optional marketing claim, delete the word '[other].'
9. Delete the 14th optional marketing claim. This claim is considered an implied safety claim.
10. Delete the 18th optional marketing claim. LipoDEET is a patented product; however, does DermAegis actually hold the patent to this technology? In addition, this optional marketing claim contains several comparative statements.

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" as well as the efficacy review of the data submitted 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.



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

Enclosures: Copy of label stamped "Accepted with Comments"
Copy of Efficacy Review, dated March 7, 2008

DermAegis LipoDEET Insect Repellent

~ OPTIONAL MARKETING LANGUAGE: SEE LAST PAGE ~

ACTIVE INGREDIENT:	
DEET	30.00%
OTHER INGREDIENTS	<u>70.00%</u>
TOTAL:	100.00%

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

[] indicates alternate text.
Underline represents new text.

ACCEPTED
with COMMENTS
In EPA Letter Dated
June 4, 2008
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under EPA Reg. No.
82810-1

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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. Remove and wash contaminated clothing before reuse.

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.
<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.** Use **Restrictions:** Apply this product only 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. Do not apply 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 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 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. Frequent reapplication 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.

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

~ 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 [other] 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. Just the right protection around the home and backyard
15. Non-greasy
16. Non Staining
17. Resists Perspiration
18. Advanced, Patented Liposome Formula, provides unique formulation technology available only in this product.
19. Family•Daytime•Fishing [Formula]