

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB 17 2009

Timothy H. Dickens, Ph.D. Registered Agent DermAegis, Inc. c/o Scientific Coordination, Inc. 4629 Cherry Valley Drive Rockville, MD 20853

RE: Notification to add Marketing Statement and Graphics

EPA Reg. No.: 82810-1

Date of Submission: November 24, 2008

Dear Dr Dickens:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated November 24, 2008, 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 action(s) 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,

Linda Arrington

Notifications & Minor Formulations Team Leader Registration Division (7505P)

Registration Division (7505P)

Office of Pesticide Programs

NOTIFICATION

OMB No. 2070-0060. Approval expire

United States

| Registration |
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| Amendmen |
| Othor |

OPP Identifier Number

| \$EPA | Environmental Protection Agency Washington, DC 20460 Amend Other | | | nent | | | | |
|--|--|---|--|--|---------------------------------------|--|------------------------------|---------------------------|
| | · | Applicatio | n for Pesticio | de - Section | l | | | |
| 1. Company/Product Numbe 82810-1 | r | | l l | Product Manager d Gebken | | | posed Cla None | ssification Restricted |
| 4. Company/Product (Name) DermAegis LipoDEET | |)2 | PM# . 10 | | | | | |
| 5. Name and Address of App DermAegis, Inc. c/o Scientific Coordination 4629 Cherry Valley Dr. Rockville, MD 20853 | | de) | (b)(i), m to: EPA F | edited Reveiw. By product is simple. By No | ilar or ide | OTHIC | ation | |
| | | | Section - I | S | | | | |
| Amendment - Explain Resubmission in resp Notification - Explain | onse to Agency letter | dated | | Final printed label Agency letter dat "Me Too" Applica Other - Explain be | ed ation. | to . | | |
| Explanation: Use addition "Notification to add marketing s at 40 CFR 152.46, and no othe U.S.C. Sec. 1001 to willfully ma 152.46, this product may be in | statements and graphics per changes have been ma ake any false statement to | per PR Notice 98 ide to the labeling o EPA. I further u | -10." "This notification or the confidential sunderstand that if this | tatement of formula on notification is not con | of this product. Insistent with th | I understand e terms of P | that it is a R Notice 98 | violation of 18 |
| | | | Section - II | ll . | | | | |
| 1. Material This Product Will | Be Packaged In: | | | | | | | |
| Child-Resistant Packaging Yes No * Certification must | Unit Packaging Yes No If "Yes" Unit Packaging wgt. | No. per container | Water Soluble Parkage wgt | No. per container | 2. Type of | Container Metal Plastic Glass Paper Other (Sp | oecify) | |
| be submitted | | | | 1 | <u></u> | | | |
| 3. Location of Net Contents Label C | Information ontainer | 4. Size(s) Reta | il Container 2, 4, 4.5, 6, 8 oz. | 5. Lo | On Labe | | | |
| 6. Manner in Which Label is | Affixed to Product | Lithogr Paper of Stencil | aph Jlued ed | Other Sh | nrink Wrap | | | |
| | | | Section - IV | 7 | | | | |
| 1. Contact Point (Complete | items directly below f | or identification | of individual to be | contacted, if nec | essary, to pro | cess this | application | p.,} |
| Name Timothy H. Dickens | | 1 | Title Authorized Agent | | | Telephone 301-570-4 | | ide Area Code) |
| i certify that the states I acknowledge that an both under applicable i | y knowlinglly false or | | all attachments the | | urate and col | nplete. | 6. Date:A Beceive (St. | amped) |
| 2. Signature | . Diekins | 3 | . Title Authorized Agent | , | | (((((((((((((((((((| | • |
| 4. Typed Name Timothy H. Dickens, Ph.D. | | 5 | i. Date QUN | i Vemleer | 2008 | | ((((((| 4, |

SCIENTIFIC COORDINATION, INC.

Helping Technology Transfer 4629 Cherry Valley Drive Rockville, MD 20853

November 24, 2008

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: Linda Arrington

Subject: DermAegis LipoDEET Insect Repellent 302

EPA Reg. No. 82810-1 NOTIFICATION

Dear Ms. Arrington:

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

- 1. Marketing statements: [Travel Size] Meets Airline [3 oz.] Carry-On Requirements, Liposome formula
- 2. Lot number
- 3. Addition of graphics:



SAWYER

Enclosed, please find the following:

- 1. Application for Pesticide (Other), EPA Form 8570-1;
- 2. One copy of a final label as a reference illustrating all label revisions; and
- 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.

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Registered Agent

encl./as listed

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DermAegis LipoDEET Insect Repellent

~ OPTIONAL MARKETING LANGUAGE: SEE LAST PAGE ~

NOTIFICATION FEB 1 7 2009

| ACTIVE INGREDIENT: | • | |
|--------------------|---|---------|
| DEET | | 30.00% |
| OTHER INGREDIENTS | | 70.00% |
| TOTAL: | | 100.00% |

Keep Out of Reach of Children WARNING

See back panel for additional precautionary statements. [See (inside)(back) panel for precautions.]

| Net [Contents][Weight] | _ [fl.] oz. | Lot Number: |
|------------------------------|-------------|-------------|
| [] indicates alternate text. | | |



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 | 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 this product to the outer surfaces of 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. 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.



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



The following graphics and symbols have been added:





NOTIFICATION

FEB 1 7 2009