

82810-1

6/26/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C 20460 0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PPEVENTION

June 26, 2012

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

**Subject Amended Labeling, Addition of Marketing Statements & Updates for PR Notice 2007-4
DermAegis LipoDEET Insect Repellent 302, EPA Reg No 82810-1
Your Submission Dated April 27, 2012**

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)

General Comment(s)

- 1 Delete all text throughout the label marked with "~~strikethrough~~"
- 2 The additional of the optional statements "[Compatible with Sunscreen Apply Sunscreen First] within the "Directions for Use" section cannot be approved on the subject label since no data was submitted nor information provided to demonstrate that this product is compatible with sunscreen as proposed, and that neither are affected by use at the application site
- 3 The additional of the optional marketing statement "Compatible with Sunscreen cannot be approved on the subject label since no data was submitted nor information provided to demonstrate that this product is compatible with sunscreen as proposed, and that neither are affected by use at the application site

Storage and Disposal section comment(s)

- 4 To facilitate inclusion of required label language from the Agency's Label Review Manual and/or PR Notice 2007-4, revise this section to read

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE Keep this product in its tightly closed original container when not in use Store in a cool, dry (preferably locked) area that is inaccessible to children and animals


PESTICIDE DISPOSAL Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility

CONTAINER DISPOSAL Nonrefillable container Do not reuse or refill this container *If empty* 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

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 section 6(e) of FIFRA 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,

 *for* Richard J Gebken

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

Enclosure *Label stamped Accepted with Comments*
082810 00001 D464982

30 of 7

DermAegis LipoDEET Insect Repellent

~ OPTIONAL MARKETING LANGUAGE SEE LAST PAGE ~

ACTIVE INGREDIENT	
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
 [See (inside)(back) panel for precautions]

Net [Contents][Weight] _____ [fl] oz

Lot Number _____

[] indicates alternate text

ACCEPTED
 With COMMENTS
 In EPA Letter Dated
June 26, 2012
 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 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 ~~[Compatible with Sunscreen. Apply Sunscreen First]~~ 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

Storage Store in a cool, dry place inaccessible to children **Disposal** Nonrefillable container Do not reuse or refill this container **If empty** 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

DermAegis, Inc
5730 Clarendon Drive
Rockford, IL 61114

EPA Reg No 82810-1

EPA Est No 58188-FL-01

6067

~ OPTIONAL MARKETING LANGUAGE ~

~~1 Compatible with Sunscreen~~

- 2 [(Department of Defense) (DoD) (National Stock Number) (NSN) 6840-01-584-8393]
- 3 [Travel Size] Meets Airline [3 oz] Carry-On Requirements
- 4 Liposome formula
- 5 Provides Protection against Mosquitoes for 11 hours
- 6 [Enjoy] 11 hours of protection from mosquitoes
- 7 Lasts [for] 11 hours [against mosquitoes][that may carry West Nile Virus]
- 8 [Proven][Effective] protection for 11 hours against mosquitoes
- 9 Repels mosquitoes that may carry West Nile Virus for 11 hours
- 10 Repels mosquitoes that may carry St Louis encephalitis and Western equine encephalitis for 11 hours
- 11 Repels biting insects for 4 hours
- 12 30% DEET
- 13 Insect Repellent
- 14 Lotion
- 15 Repels Mosquitoes
- 16 Odorless After Application
- 17 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
- 18 Non-greasy
- 19 Non Staining
- 20 Resists Perspiration
- 21 Patented Liposome Formula provides unique insect repellent formulation technology available only in this product
- 22 Family•Daytime•Fishing [Formula]

The following graphics and symbols have been added

