

50404-8

06/04/2008

1/6



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 Coulston Products, Inc.
c/o Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853-0030

**Subject: Label Amendment, Data-Supported Duration Claims & Revised Marketing Claims
Coulston's® DURANON® INSECT REPELLENT, EPA Reg. No. 50404-8
Your Submission Dated January 14, 2008 and Your Rebuttal Dated May 1, 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 of the 1st paragraph with: "Apply this product only to exposed skin as specified on this label."
2. Replace the 7th sentence of the 1st paragraph with: "Never use repellents over cuts, wounds or irritated skin."
3. The last 3 sentences of paragraph 1 should be **bolded** in order to increase the prominence of these label statements.
4. Replace the 8th sentence of paragraph 2 with: "Heavy application and saturation is unnecessary for effectiveness."
5. 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."

Marketing Claims section comment(s):

6. In the 19th marketing claim, delete Venezuelan equine encephalitis and Dengue Fever since these insect-borne diseases do not occur within North America.

Coulston Products, 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

3/16

Coulston's® DURANON® INSECT REPELLENT

~ OPTIONAL MARKETING LANGUAGE: SEE LAST PAGE ~

ACTIVE INGREDIENT:

DEET	20.00%
OTHER INGREDIENTS	80.00%
TOTAL:	100.00%

Keep Out of Reach of Children
CAUTION
 See back panel for additional precautionary statements.
 [See additional precautions on back panel]
 [See (inside)(back) panel for precautions.]

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

[] indicates alternate 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.
50404-B

4/6

This Coulston Controlled Release insect repellent uses the patented "Sub Micron Encapsulation" technology as developed by Coulston Products Inc. This process evens out the evaporation rate of DEET by encapsulating the DEET in a protein. Each application provides effective protection while at the same time limiting the skin's exposure to DEET thereby significantly reducing possible deet absorption.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
CAUTION**

Avoid contact with eyes. 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.
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. [Questions?: 800-940-4464, Weekdays from 9-5 EST.]</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 or allergic 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 I.E., PR Notice 2007-1] for disposal instructions. Never place unused product down any indoor or outdoor drain.

Coulston Products Incorporated
605 Seventh Ave. North
P.O. Box 188
Safety Harbor, FL 34695 USA

Made in U.S.A. ® & ™ Trademarks of Coulston Products Inc.
© Copyright 1995-2008 CPI All Rights Reserved 12/07
EPA Reg. No. 50404-8 EPA Est. No. 58188-FL-01

6/6

~ OPTIONAL MARKETING LANGUAGE ~

Provides Protection against Mosquitoes for 11 hours

Lasts 11 hours

[Enjoy] 11 hours of protection from mosquitoes

Lasts for 11 hours [against mosquitoes]

[Proven][Effective] protection for 11 hours against mosquitoes [that may carry [West Nile virus] [St. Louis encephalitis] [Western equine encephalitis] disease(s)]

20% DEET in a Controlled Release Formula

Insect Repellent

Lotion

Repels Mosquitoes

Odorless after Application

Time Release [DEET] Formula

Low DEET Absorption Formula

Odorless Time-Release Formula

Family [Insect Repellent]

Controlled Release

Odorless

Non-Greasy

Repels mosquitoes that may carry West Nile Virus

Repels mosquitoes that may carry [St. Louis] [Eastern equine] [Western equine] [Lacrosse] [Cache Valley] [Venezuelan equine encephalitis] and [Dengue Fever]