


50404-8

01/23/2008

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 <p><b>U.S. ENVIRONMENTAL PROTECTION AGENCY</b> Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001</p>	<b>EPA Registration No.</b>  <b>50404-8</b>	<b>Date of Issuance:</b>  <b>JAN 23 2008</b>
<p align="center"><b>NOTICE OF PESTICIDE:</b>   <input type="checkbox"/> Registration  <input checked="" type="checkbox"/> Reregistration  (under the Federal Insecticide, Fungicide and  Rodenticide Act, as amended)</p>	<b>Term of Issuance:</b> <b>Conditional</b>  <b>Name of Pesticide Product:</b> <b><i>Coulston's</i><sup>®</sup> DURANON<sup>®</sup> INSECT  REPELLENT</b>	
<b>Name and Address of Registrant (include ZIP Code):</b> Coulston Products, Inc. 605 7 <sup>th</sup> Avenue North Safety Harbor, FL 34695-0188		
<b>Note:</b> Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 4(g)(2)(c) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p>Based on your response to the Reregistration Eligibility Document(s), EPA has reregistered the product listed above provided that the following change(s) is(are) made to the label:</p> <p><u>Marketing Claims section comment(s):</u></p> <ol style="list-style-type: none"> <li>1. In the marketing claim "Repels mosquitoes that may carry West Nile Virus," replace the word "carry" with the word "transmit."</li> <li>2. In the last marketing claim, replace the word "carry" with the word "transmit" and delete Venezuelan equine encephalitis and Dengue Fever since these diseases do not occur within North America.</li> </ol> <p align="center">(continued on page 2)</p>		
<b>Signature of Approving Official:</b>  Refer to Page #3.  Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch	<b>Date:</b>  <b>JAN 23 2008</b>	

Precautionary Statements, Hazards to Humans and Domestic Animals subsection comment(s):

- 3. In the paragraph immediately preceding this section, delete the last sentence starting with "Each application provides effective protection ...," since this is an implied safety claim.
- 4. As required by PR Notice 2001-3, replace the paragraph immediately following the section title for this section with: "Harmful if swallowed. May cause eye injury. Avoid contact with 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 Statement (table) comment(s):

- 5. Replace the last row of the First Aid Statement with:

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxxx or the National Pesticide Information Center at 1-800-858-7378.<sup>1</sup>

Directions for Use section comment(s):

- 6. The statement "READ AND FOLLOW ALL DIRECTIONS AND PRECAUTIONS ON THIS PRODUCT LABEL." should be moved to a line of its own in order to increase its prominence.
- 7. As required by PR Notice 2001-3, replace paragraphs 1 and 2 with:

"SHAKE WELL BEFORE USING. Skin 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 skin areas. To apply to face, squeeze lotion into palm of hand and then apply to face. **DO NOT** apply near eyes and mouth, and apply sparingly around ears. **DO NOT** allow children to handle this product, and **DO NOT** apply to children's hands. When using on children, apply to your own hands and then put it on the child. Use just enough repellent to cover exposed skin. Heavy application and saturation is unnecessary for effectiveness. If biting insects do not respond to a thin film of repellent, apply a bit more. Never use repellents over cuts, wounds or irritated skin. Repellents should be applied only to exposed skin as directed on this product label. Wipe excess from hands after applying. **DO NOT** use under clothing. After returning indoors, wash treated skin with soap and water or bathe. This is particularly important when repellents are used repeatedly in a day or on consecutive days. Wash treated clothing before wearing it again. 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.

**NOTE:** May damage certain synthetic fabrics, acetate, Spandex and rayon. [Will not damage cotton, wool or nylon.] [DO NOT apply on or near acetate, rayon, Spandex or other synthetic fabrics, nylon furniture, plastics (such as eyeglasses and watch crystals), leather and painted or varnished surfaces (including automobiles).]"

Storage and Disposal Statement section comment(s):

- 8. The Storage and Disposal Statement must be placed within a solid text box to increase its prominence.
- 9. Replace this section with:

**STORAGE AND DISPOSAL**

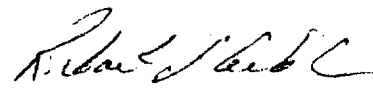
Do not contaminate water, food or feed by storage and disposal.  
**Pesticide Storage:** Store this product in a cool, dry place that is inaccessible to children.  
**Pesticide Disposal: If empty:** Do not reuse this container. Place in trash or offer for recycling if available.  
**If partially filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

<sup>1</sup> Please note that the "1-800-xxx-xxxx" must be substituted with a valid phone number that is available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

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" for this product 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 acceptance of these conditions.

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



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

Enclosure: Label stamped "Accepted with Comments"  
050404-00008 D319701

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**Coulston's® DURANON® INSECT REPELLENT**

PROVIDES 95% OR GREATER PROTECTION AGAINST MOSQUITOES [FOR] UP TO 4 HOURS

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~~)

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]

Net Contents \_\_\_\_\_ fluid [fl.] oz.

[ ] Indicates Alternate Verbiage

**ACCEPTED**  
**with COMMENTS**  
**In EPA Letter Dated**  
*January 23, 2008*  
 Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act,  
 as amended, for the pesticide  
 registered under EPA Reg. No.  
50404-B

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 AND DOMESTIC ANIMALS  
CAUTION**

Avoid contact with eyes. Use of this product may cause skin reactions in rare cases. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. 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 product with you. 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"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
If In Eyes :	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, continue rinsing the eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p> <p>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. SHAKE WELL BEFORE USING.**

Skin 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. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply to children's hands. Do not apply over cuts, wounds or irritated skin. When using on children, apply to your own hands and then put it on the child. Do not allow children to handle this product. Use just enough repellent to cover exposed skin and/or clothing. Wipe excess from hands after applying. Do not use under clothing. Avoid over-application of this product. Frequent reapplication and saturation is unnecessary for effectiveness. After returning indoors wash treated skin with soap and water.

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May damage certain synthetic fabrics, acetate, spandex and rayon. [Will not damage cotton, wool, or nylon.][Do not apply on or near acetate, rayon, spandex, or other synthetics, furniture, plastics, watch crystals, leather and painted or varnished surfaces including automobiles.]

#### STORAGE AND DISPOSAL

**Storage:** Store in a cool, dry place inaccessible to children. **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.

EPA Reg. No. 50404-8      EPA Est. No. 58188-FL-01  
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