

50404-8

05-03-2007

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



OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

May 3, 2007

Mr. Timothy H. Dickens, Ph.D.,  
Registered Agent  
Coulston Products, Inc.  
c/o Scientific Coordination, Inc.  
4629 Cherry Valley Drive  
Rockville, MD 20853-1110

**Subject: Amended Labeling, Addition of Various Insect-Borne Diseases  
Coulston's<sup>®</sup> DURANON<sup>®</sup> INSECT REPELLENT, EPA Registration No. 50404-8  
Your Submission Dated September 19, 2006**

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 provisions:

Marketing Claims section comment(s), page 1 of 3:

1. As per the Agency's letter (copy attached) dated September 28, 2006, modify the following claim by removing the text shown in ~~strikeout~~ below:

**20% DEET IN A ~~NON-ALCOHOL~~ CONTROLLED RELEASE FORMULA**

Statements or claims that express the absence of certain ingredients are misleading statements prohibited by the Agency's labeling regulation (40 CFR part 156.10(a)(5)(i) and/or 40 CFR part 156.10(a)(5)(viii)). These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it could be misleading if it is used in a way to falsely suggest to the potential purchaser that the product is in some way less risky, better or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained the substance in the first place. <sup>1</sup>

2. Remove the claim: "LOW DEET ABSORPTION FORMULA," since it is an implied safety claim.
3. Also, in accordance with the Agency's letter dated September 28, 2006, remove the claim stating that DEET has been recommended by the Centers for Disease Control. <sup>2</sup>
4. Remove the claim: "Compatible with Sun Block," since this non-pesticidal claim is potentially false and misleading about the safety of the product.
5. Delete the following insect-borne diseases from the label: (1) Japanese encephalitis; (2) Murray Valley encephalitis; (3) Ross River Fever; (4) Barmah Forest Disease; (5) Yellow Fever; and (6) Rift Valley Fever. These insect-borne diseases currently do not occur within the continental United States and/or its territories.

<sup>1</sup> For more detailed information, please refer to page 12-3 of EPA's Label Review Manual.

<sup>2</sup> For more detailed information, please refer to 40 CFR part 156.10(a)(5).

Ingredient Statement section comment(s), page 1 of 3:

- 6. Relocate the CAS number listed for DEET as a footnote on the first page of the label.

Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s), page 2 of 3:

- 7. In the paragraph immediately preceding the "PRECAUTIONARY STATEMENTS, HAZARDS TO HUMANS AND DOMESTIC ANIMALS" section title; delete the 3<sup>rd</sup> sentence starting with "Each application provides..." since it is an implied safety claim.
- 8. In the paragraph immediately following the "PRECAUTIONARY STATEMENTS, HAZARDS TO HUMANS AND DOMESTIC ANIMALS" section title; insert the following text after the existing 3<sup>rd</sup> sentence: "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."<sup>3</sup>

First Aid section comment(s), page 2 of 3:

- 9. Delete the 3<sup>rd</sup> row from this table that starts with "If you suspect a reaction to this product." For a more detailed explanation, please refer to the footnote #3 below and the comment on item #8 above.

Storage and Disposal section comment(s), page 3 of 3:

- 10. Replace the existing section with the following:

**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Store this product in a cool and dry area. Keep out of reach of 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 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**Container Disposal:** Triple rinse (or equivalent). Then offer for recycling, or puncture and dispose of in a sanitary landfill, or incineration, etc., or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

A stamped copy is attached for your records. Please submit two (2) final printed copies of the referenced label, incorporating the above changes, before releasing the product for shipment. If you have any questions regarding the label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

Sincerely yours,  


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

Attachments

<sup>3</sup> PR Notice 2001-1 is very specific about which sections are applicable for the various routes of exposure. The "If you suspect....." comment is not a part of this PR Notice, but is specifically addressed as a requirement in the DEET Reregistration Eligibility Decision (RED) dated April 1998, page 40 of 118, and should be placed in the Precautionary Statements, Hazards to Humans and Domestic Animals section and NOT in the First Aid section.

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

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

20% DEET IN A ~~NON-ALCOHOL~~ 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 • ~~Contains DEET as recommended by the Centers for Disease Control [www.cdc.gov/ncidod/dvbid/westnile/index.htm](http://www.cdc.gov/ncidod/dvbid/westnile/index.htm)~~

Non-Greasy • ~~Compatible with Sun Block~~ • Visit [www.sawyer.com](http://www.sawyer.com) to Learn More Or Ask Your Doctor

Repels mosquitoes that may carry West Nile Virus

Repels mosquitoes that may carry (St. Louis) (Eastern equine) (Western equine) (Lacrosse) (Japanese) (Cache Valley) (Venezuelan equine) (Murray Valley) encephalitis and (Ross River Fever) (Barmah Forest Disease) (Dengue Fever) (Yellow Fever) (Rift Valley Fever)

ACTIVE INGREDIENT:	
DEET (CAS No. 134-62-3) .....	20.00%
OTHER INGREDIENTS .....	80.00%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

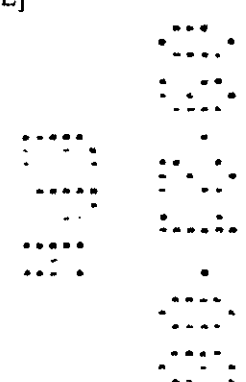
CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS  
[SEE ADDITIONAL PRECAUTIONS ON BACK PANEL]

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

[ ] Indicates Alternate Verbiage  
Underlined indicates new text

ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
*May 3, 2007*  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
5040A-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. 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>
<del>If you suspect a reaction to this product</del>	<ul style="list-style-type: none"> <li><del>• Discontinue use.</del></li> <li><del>• Take off contaminated clothing.</del></li> <li><del>• Rinse skin immediately with plenty of water for 15-20 minutes.</del></li> <li><del>• Call a poison control center or doctor for treatment advice.</del></li> </ul>
<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. 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. 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

**Pesticide Storage:** Store in a cool and dry place. Keep out of reach of 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 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

EPA Reg. No. 50404-8                      EPA Est. No. 54287-FL-01  
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50404-8AmendRef-090106