

50404-8

9-19-2003

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Please read instructions on reverse before completing form.

NOTIFICATION

OMB No. 2070-0060, Approval expires 2-28-95



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 50404-8 2. EPA Product Manager Linda Arrington 3. Proposed Classification None Restricted 4. Company/Product (Name) Coulston's® Duranon® Insect Repellent PM# 10 5. Name and Address of Applicant (Include ZIP Code) Coulston Products Inc. c/o Scientific Coordination, Inc 4629 Cherry Valley Drive Rockville, MD 20853 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name

Section - II

Amendment - Explain below. Resubmission in response to Agency letter dated. Notification - Explain below. Final printed labels in response to Agency letter dated. "Me Too" Application. Other - Explain below.

NOTIFICATION SEP 19 2003

Explanation: Use additional page(s) if necessary. (For section I and Section II.) "Notification of two marketing statements, "Low DEET Absorption Formula" and "Contains DEET as recommended by the Centers for Disease Control www.cdc.gov/ncidod/dvbid/westnile/index.htm" per PR Notice 98-10." "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In: Child-Resistant Packaging, Unit Packaging, Water Soluble Packaging, 2. Type of Container, 3. Location of Net Contents Information, 4. Size(s) Retail Container, 5. Location of Label Directions, 6. Manner in Which Label is Affixed to Product

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name: Timothy H. Dickens, Ph.D. Title: Registered Agent Telephone No.: 301-570-4390 Certification: I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. 2. Signature: Timothy H. Dickens 3. Title: Registered Agent 4. Typed Name: Timothy H. Dickens, Ph.D. 5. Date: 11 September 2003 6. Date Application Received (Stamped)

SEP 19 2003
NOTIFICATION

Coulston's®
DURANON® INSECT REPELLENT

PROVIDES 95% OR GREATER PROTECTION
AGAINST
MOSQUITOES FOR 4 OR MORE HOURS

20% DEET IN A NON-ALCOHOL
CONTROLLED RELEASE FORMULA

INSECT REPELLENT • LOTION • REPELS
MOSQUITOES

ODORLESS AFTER APPLICATION
TIME RELEASE [DFET] FORMULA

LOW DEET ABSORPTION FORMULA

Contains DEET as recommended by the
Centers for Disease Control

www.cdc.gov/ncidod/dvbid/westnile/index.htm

ACTIVE INGREDIENTS:
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.]

[] : Indicates Alternate Verbiage
Underlined denotes new verbiage.

Net Contents oz.

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"> • 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.
If you suspect a reaction to this product	<ul style="list-style-type: none"> • Discontinue use. • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • 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. **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 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 nylon.

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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
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EPA Est. No. 54287-FL-

COULSTON PRODUCTS INC., BOX 30, EASTON, PA
18044-0030

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Scientific Coordination, Inc.

Helping Technology Transfer
4629 Cherry Valley Drive
Rockville, MD 20853
September 11, 2003

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subject: Coulston's Duranon® Insect Repellent
EPA Reg. No. 50404-8
NOTIFICATION

Dear Sir or Madam:

By notification, our client, Coulston Products Inc., is adding marketing language to their label by adding the phrases:

- Low DEET Absorption Formula
- Contains DEET as recommended by the Centers for Disease Control
www.cdc.gov/ncidod/dvbid/westnile/index.htm

Addition of the "Low DEET Absorption Formula" statement is in keeping with the recent Agency acceptance of our client's DEET absorption study (MRID # 45527701).

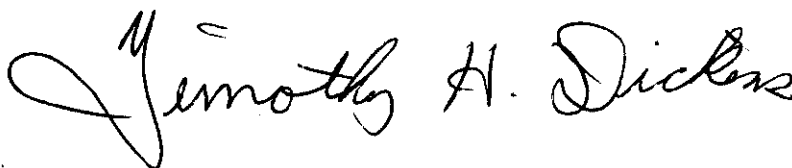
Enclosed, please find the following:

1. Application for Pesticide (Other), EPA Form 8570-1
2. One copy of a final label as a reference illustrating all label revisions.
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.
Registered Agent
encl./as listed

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