

50404-6

02/06/2009

1/7



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

FEB 6 2009

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

Re: Notification to add Marketing Statements and Graphics per PR Notice 98-10
EPA Reg No.: 50404-6
Date of Submission: November 24, 2008

Dear Dr. Dickens:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated, November 24, 2008, for the product Coulston's Permethrin Tick Repellent. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 50404-6	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) COULSTON'S PERMETHRIN TICK REPELLENT	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Coulston Products Inc, c/o Scientific Coordination, Inc. 4629 Cherry Valley Drive Rockville, MD 20853 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar to _____ in composition and labeling to: EPA Reg. No. <u>FEB 6 2009</u> Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

"Notification to add marketing statements and graphics 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 3, 6, 9, 13.5, 15 oz., 0.5, 1, 1.5 gal.		5. Location of Label Directions <input checked="" type="checkbox"/> Label	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

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	Title Authorized Agent	Telephone No. (Include Area Code) 301-570-4390
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature	3. Title Authorized Agent	
4. Typed Name Timothy H. Dickens, Ph.D.	5. Date <u>24 November 2008</u>	

4/7

COULSTON'S

PERMETHRIN TICK REPELLENT

~ OPTIONAL MARKETING LANGUAGE, SYMBOLS & GRAPHICS: SEE LAST PAGE ~

ACTIVE INGREDIENT:

PERMETHRIN* 0.50%

INERT [OTHER] INGREDIENTS: 99.50%

TOTAL:100.00%

*(3-phenoxyphenyl) methyl (+) *cis/trans* 3-(2,2-dichloroethenyl) 2,2-dimethyl -cyclopropanecarboxylate
Cis/Trans Ratio: min. 35% (+) *cis* and max. 65%(+) *trans*.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautions.
[See additional precautions on back panel.]

Net Contents: _____

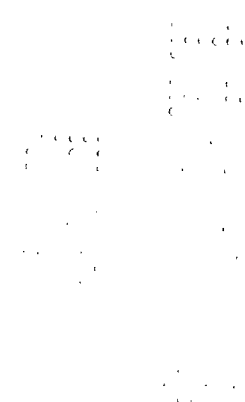
Lot Number: _____

[] Indicates alternate text

Underline represents new text.

NOTIFICATION

FEB 6 2009



DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SHAKE WELL BEFORE USING. This product should not be applied to clothing while it is being worn. Under no circumstances should bare skin or clothing on the body be treated. Do not spray directly on or otherwise allow to come in contact with skin, face, or eyes. This product is to be used as a clothing and gear treatment only. In case of accidental spraying of skin, face or eyes, see "First Aid" below. Make all applications outdoors.

For six week protection against ticks, chiggers and mosquitoes, select an outdoor area protected from the wind, spray outer surfaces of clothing (while not being worn) with a slow sweeping motion to lightly moisten the surface of the fabric, holding can at a distance of 6 to 8 inches. (A complete outfit consists of shirt, trousers, and socks.) Treat each item of clothing for a minimum of 30 seconds on each side and allow 2 hours (4 hours under humid conditions) to dry prior to being worn. Pay particular attention to socks, trouser cuffs, and shirt cuffs. Treatment should moisten the surface of the fabric enough to cause a slight color change. Use approximately $\frac{3}{4}$ of this container to treat one complete set of clothing. Use remainder on gear. Follow normal [standard] laundering procedures weekly. Reapply after six weeks and sixth laundering.

In heavily infested areas protection from ticks and chiggers will be improved by either wearing the cuffs inside footwear or taping pant cuffs around legs. Protection from mosquitoes can be further enhanced by applying an EPA approved repellent to face, hands and other exposed areas of the body.

[MOSQUITO NETTING], NETS, TENTS, SLEEPING BAGS, BACKPACKS AND GROUND CLOTHS: Do not treat inside of sleeping bag. Spray exterior surfaces of tent only. Select a well-ventilated outdoor area protected from wind and lay out gear to be treated. Hold can upright about 6 to 8 inches from surface of the article and spray with a slow sweeping motion to lightly moisten the surface of the fabric. Continue spraying over entire article, until the outer surface of the article is moist enough to cause a light color change (darkening). Turn the article over and treat the other side. Hang treated gear and allow to dry for at least 2 hours (4 hours under humid conditions) before using. Do not retreat gear more than once every six weeks.

DISPOSAL

Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency [[or 1-800-CLEANUP](tel:1-800-CLEANUP)] for disposal instructions.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Do not allow use by small children without close adult supervision. Avoid contact with face, eyes, or skin. Avoid breathing vapors or spray mist. Wash thoroughly after handling and before eating or smoking. Do not allow contact with treated surfaces until spray has dried. Do not allow to contact food or water supplies. Thoroughly wash dishes and food handling utensils contaminated with this product.

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 a poison control center or doctor. * Do not give anything by mouth to an unconscious person.
If On Skin:	<ul style="list-style-type: none"> * Rinse skin immediately with plenty of water for 15-20 minutes. * Call a poison control center or doctor for further treatment advice.
If Inhaled:	<ul style="list-style-type: none"> * Move person to fresh air, if not already done. * If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. * Call a poison control center or doctor for further treatment advice.
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, then continue rinsing eye. * Call a poison control center or doctor for further treatment advice.
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.	

NOTE: The First Aid statement's grid format will be used if market label space permits; otherwise a paragraph format will be used.

Physical or Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

Buyer assumes all risks of use, storage or handling of this product not in strict accordance with directions given herewith.

Manufactured and Marketed By:

Coulston Products Incorporated

605 Seventh Ave. North

P.O. Box 188

Safety Harbor, FL 34695 USA

Made in U.S.A.

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EPA Reg. No. 50404-6

EPA Est. No. 58188-FL-01 (LAST)

7/7

~ OPTIONAL MARKETING LANGUAGE, SYMBOLS & GRAPHICS ~

REPELS & KILLS TICKS, CHIGGERS AND MOSQUITOES

EFFECTIVE FOR 6 WEEKS • NONSTAINING

APPLIES AND DRIES ODORLESS

Clothing [And Gear]

Aerosol Spray

Insect Repellent

Odorless Permethrin

EFFECTIVE THROUGH SIX WASHINGS

PERMETHRIN ODORLESS, NONSTAINING

A TREATMENT FOR CLOTHING AND TENTS

A TREATMENT FOR CLOTHING AND GEAR

A TREATMENT FOR CLOTHING AND MOSQUITO NETTING

DO NOT APPLY TO SKIN

The following graphics and/or symbols have been added:

NOTIFICATION
FEB 6 2009

