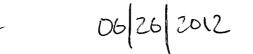
50404-8







# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D C 20460 0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 26 2012

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

**Subrect** 

Amended Labeling, Addition of Marketing Statements & Updates for PR Notice 2007 4 Coulston s® DURANON® INSECT REPELLENT, EPA Reg No 50404 8 Your Submission Dated April 27, 2012

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)

#### General Comment(s)

- 1 Delete all text throughout the label marked with strikethrough
- The additional of the optional statements [Compatible with Sunscreen Apply Sunscreen First] within the Directions for Use section cannot be approved on the subject label since no data was submitted nor information provided to demonstrate that this product is compatible with sunscreen as proposed and that neither are affected by use at the application site
- The additional of the optional marketing statement Compatible with Sunscreen cannot be approved on the subject label since no data was submitted nor information provided to demonstrate that this product is compatible with sunscreen as proposed and that neither are affected by use at the application site

#### Storage and Disposal section comment(s)

4 To facilitate inclusion of required label language from the Agency's Label Review Manual and/or PR Notice 2007 4 revise this section to read

#### STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal

<u>PESTICIDE STORAGE</u> Keep this product in its tightly closed original container when not in use Store in a cool dry (preferably locked) area that is inaccessible to children and animals

<u>PESTICIDE DISPOSAL</u> Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility

CONTAINER DISPOSAL Nonrefillable container Do not reuse or refill this container *If empty* Place in trash or offer for recycling if available *If partly filled* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain

A copy of your label stamped Accepted with Comments 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 section 6(e) of FIFRA. 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 <u>Rodia Carmen@epa gov</u>

Sincerely yours

Richard J Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7505P)

Enclosure 050404-00008 D464983

Label stamped Accepted with Comments

## Coulston's® DURANON® INSECT REPELLENT

~ OPTIONAL MARKETING LANGUAGE SEE LAST PAGE ~

ACTIVE INGREDIENT DEET OTHER INGREDIENTS TOTAL

20 00% 80 00% 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	Lot Number	
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[] indicates alternate text

ACCEPTED
With COMMENTS
In EPA Letter Dated
Jule 26, 2012
Under the Federal Insecticide Fungicide
and Rodenticide Act As amended for the
pesticide Registered under EPA Reg No

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 hands before eating drinking chewing gum using tobacco or using the toilet

#### **FIRST AID**

If Swallowed	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	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
Have the produ	ict 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

### **DIRECTIONS FOR USE**

READ AND FOLLOW ALL DIRECTIONS AND PRECAUTIONS ON THIS PRODUCT LABEL Use Restrictions Apply this product only to exposed skin as specified on this label Do not use it near food Do not use under clothing Do not apply near eyes and mouth and apoly sparingly around ears Never use repellents 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 [Compatible with Sunserson, Apply Sunserson First] Squeeze into one hand rub hands together and apply thoroughly in a thin layer to the forearms. Use additional lotion for

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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. Wipe excess from hands after applying. Avoid over application of this product. Heavy application 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. This is particularly important when this product is used repeatedly in a day or on consecutive days.

#### STORAGE AND DISPOSAL

Storage Store in a cool dry place inaccessible to children **Disposal** Nonrefillable container Do not reuse or refill this container **If empty** Place in trash or offer for recycling if available **If partly filled** Call your local solid waste agency 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

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#### ~ OPTIONAL MARKETING LANGUAGE ~

#### Compatible with Sunscreen

- 2 Provides Protection against Mosquitoes for 11 hours
- 3 Lasts 11 hours
- 4 [Enjoy] 11 hours of protection from mosquitoes
- 5 Lasts for 11 hours [against mosquitoes]
- 6 [Proven][Effective] protection for 11 hours against mosquitoes [that may transmit [West Nile virus] [St Louis encephalitis] [Western equine encephalitis] disease(s)]
- 7 20% DEET in a Controlled Release Formula
- 8 Insect Repellent
- 9 Lotion
- 10 Repels Mosquitoes
- 11 Odorless after Application
- 12 Time Release [DEET] Formula
- 13 Low DEET Absorption Formula
- 14 Odorless Time Release Formula
- 15 Family [Insect Repellent]
- 16 Controlled Release
- 17 Odorless
- 18 Non Greasy
- 19 Repels mosquitoes that may transmit West Nile Virus
- 20 Repels mosquitoes that may carry [St Louis] [Eastern equine] [Western equine] [Lacrosse] and [Cache Valley]

The following graphics and symbols have been added





