

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 29, 2021

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

Subject: Label Amendment – Add optional marketing claims and Permethrin Interim

Decision Changes

Product Name: Coulston's Permethrin Tick Repellent

EPA Registration Number: 50404-6

Application Date: May 17, 2019; January 20, 2021

Decision Number: 551607; 569826

Dear Dr. Dickens:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin Interim Decision, and has concluded that your submission is acceptable.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process.

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Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Endia Blunt by phone at 703-347-0788, or via email at Blunt.Endia@epa.gov.

Sincerely,

Kable Bo Davis

Senior Environmental Specialist Registration Division (7505P) Office of Pesticide Programs

Enclosure

COULSTON'S

PERMETHRIN TICK REPELLENT

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

For Outdoor Use Only

ACTIVE INGREDIENT:	
PERMETHRIN*	0.50%
NERT [OTHER] INGREDIENTS	99.50%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN **CAUTION**

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

Net Contents:	Batch Code [Lot Number]:

[]: Indicates alternate text

ACCEPTED

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 50404-6

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

DIRECTIONS FOR USE

For Outdoor Use Only

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. Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift. This product is to be used as a clothing and gear treatment only. In case of accidental spraying of skin see "First Aid" below. Make all applications outdoors. Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application. Not for broadcast use on indoor residential surfaces. Not for use in outdoor residential misting systems. Follow proper disposal procedures on this label.



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.

6 oz. - Use approximately [4.5 oz.] [3/4 of this container] to treat one complete outfit. Use remainder on gear.

[Directions for use "Option" to complement larger package sizes.]

- e.g. 9 oz. net package: One container [can] will treat two complete outfits. Use approximately [4.5 oz.] [1/2 of container] [can] for each complete outfit.
 - e.g. 12 oz. net package: One container [can] will treat two complete <u>outfits</u>. Use approximately [4.5 oz] [1/3 of container] [can] for each complete outfit. Use remainder on gear.
 - e.g. 18 oz. net package: One container [can] will treat four complete <u>outfits</u>. Use [4.5 oz.] [1/4 of container] [can] for each complete outfit.

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, OUTSIDE SURFACE OF SLEEPING BAGS, BACKPACKS AND GROUNDCLOTHS: 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.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry area, inaccessible to children and away from heat and open flame. **Disposal:** Do Not Puncture or Incinerate! Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Do not pour or dispose down-the-drain or sewer. Call your local solid waste Agency for local disposal options.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash 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

If On Skin or	* Take off contaminated clothing.
Clothing:	* Rinse skin immediately with plenty of water for 15-20 minutes.
	* Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for	
treatment. For additional information on this pesticide product (including health concerns, medical	
emergencies or pesticide incidents), you may call 800-356-7811, Weekdays from 9-5 EST. After 5 PM,	
call your poison control center.	

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

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to or near water. Drift and run-off may be hazardous to fish in water adjacent to treated areas. Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements. This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

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.

To the extent consistent with applicable law, 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. EPA Reg. No. 50404-6

EPA Est. No. 11623-GA-1

~ OPTIONAL MARKETING LANGUAGE, SYMBOLS & GRAPHICS ~

- 1. Treats {X} outfits {X depends on container size based on 4.5 oz. per outfit}
- 2. Treats $\{X\}$ Complete Outfits $\{X = \text{number of } 4.5 \text{ oz. increments per bottle}\}\$ An Outfit Is A Shirt, Pants, And Socks
- 3. Repels & Kills Ticks, Chiggers and Mosquitoes
- 4. Repels and Kills Mosquitoes and Ticks when used as a treatment for clothing and gear
- 5. Effective for 6 Weeks Non-staining
- 6. Effective for 42 days or 6 washings
- 7. lasts up to 1,000 hours [lasts 1,000 hours]
- 8. Applies and Dries Odorless
- 9. Clothing [And Gear] Treatment Only
- 10. Aerosol Spray
- 11. Insect Repellent Treatment
- 12. Odorless Permethrin
- 13. Convenient Spray
- 14. Effective through six washings
- 15. Permethrin Odorless, Non-staining
- 16. A Treatment for Clothing and Tents
- 17. A Treatment for Clothing and Gear
- 18. A Treatment for Clothing and Mosquito Netting
- 19. Do Not Apply to Skin
- 20. We Keep You Outdoors



- 22. For Treating Hunting, Fishing, Camping, & Scouting Clothing and Gear
- 23. Permethrin Insect Repellent Treatment for Clothing, Gear & Tents
- 24. [Permethrin] Clothing [and] [Gear] [and] [Gardening Apparel] [Treatment]

- 25. A Treatment for Clothing [and Gear] [and Mosquito Netting, Nets, Tents, Canopies, Screen Enclosures, Outside surface of Sleeping Bags, Backpacks, Groundcloths, Hammocks and Camping Chairs]
- 26. Repels & Kills Ticks, Chiggers, Mites and Mosquitoes when used as a treatment for clothing and Gear
- 27. Repels and Kills Ticks which may carry Lyme Disease and Rocky Mountain Spotted Fever when used as a treatment for clothing and gear
- 28. Treats [Clothing], [Gear], [and] [Gardening Apparel]
- 29. [Repel(s)] [Protect(s)] against [Aedes] mosquitoes that may [carry] [transmit] [diseases] [such as] [Zika] [virus], [West Nile virus], [Dengue], [Chikungunya], [and] [Eastern Equine Encephalitis] when used as a treatment for clothing and gear.
- 30. Does not harm [any] fabrics or finishes
- 31. Do Not Apply to Skin, Apply to Fabric Only
- 32. [Product Name] is an insect repellent [treatment] and can be applied to clothing, gear, [tents] and fabrics.
- 33. Once the insect repellent treatment has dried, it is [completely] odorless and will last for [6 weeks] [42 days] or 6 washes.
- 34. This [fabric] [insect repellent] treatment does not harm [any] fabrics or finishes and can be used to treat clothing, footwear, workwear, bibs, canvas, work-stations, seat covers, hammocks, chairs, tents, Camping Gear, Mosquito Netting, Nets, Outside of Sleeping Bags, Backpacks and Ground Cloths, and other fabrics.
- 35. [Be sure to] [thoroughly] shake the bottle before use.
- 36. [For the application process] Hang clothing up outside to treat or lay down flat in a well-ventilated area to help the permethrin treatment bond with the fabric fibers and maximize the repellent's effectiveness and longevity
- 37. Permethrin is harmful to cats and cats should not be exposed to product during application or drying time.
- 38. Do not wear or use clothing or gear treated with Permethrin [insect repellent] [fabric] treatment around cats until the item has completely dried.
 - 39. Graphics and/or symbols:

















