

79533-4

06-15-2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

79533-4

Date of Issuance:

JUN 15 2011

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Coleman® Insect Repellent

Name and Address of Registrant (include ZIP Code):

Wisconsin Pharmacal Co., LLC
1 Pharmacal Way
Jackson, WI 53037

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you:

1. Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under section 4 of FIFRA.

(continued on page #2)

Signature of Approving Official:

Refer to Page #2.

Richard J. Gebken, Product Manager (10)
Insecticide Branch, Registration Division (7504P)

Date:

JUN 15 2011

2. Make the following change to the label:

- a. Change the product registration number to "EPA Reg. No. 79533-4"
- b. Make the following label revisions:

General Statement:

- 1. Delete all text throughout the label marked with "~~strikethrough~~."

HOTLINE NUMBER subsection comment(s):

- 2. Revise 2nd sentence to read "For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call the National Pesticide Information Center at 1-800-858-7378, 6:30 a.m. to 4:30 p.m. PST. After 4:30 p.m., call your poison control center at 1-800-222-1222."

OPTIONAL MARKETING LANGUAGE section comment(s):

- 3. Revise the 1st optional marketing claim to read "DEET protection that provides up to 8 hours of protection against mosquitoes."

Conditional Data Requirements:

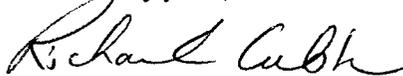
- 4. Within one (1) year from the date of this registration, Wisconsin Pharmacal Co., LLC is obligated to submit a One Year Storage Stability (830.6317) study and a Corrosion Characteristics (830.6320) study on this product in support of this registration.¹
3. Submit two (2) copies of the final printed 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.

Current labels on DEET repellent products tend to dissolve from contact with the repellent (usually liquids). All DEET product labels must use materials that remain permanent and readable for the reasonable life of the product.

Should Wisconsin Pharmacal Co., LLC wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA 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 section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists 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 be substantially differ from those claims approved through the registration process. 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 EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, Wisconsin Pharmacal Co., LLC may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records along with hard copies of the acute toxicity and product chemistry reviews completed for this product. If you have any questions about this labeling review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,



Richard J. Gebken,
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

Enclosures: Copy of label stamped "Accepted with Comments"
Copy of acute toxicity review, dated June 10, 2011
Copy of product chemistry review, date d May 4, 2011

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¹ For more detailed information, please refer to page 4 of 4 of the product chemistry review completed for this product.

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(Front Panel)

Coleman® Insect Repellent

ACTIVE INGREDIENT:

DEET 40.0%

OTHER INGREDIENTS: 60.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

Read cautions on back

Net (Contents:) 4 fl oz (11 mL)

ACCEPTED
With COMMENTS
In EPA Letter Dated:

June 15, 2011

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

79533-4

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(Back Panel) (STOP – Read and follow all directions and precautions on this product label.)

DIRECTIONS FOR USE

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

Do not spray in enclosed areas. Hold bottle 6 inches from skin and clothing while spraying, keeping sprayer pointed away from face. Slightly moisten skin. Use just enough repellent to cover exposed skin and/or clothing. Do not use under clothing.

If used on the face, spray on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face. Do not apply near eyes and mouth. Apply sparingly around ears. Do not apply over cuts, wounds or irritated skin. Do not apply to sunburned skin. Do not apply to children's hands. Do not allow children to handle this product. When using on children, apply to your own hands and then put it on the child.

Spray on outer surfaces of clothing at openings such as neckband, waistband, pant and sleeve cuffs, sock tops and other areas where insects may crawl under clothing.

Avoid over-application of this product. After returning indoors, wash treated skin with soap and water {and double-check yourself, other family members and pets for ticks.} Wash treated clothing before wearing it again. Will not damage nylon, cotton, or wool. May damage some synthetic fabrics, plastics, watch crystals, leather, painted or varnished surfaces.

STORAGE AND DISPOSAL

STORAGE: Store the product in a cool, dry place. Keep out of reach of children.

DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container.

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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - WARNING: Causes substantial but temporary eye injury. Do not get in eyes. Harmful if swallowed. Use of this product may cause skin 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. Remove and wash contaminated clothing before reuse. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

PHYSICAL OR CHEMICAL HAZARDS - COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

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, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

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 a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

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Have the product container or label with you when calling a Poison Control Center or Doctor, or going for treatment. **HOTLINE NUMBER:** For more information on this pesticide product call the National Pesticide Information Center at 1-800-858-7378, 6:30 am – 4:30 pm PST, Monday - Saturday.

NOTE TO PHYSICIAN: Probably mucosal damage may contraindicate the use of gastric lavage.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

Questions or Comments: Call 1-800-558-6614

{Visit our web site at www.pharmacalway.com}

Distributed by:

Wisconsin Pharmacal Co., LLC
1 Pharmacal Way, Jackson,
WI 53037 U.S.A.

EPA Reg. No. (pending as File Symbol 79533-U)

EPA Est. No. 75272-WI-001

(Batch code / Lot No.: _____)

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OPTIONAL MARKETING LANGUAGE

~~Strong~~ DEET protection that lasts up to 8 hours.

{OPTION 1

Developed especially for campers, backpackers, fisherman, hunters and other active outdoor enthusiasts. Coleman Insect Repellent repels mosquitoes for up to 8 hours. The non-greasy formula provides up to 4 hours protection from ticks, biting flies, gnats, chiggers, fleas and no-see-ums}

{OPTION 2

Coleman Insect Repellent provides up to 8 hours protection from mosquitoes and up to 4 hours protection from biting flies. Developed especially for hunters and fishermen, Coleman Insect Repellent has no added {scent} {fragrance}. This formulation also offers up to 4 hours protection from ticks, chiggers, no-see-um, gnats, and fleas.}

{OPTION 3

Coleman Insect Repellent spray is formulated to provide up to 8 hours of protection from mosquitoes. This formulation also offers up to 4 hours protection from biting flies, ticks, chiggers, fleas and no-see-ums. Coleman's unique formula is not greasy, won't stain, and has no unpleasant odor.}

• INSECT REPELLENT

- Protection from mosquitoes, ticks, biting flies, gnats, chiggers, no-see-ums and fleas · Lasts up to 8 hours against mosquitoes
- Provides up to 8 hours of protection against mosquitoes
- Protection that lasts up to 8 hours against mosquitoes
- Provides protection for up to 8 hours against mosquitoes
- 8 hours protection against mosquitoes
- Effective protection from Mosquitoes, chiggers, ticks, biting flies, no-see-ums, gnats and fleas
- Tough on bugs
- Repels mosquitoes, chiggers, ticks, biting flies, no-see-ums, gnats and fleas
- Repels listed biting insects for up to 4 hours
- Repels Mosquitoes That May Carry West Nile Virus
- Mosquito Repellent
- CONTAINS DEET {n,n-Diethyl-m-toluamide}
- 40% DEET
- The non-greasy formula provides up to 8 hours of protection against mosquitoes and up to 4 hours of protection against listed biting insects
- Non-greasy
- Not greasy or oily
- Spray on exposed skin and/or outer surfaces of clothing
- It won't stain
- Won't stain
- Non-staining
- Starts to work immediately
- Sportsmen
- Unscented formula{tion} for effective protection while hunting
- Unscented
- Unscented protection
- Convenient pump
- {New} pump formula}
- Pocket Size