

5/28/96 F40

PM 10

6148-11

PP 175

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number 244613

Application for Pesticide - Section I

1. Company/Product Number 6148-11
2. EPA Product Manager Mr. Richard Keigwin
3. Proposed Classification [X] None [] Restricted
4. Company/Product (Name) Coppertone Sun and Bug Block
5. Name and Address of Applicant Schering-Plough HealthCare Products
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 JUN 4 1996

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of Alternate Brand Name and Label Text Changes per PR Notice 95-2. See continuation sheet for required PR Notice 95-2 statement.

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 Doreen Frank, Title Manager, Regulatory Affairs, Telephone No. (908) 604-1655. Certification: I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. 2. Signature, 3. Title Vice President, Regulatory Affairs, 4. Typed Name Joseph D. Clark, Jr., PhD., 5. Date 5/24/96, 6. Date Application Received stamped MAY 28 P2:54

Continuation Sheet - OPP Identifier Number 244613

Section II

This notification is consistent with the provisions of PR Notice 95-2 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 95-2 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.

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Front Panel

Label Text Changes - 5/24/96

COPPERTONE® BUG & SUN
Sunscreen with Insect Repellent

ADULT FORMULA

COPPERTONE® SUN AND BUG BLOCK

Water-resistant ~~Waterproof~~ SPF 15 Sunblock

ACTIVE INGREDIENTS:*

N,N-diethyl-~~m~~-toluamide 9.5%
Other Isomers 0.5%

INERT INGREDIENTS: 90.0%

TOTAL 100.0%

*Insect Repellent

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See directions and additional precautions ~~precautionary~~
~~statements~~ on back panel.

4 fl oz (118 mL)

Back Label

Label Text Changes - 5/24/96

Back Label

~~Coppertone® Sun and Bug Block~~ ~~Coppertone® Bug & Sun Sunscreen with Insect Repellent ADULT Formula~~ lotion is specially formulated to provide protection for over two hours against mosquitoes, gnats, and biting flies (sand flies, black flies, and deer flies), as it protects you from the sun. ~~Coppertone® Bug & Sun Sunscreen with Insect Repellent ADULT Formula~~ offers convenient dual protection in one bottle, for total outdoor skin protection. It is water-resistant and provides protection from UVA and UVB rays. This **WATERPROOF** SPF 15 sunscreen protects from harmful UVA and UVB rays, while it also repels mosquitos, gnats, deer flies, stable flies, and black flies, on exposed skin surfaces. This pleasantly-fragranced, PABA-free, **NON-GREASY** lotion also **MOISTURIZES** dry skin with soothing Aloe Vera. ~~It moisturizes dry skin and~~ Regular use may help reduce the chance of long term sun damage such as premature aging, wrinkling, and skin cancer.

DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling. **Read all directions before using this product.** Shake well. Apply evenly before exposure to sun and insects. Reapply after prolonged swimming or excessive perspiration. Use just enough product to cover exposed skin. Do not use under clothing. Frequent reapplication and saturation is unnecessary for effectiveness. If you suspect that you or your child is reacting to this product, wash treated skin and call your local Poison Control Center. If your go to the doctor, take this repellent with you. Do not apply to eyes and mouth, and do not apply to the hands of young children. Wipe palms after applying. Avoid overexposure. After returning indoors, wash treated skin with soap and water. Consult a physician before use on children under 6 months of age.

PRECAUTIONARY STATEMENTS: ~~HAZARD TO HUMANS-~~ **CAUTION:** Harmful is swallowed. Do not apply over cuts, wounds, or irritated skin. Avoid contact with eyes and lips. Causes moderate eye irritation. Use of this product may cause skin reactions in rare cases. Avoid contact with plastic and fabric such as acetate, rayon and dnyel. May damage some plastics, furniture finishes, painted surfaces, and linoleum. Will not damage nylon, cotton, wool, or polyester.

STATEMENT OF PRACTICAL TREATMENT: **If in eyes-** flush with plenty of water. Call a physician if irritation persists. **If on skin-** May cause skin reactions in rare cases. If so wash with soap and water. Get medical attention if irritation persists. **If swallowed** call a physician or Poison Control Center, immediately.

Disposal: Do not reuse empty container, wrap container and put in trash.

Back Label-Continued

Label Text Changes - 5/24/96

ACTIVE SUNSCREEN INGREDIENTS: Ethylhexyl p-Methoxycinnamate, Oxybenzone, 2-Ethylhexyl Salicylate, Homosalate.

OTHER INGREDIENTS: ~~Water, sorbitan oleate, sorbitol, glyceryl stearate SE, sorbitan stearate, stearic acid, hydrogenated vegetable oil, octadecene/MA copolymer, triethanolamine, benzyl alcohol, fragrance, dimethicone, methylparaben, imidazolidinyl urea, propylparaben, tocopherol (vitamin E), aloe extract, jojoba oil, acrylates/C10-3 alkyl acrylate crosspolymer, disodium EDTA.~~

EPA Reg. No. 6148-11

EPA Est. No. 066804-FL-001

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