

10/3/96

PM 10 6148-11 pg 1/4

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

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

OPP Identifier Number
244615

Application for Pesticide - Section I

1. Company/Product Number 6148-11	2. EPA Product Manager Mr. Richard Keigwin	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Schering-Plough HealthCare Products 3030 Jackson Avenue Memphis, Tennessee 38151 <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 or identical in composition and labeling to: EPA Reg. No. _____ 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 of alternate brand name and label text changes per PR Notice 95-2. The continuation sheet for required PR Notice 95-2 movement.

NOTIFICATION
10/3/96

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input 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 Doreen Frank	Title Manager, Regulatory Affairs	Telephone No. (include Area Code) 908-604-1555
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.		8. Date Application Received (Stamped)
2. Signature 	3. Title Vice President, Regulatory Affairs	
4. Typed Name Joseph D. Clark, Ph.D.	5. Date 9/26/96	

Front Panel

Label Text Changes - 9/26/96

COPPERTONE[®] BUG & SUN
Sunscreen with Insect Repellent

ADULT FORMULA

Alternate Name:

COPPERTONE[®] BUG & SUN
BLOCK
Sunscreen with Insect Repellent

ADULT FORMULA

Waterproof SPF 15

ACTIVE INGREDIENTS:

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

INERT INGREDIENTS:

90.0%

TOTAL

100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See additional precautionary statements on back panel.

4 fl oz (118 mL)

10.396

NOTIFICATION

Back Panel

001 2-1998

Label Text Changes - 9/26/96

Coppertone® Bug & Sun Sunscreen with Insect Repellent ADULT Formula

Coppertone® Bug & Sun Block Sunscreen with Insect Repellent ADULT Formula

offers convenient dual protection in one bottle, for total outdoor skin protection. 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. 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 you 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 if 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 Dynel. 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.

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

EPA Reg. No. 6148-11
EPA Est. No. 066804-FL-001

Back Label-Continued
Label Text Changes - 5/24/96

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