DM 10 6148-11

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A EDA	U	nited States			- Form App		Registra		OPP Identifier Number		
\$EPA	on Age	псу			Amendr Other		215818				
Application for Pesticide - Section I											
1. Company/Product Number				2. EPA Product Manager					3. Proposed Classification		
6148-11					ichard K	eigv	/in	X	None Restricted		
4. Company/Product (Name) Coppertone Sun & Bug Block				PM#	0	29:00:00 <u>2-</u> 25;	erije <u>an yr</u> eijih kunyum mag ik				
5. Name and Address of App Schering-Plough 3030 Jackson Ave Memphis, Tenness	6. Expedited Reveiw. 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 X Notification - Explain below.				Final printed labels in repsonse to Agency letter dated "Me Too" Application. Other - Explain below.							
A nothernoon											
Notification of alternate name (brand name) and Label text changes per PR Notice 95-2. The continuation sheet for required PR Notice 95-2 statement.											
Section - III											
1. Material This Product Will Be Packaged In:									富安地区		
Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging				2. Type of Container Metal					
No	Yes Yes No			Yes			Plastic				
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes	No ge wgt	No. per container	<u></u>		Glass Paper Other (Specify)			
3. Location of Net Contents Information 4. Size(s) R				ner	ons _						
Label Container									— ak		
6. Manner in Which Label is Affixed to Product		Lithog Paper Stend	ogreph Other					<u> </u>	To The second of		
				ion - I	/				£		
1. Contact Point (Complete	items directly below t	or identification	on of indiv	idual to b	contacted,	if nec	essary, to p	ocess this	application.		
Name Doreen Frank			Title Manager- Regulatory Affairs			ffairs	Telephone No. (Include Area Code)				
3013311 7.1311	<u> </u>	Certifica	l	-80-7			aramanar ne		6: Date Application		
	i all attacl	all attachments thereto are true, accurate and complete, ement may be punishable by fine or imprisonment or					Received (Stamped)				
2. Signature			3. Title								
Clah			Vice President-Regualtory Affairs					irs	6 6 6 6 6 6 6 6 6		
4. Typed Name			5. Date								
Joseph D. Clark, Ph.D.			10/7/96								

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Continuation Sheet - OPP Identifier Number 215818

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 - 10/7/96

COPPERTONE ® BUG & SUN Sunscreen with Insect Repellent

ADULT FORMULA

Alternate Name:

COPPERTONE® BUG & SUN BLOCK

Sunscreen with Insect Repellent

ADULT FORMULA

Alternate Name:

MUSKOL® 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)

Back Panel
Label Text Changes 10/7/96

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

Muskol® 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 Methoxycinnaniate, Oxybenzone, 2-Ethylhexyl Salicylate, Homosalate

EPA Reg No 6148 11 EPA Est No 066804 FL 001

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Back Label-Continued
Label Text Changes 10/7/96

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