OCEAN POTION QUICK DRY 15 SUNSCREEN - avobenzone, homosalate,octisalate lotion Sun & Skin Care Research, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Homosalate: 7.5% Octisalate: 5% Avobenzone: 1.2%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- If used as directed with other skin protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only. Do not use on damaged or broken skin. **Stop use and ask a doctor if** rash occurs. **When using this product** keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply after 80 minutes of swimming or sweating and immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including limiting time in the sun, especially from 10a.m.-2p.m., wear long-sleeved shirts, pants hats and sunglasses.
- children under 6 months: Ask a doctor

Other Information

- For use on skin only
- Avoid contact with fabric
- Protect this product from excessive heat and direct sun

*WHEN USED REGULARLY AS DIRECTED. HELPS PREVENT PREMATURE SKIN AGING CAUSED BY THE SUN'S HARMFUL RAYS.

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Inactive Ingredients Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Caprylyl Glycol, Carborner, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Macrocystis Pyrifera Extract, Phenoxyethanol, Polyester-8, Propylene Glycol, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, Water

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MANUFACTURED AND DISTRIBUTED BY Sun & Skin Care Research, Inc. 851 Greensboro Rd., Cocoa, FL 32926 Made in U.S.A. **www.oceanpotion.com**

1-800-715-3485



Black



OCEAN POTION QUICK DRY 15 SUNSCREEN

avobenzone, homosalate, octisalate lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62802-140

Route of Administration TOPICAL

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Active ingredient/Active Molety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 mL in 100 mL	
OCTISALATE (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)	OCTISALATE	5 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809 Y72KV36)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
CARBOMER HOMOPOLYMER TYPE B/C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CHOLECALCIFEROL (UNII: 1C6 V77QF41)	
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)	
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2JEZ)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78 RG6 M2N2)	
PHENO XYETHANO L (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-140-08	237 mL in 1 BOTTLE		
2	NDC:62802-140-03	89 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	0 1/0 1/20 12	

Labeler - Sun & Skin Care Research, LLC (849772207)

Establishment			
Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture

Revised: 5/2012 Sun & Skin Care Research, LLC