OCEAN POTION QUICK DRY SPF 70 SUNSCREEN - avobenzone, homosalate, oxybenzone, octisalate, octocrylene lotion Sun & Skin Care Research, Inc

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

Homosalate: 15% Oxybenzone 6% Octisalate: 5% Octocrylene: 2% Avobenzone: 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 aska 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



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- protection measures including: limit time in the sun, especially from 10 a.m. – 2 p.m.
- · wear long-sleeved shirts, pants, hats, and sunglasses children under 6 months: Ask a doctor

Inactive Ingredients Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, C12-15 Alkyl Benzoate, Carbomer, Cholecalciferol, Dimethyl Capramide, Disodium EDTA, Fragrance, Iodopropynyl Butylcarbamate, Macrocystis Pyrifera (Kelp) Extract, Olea Europaea (Olive) Fruit Oil, Peg-40 Hydrogenated Casto Oil, Phenoxyethanol, Polyester-8, Propylene Glycol, Retinyl Palmitate, Sorbitan Oleate. Tocopheryl Acetate. Triethanolamine. Water

Other Information

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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

PMS 301

PMS 1788

PMS 1955

Black

die line



OCEAN POTION QUICK DRY SPF 70 SUNSCREEN

avobenzone, homosalate, oxybenzone, octisalate, octocrylene lotion

Product Information HUMAN OTC DRUG NDC:62802-144 Product Type Item Code (Source) TOPICAL **Route of Administration**

Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 mL in 100 mL
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)	
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2JEZ)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ALPHA-TO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0)	
TRO LAMINE (UNII: 903K93S3TK)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62802-144-08	237 mL in 1 BOTTLE		
2 NDC:62802-144-03	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, Inc (849772207)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sun & Skin Care Research, Inc		849772207	manufacture(62802-144)	