

OCEAN POTION QUICK DRY 50 SUNSCREEN - avobenzone, homosalate, octisalate, octocrylene 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: 15%

Octisalate: 5%

Octocrylene: 7%

Avobenzone: 3%

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

VITAMIN D IS ESSENTIAL TO YOUR HEALTH. EACH 1 OZ APPLICATION DELIVERS 200 IU OF VITAMIN D3 TO YOUR SKIN. FORMULATED WITHOUT HARSH INGREDIENTS SUCH AS OXYBENZONE AND PARABENS.

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

Drug Facts

Active ingredients	Purpose
Avobenzone 3.0%, Homosalate 12.0%, Octisalate 5.0%, Octocrylene 5.0%	Sunscreen

Uses
helps prevent sunburn ■ if used as directed with other sun 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 reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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 - 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, Caprylyl Glycol, Carbomer, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium Edta, Fragrance, Hydroxypropyl Methylcellulose, Macrocystis Pyrifera Extract, Phenoxethanol, Polyester-8, Propylene Glycol, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, Water

Other Information
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Manufactured and Distributed by



Sun And Skin Care Research, Inc.
851 Greensboro Rd., Cocoa, FL 32926
Made in U.S.A. www.oceanpotion.com
1-800-715-3485

- heavy UV or Silk Screen white
- PMS 300
- PMS YELLOW
- PMS 1788
- Silk Screen white
- Black
- PMS 2583
- PMS 2623



Anti skin Aging*
QUICK DRY
50+
SUNSCREEN

Broad Spectrum
SPF 50+

now:

- ✓ Oxybenzone Free
- ✓ Paraben Free
- ✓ Vitamin D₃ Fortified

Water Resistant
(80 minutes)

8 FL OZ (237 mL)

OCEAN POTION QUICK DRY 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-147
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE 2208 (15000 MPAS) (UNII: Z78RG6M2N2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-147-08	237 mL in 1 BOTTLE		
2	NDC:62802-147-03	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	01/01/2012	

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

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