

OCEAN POTION SPF30 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion
SolSkyn Personal Care 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.

OP SPF 30 100ml

OP SPF 30 Lotion

Active Ingredients

Avobenzone 3%, Homosalate 8%, Octisalate 4.5%, Octocrylene 6%

Purpose

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
- Flammable: keep away from fire or flame.

Do not use on damaged or broken skin.

When using this product keep out of eyes.

Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- re-apply:
 - after 80 minutes of swimming or sweating
 - 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 broad spectrum SPF of 15 or higher and other sun 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

Other information

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

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Ascorbic Acid (Vitamin C), C28-52 Olefin/Undecylenic Acid Copolymer, Caprylyl Glycol, Cetearyl Alcohol, Diisopropyl Adipate, Dimethicone, Disodium EDTA, Fragrance, Glycerin, Glyceryl Stearate, Hydrogenated Palm Glycerides, Laminaria Saccharina Extract, Macrocystis Pyrifera Extract, Neopentyl Glycol Diheptanoate, PEG-16 Macadamia, PEG-100 Stearate, Phenethyl Benzoate, Phenoxyethanol, Polyglyceryl-3 Methylglucose Distearate, Potassium Cetyl Phosphate, Pyridoxine HCl (Vitamin B6), Sodium Hydroxide, Tapioca Starch Polymethylsilsesquioxane, Thermus Thermophilus Ferment, Tocopheryl Acetate (Vitamin E), Trisiloxane, Water, Xanthan Gum

Questions or comments?

www.oceanpotion.com call toll-free 1-800-715-3485

MAY STAIN SOME FABRICS, PLASTICS AND WOOD SURFACES.

PRINCIPAL DISPLAY PANEL

OCEAN
POTION
SUNCARE
30
SUNSCREEN LOTION
Scent of sunshine
3.4 FL OZ (100 mL)

Ocean Potion® Nourishing Beach Formulas are Sheer, Non-greasy. Enriched with Vitamins B, C, E, Deep Sea Minerals, Seaweed and Algae Extracts.



Scent of Sunshine™

**Oxybenzone Free, Reef-friendly
No Added Parabens, Gluten
With Sea Plants & Antioxidants**

**Broad Spectrum SPF 30
UVA/UVB Protection
Water Resistant (80 Minutes)**

3.4 FL OZ (100 mL)

Drug Facts

Active Ingredients:	Purpose
Avobenzone 3%, Homosalate 8% Octisalate 4.5%, Octocrylene 6%	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: • Apply liberally 15 minutes before sun exposure. • Reapply: ▫ after 80 minutes of swimming or sweating ▫ 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 of 15 or higher and other sun 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.

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avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7028 1-504
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 100 mg

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 mg in 100 mg
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4.5 mg in 100 mg
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	6 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
LAMINARIA SACCHARINA EXTRACT (UNII: 68CMP2MB55)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
PEG-16 MACADAMIA GLYCERIDES (UNII: 2OTC93KMHU)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-504-24	100 mg in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/15/2017	

Labeler - SolSkyn Personal Care LLC (080010329)