

**OCEAN POTION SPF15 SUNSCREEN- avobenzene, homosalate, octisalate and 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.*

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**OP SPF 15 200ml**

OP SPF 15 Lotion

***Active Ingredients***

Avobenzene 2%, Homosalate 8%, Octisalate 5%, Octocrylene 5%

***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, Aloe Barbadosis Leaf Juice, Ascorbic Acid (Vitamin C), C28-52 Olefin/Undecylenic Acid Copolymer, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Diisopropyl Adipate, Dimethicone, Disodium EDTA, Fragrance, Glycerin, Hydrogenated Palm Glycerides, Laminaria Saccharina Extract, Macrocytis Pyrifera Extract, Neopentyl Glycol Diheptanoate, PEG-16 Macadamia, Phenethyl Benzoate, Phenoxyethanol, Polyglyceryl-3 Methylglucose Distearate, Potassium Cetyl Phosphate, Pyridoxine HCl (Vitamin B6), Sodium Hydroxide, Stearic Acid, Tapioca Starch Polymethylsilsesquioxane, Thermus Thermophilus Ferment, Tocopheryl Acetate (Vitamin E), Water

### ***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  
15  
SUNSCREEN LOTION  
Scent of sunshine  
6.8 FL OZ (200 mL)

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



**NO ADDED:**

PARABENS • OXYBENZONE • OCTINOXATE  
 PROPYLENE GLYCOL • RETINYL PALMITATE  
 OILS • PABA • GLUTEN • BHT • BPA

NO ANIMAL TESTING • SEPARATE TUBE & CAP TO RECYCLE



**OCEAN  
 POTION®**  
 SUNCARE

**15**

**SUNSCREEN LOTION**

*Scent of Sunshine™*

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

**Broad Spectrum SPF 15  
 UVA/UVB Protection  
 Water Resistant (80 Minutes)**

**6.8 FL OZ (200 mL)**

**Drug Facts**

**Active Ingredients:** Avobenzone 2%, Homosalate 8%, Octisalate 5%, Octocrylene 5% **Purpose:** Sunscreen

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**Questions or Comments?**

oceanpotion.com or call toll-free 800-715-3485

Distributed by: SolSkyn Personal Care LLC  
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PKTB-11430-DM01



**OCEAN POTION SPF15 SUNSCREEN**

avobenzone, homosalate, octisalate and octocrylene lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70281-506
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mg in 100 mg
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 mg in 100 mg
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mg in 100 mg

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 mg in 100 mg
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### 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)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
SACCHARINA LATISSIMA (UNII: 68CMP2MB55)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
PEG-16 MACADAMIA GLYCERIDES (UNII: 2OTC93KMHU)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
THERMUS THERMOPHILUS LYSATE (UNII: 775R692494)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-506-24	200 mg in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/15/2015	

**Labeler** - SolSkyn Personal Care LLC (080010329)