# OP SPF 70 ANTI AGING SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, oxybenzone 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 Protect Nourish Sunscreen Ltn SPF 70

OP SPF 70 Anti Aging Sunscreen

### Active ingredients

Avobenzone 2.0%

#### Active ingredients

Homosalate 15.0%

#### Active ingredients

Octisalate 5.0%

#### **Active ingredients**

Octocrylene 2.0%

#### Active ingredients

Oxybenzone 6.0%

#### **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.
- 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.
- 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 a Broad Spectrum SPF value 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.

#### **Inactive Ingredients**

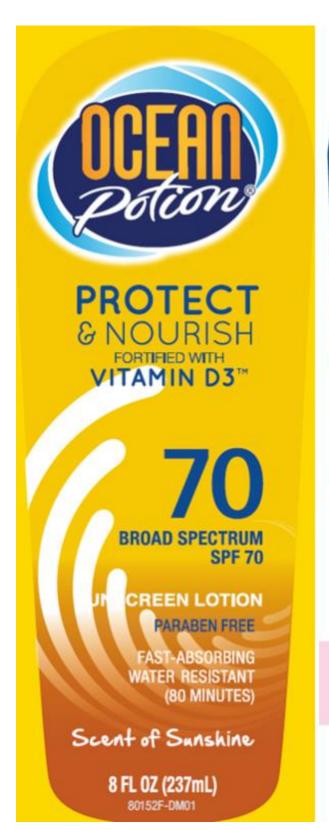
Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, C12-15 Alkyl Benzoate, Carbomer, Cholecalciferol, Dimethyl Capramide, DisodiumEDTA, Fragrance, Iodopropynyl Butylcarbamate, Macrocystis Pyrifera (Kelp) Extract, Olea Europaea (Olive) Fruit Oil, Peg-40 Hydrogenated Castor Oil, Phenoxyethanol,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

#### **Other Information**

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

#### PRINCIPAL DISPLAY PANEL

Ocean Potion Protect & Nourish Vitamin D3 SPF 70 8 fl oz (237 mL)



Ocean Potion® Protect & Nourish fortified with Vitamin D3™ and antioxidants, provides UVA/UVB sun protection while keeping skin healthy & youthful looking. This non-greasy, fast absorbing lotion with its signature scent is sunshine in a bottle. Trust the protection. Enjoy the experience!

#### Drug Facts

Active Ingredients

Purpose

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

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No Animal Testing Distributed by SolSkyn Personal Care LLC \$ 1725 North Brown Rd., Lawrenceville, GA 30043

oceanpotion.com 800-715-3485 MADE IN USA

#### OP SPF 70 ANTI AGING SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70281-220

**Route of Administration** TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	6 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2JEZ)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
MACRO CYSTIS PYRIFERA (UNII: K31S3OG5C4)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
SORBITAN MONOOLEATE (UNII: 06 XEA2 VD56)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

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ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1	NDC:70281-220-24	227 g in 1 CONTAINER; Type 0: Not a Combination Product	09/15/2015	

Marketing Informat	Iarketing 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)