

OP SPORT SUNSCREEN SPF30- avobenzene, 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-SPF30 3oz Sport Cooling Sunscreen Lotion

OP Sport Sunscreen Lotion spf30

Active Ingredients

Avobenzene 3.0%, Homosalate 12.0%, Octisalate 5.0%, Octocrylene 5.0%

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 prior to 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, Carbomer, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Hydroxypropyl Methylcellulose, Idopropynyl Butylcarbamate, Macrocystis Pyrifera Extract, Menthol, Phenoxyethanol, Polyester-8, Propylene Glycol, Silica, 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
SPORT COOLING
30 BROAD SPECTRUM
SPF 30
SUNSCREEN LOTION
3 FL OZ (89mL)



SUNSCREEN LOTION**OXYBENZONE & PARABEN FREE****FAST-ABSORBING
WATER RESISTANT
(80 MINUTES)****FRAGRANCE FREE****3 FL OZ (89mL)**

30146F-DMD1

*Trust the protection.
Enjoy the experience!***Drug Facts****Active Ingredients**Avobenzone 3.0%, Homosalate 12.0%,
Octisalate 5.0%, Octocrylene 5.0%**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
■ 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 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, Octopylmethacrylate, Copolymer, Carbomer, Cholecalciferol, Ethylhexyl Methacrylate, Dimethyl Caprylate, Disodium EDTA, Hydroxypropyl Methylcellulose, Isopropyl Myristate, Microcystin Pyrethrin Extract, Menthol, Phenylethyl Alcohol, Polyester-8, Propylene Glycol, Silica, Sorbitan Oleate, Tocopheryl Acetate, Triethoxycellulose, Water**Other information** For use on skin only. Avoid contact with fabric • protect this product from excessive heat and direct sun

30146 P-0W1

No Animal Testing*Distributed by***SolSkyn Personal Care LLC**

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MADE IN USA

OP SPORT SUNSCREEN SPF30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	12 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
MENTHOL (UNII: L7T10EIP3A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-207-04	85 g in 1 CONTAINER; 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)

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SolSkyn Personal Care LLC