

OP PROTECT AND NOURISH SPF 30 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 Protect Nourish SPF 30 Sunscreen Lotion

OP Protect & Nourish SPF 30 Sunscreen Lotion

Active Ingredients

Avobenzone 3.0%

Active Ingredients

Homosalate 12.0%

Active Ingredients

Octisalate 5.0%

Active Ingredients

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, Fragrance, Hydroxypropyl Methylcellulose, Idopropynyl Butylcarbamate, Macrocystis Pyrifera Extract, Phenoxyethanol, Polyester-8, Propylene Glycol, 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 30
Sunscreen Lotion
3 FL OZ (89mL)



PROTECT & NOURISH
FORTIFIED WITH
VITAMIN D3™

30
BROAD SPECTRUM
SPF 30

SUNSCREEN LOTION
OXYBENZONE FREE
PARABEN FREE

FAST ABSORBING
WATER RESISTANT
(80 MINUTES)

Scent of Sunshine
3 FL OZ (89mL)
30145F-DM01

*Trust the protection.
Enjoy the experience!*

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 ■ 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 Crosspolymer, Acrylates Copolymer, Carbomer, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Idopropynyl Butylcarbamate, Macrocystis Pyrrifera Extract, Phenoxyethanol, Polyester-8, Propylene Glycol, 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	



30145R-DM01



No Animal Testing
Distributed by
SoiSkyn Personal Care LLC
1725 North Brown Rd., Lawrenceville, GA 30043
oceanpotion.com 800-715-3485
MADE IN USA

OP PROTECT AND NOURISH SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 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)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (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:70281-208-04	89 g in 1 CONTAINER; 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)

Revised: 2/2018

SolSkyn Personal Care LLC