

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 8OZ

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:

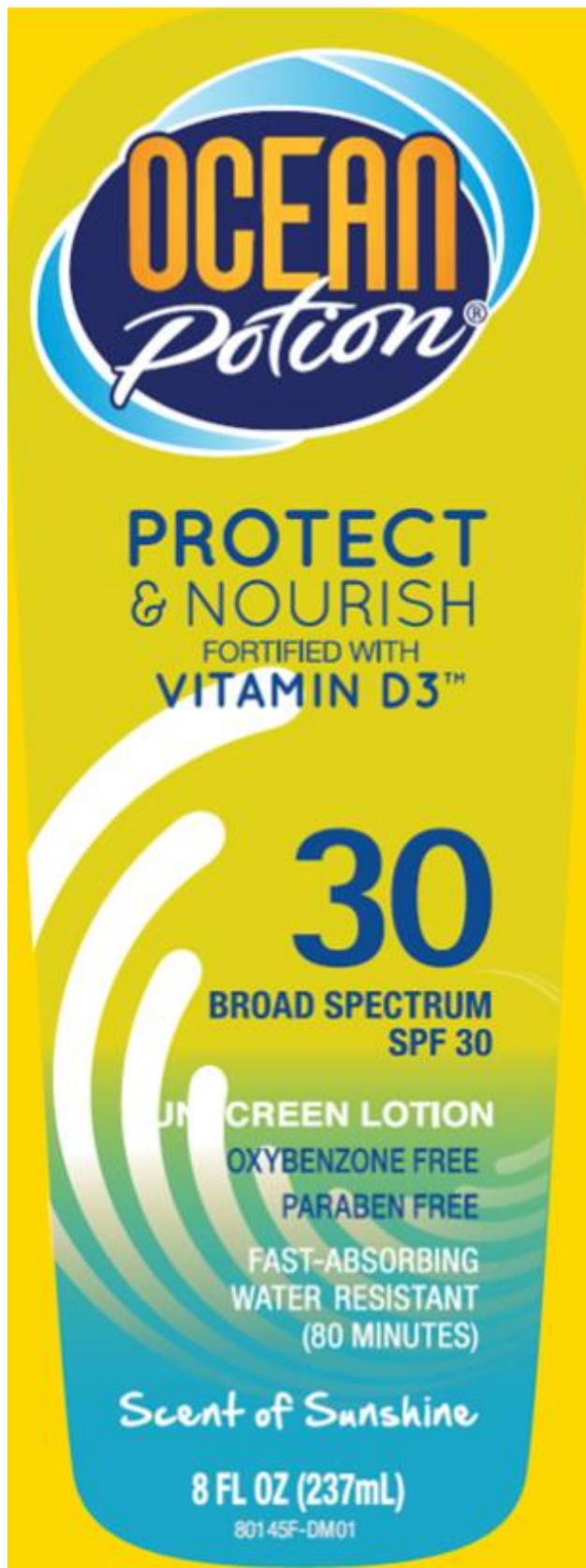
Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Carbomer, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Idopropynyl Butylcarbamate, Macrocystis Pyrifera Extract, Phenoxyethanol, Polyester-8, Propylene Glycol, Sorbitan 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
SPF 30
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	
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Avobenzene 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	
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■ reapply:	
• after 80 minutes of swimming or sweating	
• immediately after towel drying • at least every 2 hours	
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Inactive Ingredients	
Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Carbomer, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Iodopropinyl Butylcarbamate, Macrocystis Pyritera 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	



80145F-DM01

No Animal Testing

Distributed by
SolSkyn Personal Care LLC
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MADE IN USA

OP PROTECT AND NOURISH SPF 30 SUNSCREEN

avobenzene, homosalate, octisalate, octocrylene lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70281-210

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 BUTYL CARBAMATE (UNII: 603P14DHEB)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL 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:70281-210-24	227 g in 1 CONTAINER; Type 0: Not a Combination Product	09/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/15/2016	

Labeler - SolSkyn Personal Care LLC (080010329)

Revised: 2/2018

SolSkyn Personal Care LLC