

OP PROTECT AND RENEW FACE SPF 35- avobenzone, homosalate, octocrylene, octyl salicylate 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-SPF35 3oz Protect Renew Face

OP Protect & Renew Face SPF 35

Active Ingredients

Avobenzone 3.0%

Active Ingredients

Homosalate 15.0%

Active Ingredients

Octocrylene 2.7%

Active Ingredients

Octyl Salicylate 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.
- Re-apply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every two 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

Caprylyl Methicone, Carbomer, Cetearyl Alcohol, Disodium EDTA, Ethylhexylglycerin, Glycerin, Phenoxyethanol, Palmitoyl Tripeptide-5, Potassium Cetyl Phosphate, Tapioca Starch, Tocopherol, Tocopherol Acetate, Triethanolamine, Water, Xanthan Gum

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
& Renew
face
SPF 35
3 fl oz (89ml)

NEW



PROTECT & RENEW™

FACE



ANTI-WRINKLE with PEPTIDES & VITAMIN E

ULTRA-SHEER SUNSCREEN
FRAGRANCE FREE
FAST-ABSORBING
WATER RESISTANT
(80 MINUTES)

3 fl oz (89ml)

Drug Facts

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DISTRIBUTED BY

SoiSdyn Personal Care LLC

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Lawrenceville, GA 30043

800-715-3485

OCEANPOTION.COM



NO ANIMAL TESTING
MADE IN USA

OP PROTECT AND RENEW FACE SPF 35

avobenzone, homosalate, octocrylene, octyl salicylate lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70 281-211

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	15 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL TRISILOXANE (UNII: Q95M2PIKJL)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-211-24	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)