

**OP PROTECT AND RENEW BODY SPF 45- avobenzone, homosalate, octocrylene, octyl salicylate, 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-SPF45 6oz Protect Renew Body 72-hr Moisture**

OP Protect & Renew Body SPF 45

***Active Ingredients***

Avobenzone 3.0%

***Active Ingredients***

Homosalate 15.0%

***Active Ingredients***

Octocrylene 2.35%

***Active Ingredients***

Octyl Salicylate 5.0%

***Active Ingredients***

Oxybenzone 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***

Acrylates/C10-30 Alkyl Acrylate Crossolymer, Butylparaben, Caprylyl Methicone, Citric Acid, Diisostearyl Malate, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hyrdogenated Coco-Glycerides, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Potassium Cetyl Phosphate, PPG-17/IPDI/DMPA Coploymer, Polydimethylsiloxane, Saccharide Isomerate, Silica, Sodium Citrate, Tocopheryl Acetate, Triethanolamine, Water

***Other Information***

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

**PRINCIPAL DISPLAY PANEL**

Ocean Potion  
Protect  
& Renew  
Body  
SPF 45  
6 fl oz (177 mL)

**NEW**



**PROTECT  
& RENEW™**

**BODY**

**45**

BROAD SPECTRUM  
SPF 45

72-HR MOISTURE



**TARGETS AGE SPOTS  
with VITAMIN B**

SKIN BRIGHTENING  
SHEER SUNSCREEN  
NON- GREASY  
FRAGRANCE FREE

6 fl oz (177ml)

**Drug Facts**

|   |   |                             |
|---|---|-----------------------------|
| <b>Active Ingredients</b><br>Avobenzone 3.0%, Homosalate 15%,<br>Octocrylene 2.35%, Octyl Salicylate 5.0%,<br>Oxybenzone 5.0% | } | <b>Purpose</b><br>Sunscreen |
|---|---|-----------------------------|

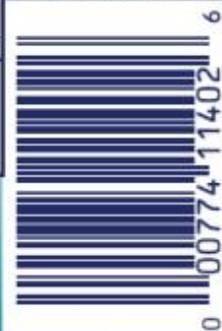
**Uses**  
- helps prevent sunburn - if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

**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 40 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-sleeve shirts, pants, hats, and sunglasses  
- children under 6 months: Ask a doctor

**Inactive Ingredients**  
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylparaben, Caprylyl Methicone, Citric Acid, Diisostearyl Malate, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Hydrogenated Coco-Glycerides, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Potassium Cetyl Phosphate, PPG-17/ IPDI/DMPA Copolymer, Polydimethylsiloxane, Saccharide Isomerate, Silica, Sodium Citrate, Tocopheryl Acetate, Triethanolamine, Water

**Other Information**  
- protect this product from excessive heat and direct sun  
- for use on skin only.  
Avoid contact with fabric



DISTRIBUTED BY  
**SolSkyn Personal Care LLC**  
1725 North Brown Road  
Lawrenceville, GA 30043  
800-715-3486  
**OCEANPOTION.COM**

**NO ANIMAL TESTING  
MADE IN USA**

**OP PROTECT AND RENEW BODY SPF 45**

avobenzone, homosalate, octocrylene, octyl salicylate, oxybenzone lotion

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70281-212 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 3 g in 100 g    |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 15 g in 100 g   |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 2.35 g in 100 g |

|   |            |              |
|---|------------|--------------|
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 5 g in 100 g |
| <b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 5 g in 100 g |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO) |          |
| <b>BUTYL PARABEN</b> (UNII: 3QPIU3FV8)                             |          |
| <b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)                     |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)                  |          |
| <b>DIISOSTEARYL MALATE</b> (UNII: QBS8A3XZGQ)                      |          |
| <b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)               |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)                       |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                                 |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                    |          |
| <b>HYDROGENATED COCO-GLYCERIDES</b> (UNII: XDD37N2GPR)             |          |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4)                              |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)                         |          |
| <b>PHENOXYETHANOL</b> (UNII: HE492ZZ3T)                            |          |
| <b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)                |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)                              |          |
| <b>SACCHARIDE ISOMERATE</b> (UNII: W8K377W98I)                     |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                          |          |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)                           |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)               |          |
| <b>TROLAMINE</b> (UNII: 9O3K93S3TK)                                |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                    |          |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70281-212-14 | 170 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)