

**OP SPF50 AND SPORT 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-SPF50 8oz Sport Cooling Sunscreen Lotion**

OP spf50+ Sport Sunscreen

***Active ingredients:***

Avobenzone 3.0%

***Active ingredients:***

Homosalate 15.0%

***Active ingredients:***

Octisalate 5.0%

***Active ingredients:***

Octocrylene 7.0%

***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 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, Iodopropynyl 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  
Protect  
& Nourish  
Sport  
cooling  
SPF 50  
8 fl oz (237 mL)

**PROTECT & NOURISH**  
 FORTIFIED WITH  
**VITAMIN D3™**

**SPORT**

---

**COOLING**

**50**

**BROAD SPECTRUM  
 SPF 50**

**SUNSCREEN LOTION**  
**OXYBENZONE & PARABEN FREE**

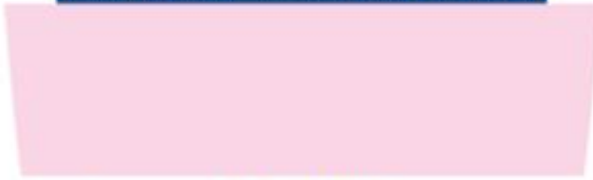
FAST-ABSORBING  
 WATER RESISTANT  
 (80 MINUTES)

FRAGRANCE FREE

**8 FL OZ (237mL)**  
 80148F-DM01

*Ocean Potion®  
 Sport sunscreen with skin  
 nourishing Vitamin D3 and cooling  
 menthol provides ultimate UVA/UVB sun  
 protection. This non-greasy, fragrance free lotion  
 feels light and is fast absorbing. Trust the protection.  
 Enjoy the experience!*

| Drug Facts   |                             |
|--|-----------------------------|
| <b>Active Ingredients</b><br>Avobenzone 3.0%, Homosalate 15.0%,<br>Octisalate 5.0%, Octocrylene 7.0%   | <b>Purpose</b><br>Sunscreen |
| <b>Uses</b><br>helps prevent sunburn ■ if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun   |                             |
| <b>Warnings</b><br>For external use only.<br><b>Do not use</b> on damaged or broken skin<br><b>Stop use and ask a doctor</b> if rash occurs<br><b>When using this product</b> keep out of eyes. Rinse with water to remove.<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |                             |
| <b>Directions</b><br>■ apply liberally 15 minutes before sun exposure<br>■ reapply:<br>• after 80 minutes of swimming or sweating<br>• immediately after towel drying • at least every 2 hours<br>■ <b>Sun Protection Measures.</b> 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:<br>• limit time in the sun, especially from 10 a.m. – 2 p.m.<br>• wear long-sleeved shirts, pants, hats, and sunglasses<br>■ children under 6 months: Ask a doctor |                             |
| <b>Inactive Ingredients</b><br>Acrylates / C10-30 Alkyl Acrylate Copolymer, Acrylates Copolymer, Carbomer, Cholecalciferol, Dilsopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Hydroxypropyl Methyloellulose, Iodopropynyl Butylcarbamate, Macrocystis Pyrifera Extract, Menthol, Phenoxyethanol, Polyester-8, Propylene Glycol, Silica, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, Water  |                             |
| <b>Other Information</b><br>■ For use on skin only. Avoid contact with fabric ■ protect this product from excessive heat and direct sun  |                             |



80148F-DM01  
 No Animal Testing  
 Distributed by  
**SolSkyn Personal Care LLC**  
 1725 North Brown Rd., Lawrenceville, GA 30043  
 oceanpotion.com 800-715-3485  
 MADE IN USA

**OP SPF50 AND SPORT SUNSCREEN**  
 avobenzone, homosalate, octisalate, octocrylene lotion

| Product Information |                |                    |               |
|---------------------|----------------|--------------------|---------------|
| Product Type        | HUMAN OTC DRUG | Item Code (Source) | NDC:70281-217 |

|                                |         |
|--------------------------------|---------|
| <b>Route of Administration</b> | TOPICAL |
|--------------------------------|---------|

| <b>Active Ingredient/Active Moiety</b>                         |                          |                 |
|--|--------------------------|-----------------|
| <b>Ingredient Name</b>   | <b>Basis of Strength</b> | <b>Strength</b> |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE               | 3 g in 100 g    |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE               | 15 g in 100 g   |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE               | 5 g in 100 g    |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE              | 7 g in 100 g    |

| <b>Inactive Ingredients</b>  |                 |
|--|-----------------|
| <b>Ingredient Name</b>   | <b>Strength</b> |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)            |                 |
| CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)                                |                 |
| CHOLECALCIFEROL (UNII: 1C6V77QF41)                                     |                 |
| DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)                                 |                 |
| DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)                                  |                 |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)                          |                 |
| HYPROMELLOSE, UNSPECIFIED (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: 059QF0KO0R)   |                 |

| <b>Packaging</b> |                  |   |                      |                    |
|------------------|------------------|---|----------------------|--------------------|
| #                | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
| 1                | NDC:70281-217-24 | 227 g in 1 CONTAINER; Type 0: Not a Combination Product | 09/15/2015           |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| 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)