

OP PROTECT AND NOURISH SPF 50 SUNSCREEN- 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.

OP Protect Nourish Sunscreen Ltn SPF 50

OP Protect & Nourish SPF 50 Sunscreen Lotion

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 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

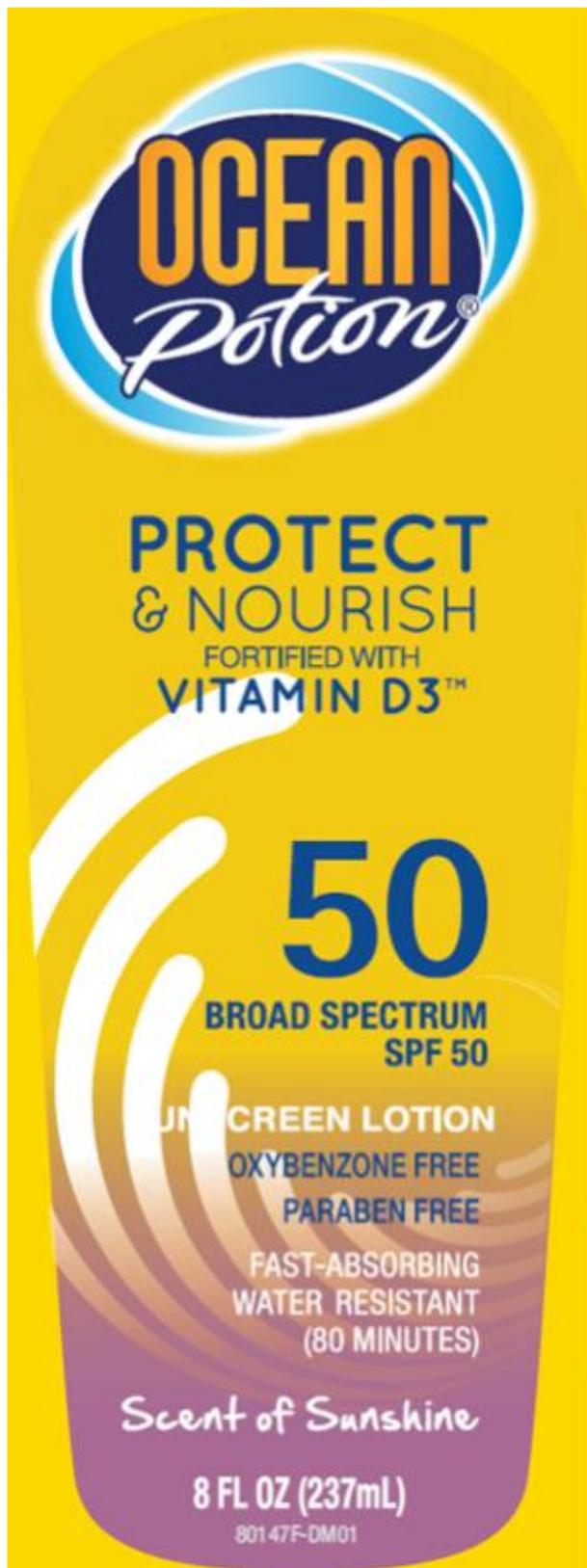
Acrylates / C10-30 Alkyl Acrylate Crosspolymer, Acrylates Copolymer, Carbomer, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Idopropynyl Butylcarbamate, Macrocystis Pyrifera Extract, Phenoxyethanol, Polyester-8, Propylene Glycol, Sorbitan, 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 50
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

| Active Ingredients | Purpose |
|---|-----------|
| Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 7.0% | 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

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Stop use and ask a doctor if rash occurs

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Directions

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■ reapply:

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• 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, Iodopropynyl Butylcarbamate, Macrocystis Pyrifera Extract, Phenoxethanol, 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

801 47F-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 PROTECT AND NOURISH SPF 50 SUNSCREEN

avobenzone, homosalate, octocrylene, octyl salicylate, oxybenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:7028 1-218 |
| 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 |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 5 g in 100 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 7 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 (UNII: 6O92ICV9RU) | |
| OLEIC ACID (UNII: 2UM9U37CP) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70281-218-24 | 227 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)