# OP PROTECT AND NOURISH KIDS SPF 50- 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 Kids Sunscreen Lotion

OP Protect & Nourish Kids SPF 50 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 Kids 50



Ocean Potion® Kids sunscreen with nourishing Vitamin D3 and antioxidants, provides UVA/UVB sun protection while keeping young skin healthy. Kids will enjoy wearing this non-greasy, fast absorbing lotion with a fresh tropical fruit fragrance. Trust the protection. Enjoy the experience!

### Drug Facts

Active Ingredients

Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 7.0%

Purpose

Sunscreen

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 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 / 010-30 Alkyl Acrylate Crosspolymer, Acrylates
Copolymer, Carborner, Cholecalciferol, Diisopropyl Adipate,
Dimetryl Capramide, Disodium EDTA, Fragrance, Hydroxypropyl
Methylcellulose, Iodopropynyl Butylcarbamate, Macrocysts 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

MADE IN USA





No Animal Testing Distributed by SolSkyn Personal Care LLC \$ 1725 North Brown Rd., Lawrenceville, GA 30043 oceanpotion.com 800-715-3485

BO1 BOF OMO1

#### OP PROTECT AND NOURISH KIDS SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70281-216

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: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	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: 0 A5MM307FC)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)	
<b>DIMETHYL CAPRAMIDE</b> (UNII: O29 Y6 X2JEZ)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
MACRO CYSTIS PYRIFERA (UNII: K31S3OG5C4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296 U138 P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06 XEA2VD56)	
ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 NDC:70281-216-24	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)

Revised: 2/2018 SolSkyn Personal Care LLC