

OP PROTECT AND NOURISH BABIES AND SENSITIVE 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 Baby Sensitive Sunscreen Ltn 50

OP Protect & Nourish Babies & Sensitive SPF 50

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, 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
 Babies &
 Sensitive
 SPF 50
 8 fl oz (237 mL)



PROTECT & NOURISH
FORTIFIED WITH VITAMIN D3™

BABIES & SENSITIVE

50

BROAD SPECTRUM SPF 50

SUNSCREEN LOTION

OXYBENZONE FREE
PARABEN FREE
HYPO-ALLERGENIC
WATER RESISTANT (80 MINUTES)

Fragrance Free

8 FL OZ (237mL)
80185F-DM01

Ocean Potion®
Babies & Sensitive sunscreen with Soloplex™ nourishes with Vitamin D3 and antioxidants and provides UVA/UVB sun protection for delicate skin. This non-greasy, fragrance-free lotion is hypoallergenic and gentle enough for everyday use. 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	
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	
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• 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 Copolymer, Acrylates Copolymer, Carbomer, Cholecalciferol, Diisopropyl Adipate, Dimethyl Capramide, Dodecyl EDTA, Hydroxypropyl Methacrylate, Isopropyl Myristate, Macrocystis Pyrifera Extract, Phenylethanol, 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	



80185F-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 BABIES AND SENSITIVE SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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 BUTYL CARBAMATE (UNII: 603P14DHEB)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-215-24	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)

Establishment

Name	Address	ID/FEI	Business Operations
KIK Custom Products – Rexdale plant		243547333	ANALYSIS(70281-215) , MANUFACTURE(70281-215)