

OP SPF45 FACE CLEAR ZINC POTION- octinoxate, zinc oxide, oxybenzone, octisalate, octocrylene cream

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 Face 45 Zinc

OP spf45 1oz Face Clear Zinc Potion

Active Ingredients

Octinoxate 7.5%

Active Ingredients

Zinc Oxide 7.0%

Active Ingredients

Oxybenzone 5.0%

Active Ingredients

Octisalate 5.0%

Active Ingredients

Octocrylene 2.0%

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.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

If product is 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 Copolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzote, Cetearyl Alcohol, Diazolidinyl Urea, Dimethicone, Methylparaben, Propylene Glycol, Propylparaben, Sorbitan Stearate, Sorbityl Laurate, Stearyl Alcohol, Triethoxycaprylylsilane, Water, Xanthan Gum

Other Information

- Protect this product from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-715-3485

PRINCIPAL DISPLAY PANEL

Clear Zinc Oxide
Face Potion
sunscreen
Net WT. 1.0 OZ (28.5 g)



OP SPF45 FACE CLEAR ZINC POTION

octinoxate, zinc oxide, oxybenzone, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58 X)	
SORBITYL LAURATE (UNII: 23XPH3M9LR)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-203-00	28.35 g in 1 CONTAINER; Type 0: Not a Combination Product	02/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	02/01/2017	

Labeler - SolSkyn Personal Care LLC (080010329)

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SolSkyn Personal Care LLC