NO-AD SPF 8 TANNING- octinoxate, octisalate 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.

No-Ad SPF 8 Sunscreen Lotion

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Active Ingredients

Octinoxate 4.5%, Octisalate 5%

Purpose

Sunscreen

Uses

• helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 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 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

Acrylates Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Extract, Carbomer, C12-15 Alkyl Benzoate, Daucus Carota Sativa (Carrot) Root Extract, Disodium EDTA, Ethylhexyl Palmitate, Ethylhexyl-glycerin, Fragrance, Glycerin, Glycine Soja (Soybean) Oil, Hydroxypropyl Methylcellulose, Phenoxyethanol, Propylene Glycol, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl (Vitamin E) Acetate, Triethanolamine, Water

Other Information

- for use on skin only. Avoid contact with fabric
- protect this product from excessive heat and direct sun

Questions or comments?

www.no-ad.com or call toll free 1-800-715-3485

PRINCIPAL DISPLAY PANEL

NO-AD SUN CARE 8 paraben free 16 FL OZ (475 mL)



NO-AD SPF 8 TANNING

octinoxate, octisalate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.5 g in 100 g	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength

CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARROT (UNII: L56Z1JK48B)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SO YBEAN O IL (UNII: 241ATL177A)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06 XEA2VD56)	
COCOA BUTTER (UNII: 5120 YT1CRR)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70281-100-44	475 g in 1 BOTTLE; Type 0: Not a Combination Product	09/15/2015	
Marketing Information				

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)

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