

SUNSHIELD SPF-30- octinoxate, octisalate, zinc oxide cream
CLINICAL CARE SKIN SOLUTIONS, INC

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.

CLINICAL CARE SKIN SOLUTIONS - SUNSHIELD (70900-202)

ACTIVE INGREDIENTS:

OCTINOXATE 6.9%, OCTISALATE 3%, ZINC OXIDE 4%

USES:

HELPS PREVEN SUNBURN

WARNINGS:

SKIN CANCER/SKIN AGING ALERT: SPENDING TIME IN THE SUN INCREASES YOUR RISK OF SKIN CANCER AND EARLY AGING SKIN. THIS PRODUCT HAS BEEN SLOWN ONLY TO PREVEN SUNBURN, NOT SKIN CANCER OR EALY SKIN AGING.

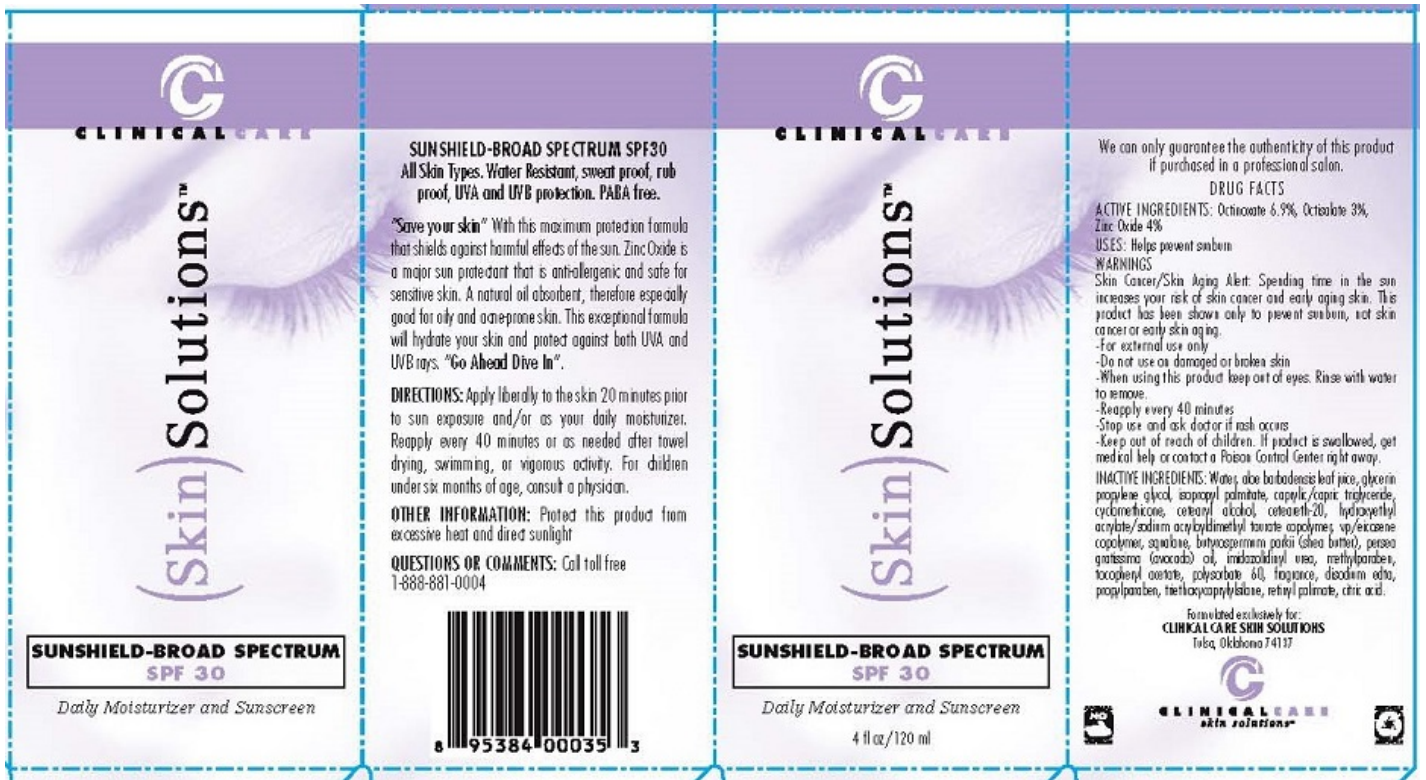
- FOR EXTERNAL USE ONLY.
- DO NOT USE ON DAMAGED OR BROKEN SKIN.
- WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.
- REAPPLY EVERY 40 MINUTES.
- STOP USE AND ASK DOCTOR IF RASH OCCURS.

KEEP OUT OF REACH OF CHILDREN.

IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

INACTIVE INGREDIENTS:

WATER, ALOE BARBADENSIS LEAF JUICE, GLYCERIN, PROPYLENE GLYCOL, ISOPROPYL PALMITATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CYCLOMETHICONE, CETEARYL ALCOHOL, CETEARETH-2, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, VP/EICOSENE COPOLYMER, SQUALANE, BUTYROSPERMUM PARKII (SHEA) BUTTER, PERSEA GRATISSIMA (AVOCADO) OIL, IMIDAZOLIDINYL UREA, METHYLPARABEN, TOCOPHERYL ACETATE, POLYSORBATE 60, FRAGRANCE, DISODIUM EDTA, PROPYLPARABEN, TRIETHOXYCAPRYLYLSYLANE, RETINYL PALMITATE, CITRIC ACID.



SUNSHIELD SPF-30

octinoxate, octisalate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70900-202
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.9 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	

HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
SHEA BUTTER (UNII: K49155WL9Y)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
IMIDUREA (UNII: M629807ATL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70900-202-54	1 in 1 BOX	08/04/2016	
1	NDC:70900-202-14	120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/04/2016	

Labeler - CLINICAL CARE SKIN SOLUTIONS, INC (879540557)

Revised: 2/2023

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