

**PREMIUM SUNSCREEN SPF-30- zinc oxide, octinoxate lotion
SALT AND STONE**

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.

MINERAL BASED SALT & STONE PREMIUM SUNSCREEN SPF-30

ACTIVE INGREDIENTS

ZINC OXIDE 10%

OCTINOXATE 7%

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 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.

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 SUN SCREEN WITH A BROAD SPECTRUM OF SPF 15 OR HIGHER AND OTHER SUN PROTECTION MEASURES INCLUDING:

- LIMIT TIME IN THE SUN, FROM 10 A.M. - 2 P.M.
- WEAR LONG-SLEEVE SHIRTS, PANTS, HATS, AND SUNGLASSES
- CHILDREN UNDER 6 MONTHS: ASK A DOCTOR

INACTIVE INGREDIENTS

* ALOE BARBADENSIS JUICE, * COCOS NUCIFERA (COCONUT) OIL, * HELIANTHUS ANNUUS (SUNFLOWER) OIL, GLYCERYL STEARATE, * THEOBROMA CACAO (COCOA) BUTTER, * VITELLARIA PARADOX (SHEA) BUTTER, STEARIC ACID, CETEARYL ALCOHOL, SODIUM STEARYL LACTATE, * SIMMONDSIA CHINENSIS (JOJOBA) OIL, * CERA ALBA (BEESWAX), * VANILLA, PHENOXYETHANOL, XANTHAN GUM, * TOCOPHEROL (VITAMIN E), SODIUM CITRATE, HYDROXYETHYLCELLULOSE, CITRIC ACID

* CERTIFIED ORGANIC

OTHER INFORMATION

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN

QUESTIONS OR COMMENTS?

CALL TOLL FREE 888 952 4250

<p>MINERAL-BASED FACE AND BODY REEF SAFE</p>	<p>BROAD SPECTRUM SPF 30 WATER RESISTANT (80 MIN)</p>
<p>DRUG FACTS</p>	<p>SALT & STONE</p>
<p>Active Ingredients Non-Nano Zinc Oxide 10% Octinoxate 7%</p>	
<p>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.</p>	
<p>Warning 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.</p>	
<p>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 sun screen with 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.</p>	
<p>Other Information Protect this product from excessive heat and direct sun.</p>	
<p>Inactive Ingredients Aloe Barbadensis Juice*, Cocos Nucifera (Coconut) Oil*, Helianthus Annuus (Sunflower Seed) Oil*, Glyceryl Stearate, Theobroma Cacao (Cocoa) Butter*, Vitellaria Paradox (Shea) Butter*, Stearic Acid, Cetearyl Alcohol, Sodium Stearyl Lactate, Simmondsia Chinensis (Jojoba) Oil*, Cera Alba (Beeswax)*, Vanilla*, Phenoxyethanol, Xanthan Gum, Tocopherol (Vitamin E)*, Sodium Citrate, Hydroxyethylcellulose, Citric Acid. *Certified Organic</p>	<p>SPF 30</p>
<p> SA LT AND STONE.COM @SA LT AND STONE</p>	<p>3 FL OZ / 88 ML</p>

PREMIUM SUNSCREEN SPF-30

zinc oxide, octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71585-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SHEA BUTTER (UNII: K49155WL9Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
JOJOBA OIL (UNII: 724GKU717M)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
VANILLA (UNII: Q74T35078H)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71585-102-21	88 mL in 1 TUBE; Type 0: Not a Combination Product	08/29/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/29/2017	

Labeler - SALT AND STONE (080683697)

Establishment

Name	Address	ID/FEI	Business Operations
JOSHUA TREE PRODUCTS LLC		016171726	manufacture(71585-102)

Revised: 4/2019

SALT AND STONE