

**PREMIUM SUNSCREEN SPF-30- zinc oxide 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.

SALT & STONE PREMIUM SUNSCREEN SPF-30

ACTIVE INGREDIENTS

ZINC OXIDE 20%

PURPOSE

SUNSCREEN

USE

HELPS PREVENT SUNBURN.

WARNINGS

FOR EXTERNAL USE ONLY.

DO NOT USE ON DAMAGED OR BROKEN SKIN.

IF RASH OCCURS, DISCONTINUE USE AND CONSULT A HEALTH CARE PRACTITIONER.

WHEN USING THIS PRODUCT: KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.

KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

For use on children less than 6 months of age, consult a health care practitioner. Apply liberally/generously (and evenly) 15 minutes before sun exposure. Reapply at least every 2 hours. Reapply after 80 minutes of swimming or sweating. Reapply immediately after towel drying. 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 10am - 2pm. wear long-sleeved shirts, pants, hats and sunglasses.

INACTIVE INGREDIENTS

*Aloe Barbadensis Juice, *Cera Alba (Beeswax), Cetearyl Alcohol, Citric Acid, *Cocos Nucifera (Coconut) Oil, Glyceryl Stearate, *Helianthus Annuus (Sunflower) Seed Oil, Hydroxyethylcellulose, Phenoxyethanol, *Simmondsia Chinesnsis (Jojoba) Oil, Sodium Citrate, Sodium Stearoyl Lactylate, Stearic Acid, *Theobroma Cacao (Cocoa) Butter, *Tocopherol (Vitamin E), *Vanilla, *Vitellaria Paradox (Shea) Butter, Xanthan Gum

*Certified Organic

OTHER INFORMATION

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN

QUESTIONS OR COMMENTS?

CALL TOLL FREE 888 952 4250

**MINERAL-BASED
FACE AND BODY
REEF SAFE**

DRUG FACTS

Active Ingredients
Non-Nano Zinc Oxide 10%
Octinoxate 7%

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.

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.

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 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

Other Information
Protect this product from excessive heat and direct sun

Inactive Ingredients
Aloe Barbadosis Juice*, Cocos Nucifera (Coconut) Oil*, Helianthus Annuus (Sunflower Seed) Oil*, Glycerol Stearate, Theobroma Cacao (Cocoa) Butter*, Vitellaria Paradox (Shea) Butter*, Stearic Acid, Cetearyl Alcohol, Sodium Stearoyl Lactylate, Simmondsia Chinensis (Jojoba) Oil*, Cera Alba (Beeswax)*, Vanilla*, Phenoxethanol, Xanthan Gum, Tocopherol (Vitamin E)*, Sodium Citrate, Hydroxyethylcellulose, Citric Acid
*Certified Organic

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**BROAD SPECTRUM SPF 30
WATER RESISTANT (80 MIN)**

SALT
&
STONE

SPF 30

3 FL OZ / 88 ML

PREMIUM SUNSCREEN SPF-30			
zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71585-105
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	20 g in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
COCONUT OIL (UNII: Q9L0O73W7L)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
JOJOBA OIL (UNII: 724GKU717M)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
COCOA BUTTER (UNII: 512OYT1CRR)				
TOCOPHEROL (UNII: R0ZB2556P8)				
VANILLA (UNII: Q74T35078H)				
SHEA BUTTER (UNII: K49155WL9Y)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71585-105-21	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)

Revised: 7/2019

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