MINERAL SUNSCREEN - WATER RESISTANT SPF-50- 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 MINERAL SUNSCREEN SPF-50 - WATER RESISTANT

ACTIVE INGREDIENTS

ZINC OXIDE 22.8%

PURPOSE

SUNSCREEN

USE

- 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
- 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 the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher & other sun protection measures including:

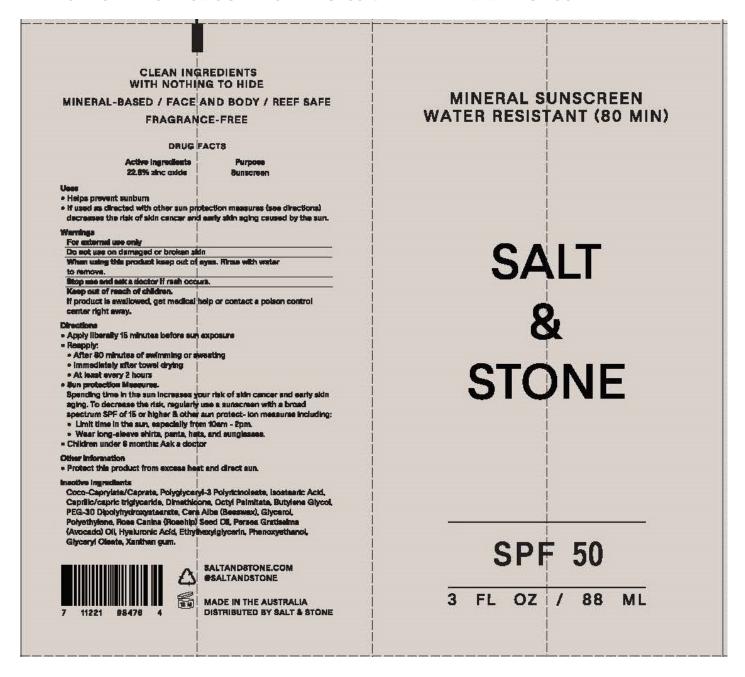
- Limit time in the sun, especially from 10am 2pm.
- Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor

INACTIVE INGREDIENTS

Coco-Caprylate/Caprate, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Caprilic/capric triglyceride, Dimethicone, Octyl Palmitate, Butylene Glycol, PEG-30 Dipolyhydroxystearate, Cera Alba (Beeswax), Glycerol, Polyethylene, Rosa Canina (Rosehip) Seed Oil, Persea Gratissima (Avocado) Oil, Hyaluronic Acid, Ethylhexylglycerin, Phenoxyethanol, Glyceryl Oleate, Xanthan gum.

OTHER INFORMATION

PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN



MINERAL SUNSCREEN - WATER RESISTANT SPF-50 zinc oxide lotion Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	22.8 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)		
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)		
ISOSTEARIC ACID (UNII: X33R8 U0062)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
ETHYLHEXYL PALMITATE (UNII: 2865993309)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
PEG-30 DIPOLYHYDRO XYSTEARATE (UNII: 9713Q0S7FO)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
ROSA CANINA SEED (UNII: 4503R1M9UT)		
AVO CADO O IL (UNII: 6 VNO 72 PFC 1)		
HYALURO NIC ACID (UNII: S270 N0 TRQY)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
GLYCERYL MONOOLEATE (UNII: C4YAD5F5G6)		
XANTHAN GUM (UNII: TTV12P4NEE)		

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:71585-109-21	88 mL in 1 TUBE; Type 0: Not a Combination Product	07/28/2019		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/28/2019		

Labeler - SALT AND STONE (080683697)

Revised: 7/2019 SALT AND STONE