

**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/Caprata, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Caprylic/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

**CLEAN INGREDIENTS
WITH NOTHING TO HIDE**

**MINERAL-BASED / FACE AND BODY / REEF SAFE
FRAGRANCE-FREE**

DRUG FACTS

Active Ingredients	Purpose
22.6% zinc oxide	Sunscreen

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.

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 - 4pm.
 - Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor

Other information

- Protect this product from excess heat and direct sun.

Inactive Ingredients

Coco-Caprylate/Caprata, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Caprylic/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.

SALTANDSTONE.COM
@SALTANDSTONE

MADE IN THE AUSTRALIA
DISTRIBUTED BY SALT & STONE

7 11221 88478 4

**MINERAL SUNSCREEN
WATER RESISTANT (80 MIN)**

SALT
&
STONE

SPF 50

3 FL OZ / 88 ML

MINERAL SUNSCREEN - WATER RESISTANT SPF-50

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71585-109
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: X33R8U0062)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ROSA CANINA SEED (UNII: 4503R1M9UT)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
HYALURONIC ACID (UNII: S270N0TRQY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOOLEATE (UNII: C4YAD5F5G6)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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