

**ALL NATURAL LIP BALM 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 - ALL NATURAL LIP BALM SPF-30

ACTIVE INGREDIENTS

ZINC OXIDE 8%

PURPOSE

SUNSCREEN

USES

- 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 PROTECTIONS 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

ARGANIA SPINOSA (ARGAN) KERNEL OIL, BEESWAX (CERA ALBA), BEHENYL BEHENATE, BISABOLOL, BUTYROSPERMUM PARKII (SHEA BUTTER), EUPHORBIA CERIFERA (CANDELILLA) WAX, CAPRYLIC/CAPRIC TRIGLYCERIDES, COCOS NUCIFERA (COCONUT) OIL, COPERNICIA CERIFERA (CARNAUBA) WAX, GLYCERYL CAPRYLATE, GLYCERYL UNDECYLENATE, HYDROGENATED METHYL ABIETATE, ISOSTEARIC ACID, LECITHIN, POLYHYDROXYSTEARIC ACID, POLYGLYCERYL-3 POLYRICINOLEATE, RICINUS COMMUNIS (CASTOR) SEED OIL, STEAIA REBAUDIANA, TOCOPHERYL ACETATE, VEGETABLE OIL.

OTHER INFORMATION

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN

<p>PEEL FOR DRUG FACTS</p> <p>SUNSCREEN LIP BALM</p> <h1>SALT & STONE</h1> <p>0.15 OZ 4.3 G</p> <p>BROAD SPECTRUM</p> <h2>SPF 15</h2> <p>MADE IN THE USA SALTANDSTONE.COM</p>  <p>7 11221 98345 3</p> <p>@SALTANDSTONE</p>	<h3>DRUG FACTS</h3> <p>Active Ingredients: Non-Nano Zinc Oxide 12%</p> <p>Purpose: Sunscreen</p> <p>Inactive Ingredients: Cera Alba (Beeswax)*, Cocos Nucifera (Coconut) Oil*, Olea Europea (Olive) Fruit Oil*, Mentha Piperita (Peppermint) Oil*.</p> <p>* Organic Ingredient</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. For best results use daily.</p>
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2.1355"

4.1250"

<h3>DRUG FACTS (Continued)</h3> <p>Uses: Helps prevent sunburn if use as directed with other sun protection measures. See directions. Decreases risk of skin cancer and early skin aging caused by the sun. 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>Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other long-sleeve shirts, pants, or hats, and sunglasses. Children under 6 months: Ask a doctor.</p>	
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ALL NATURAL LIP BALM SPF-30
zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71585-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ARGAN OIL (UNII: 4V59G5UW9X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
LEVOMENOL (UNII: 24WE03BX2T)	
SHEA BUTTER (UNII: K49155WL9Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
HYDROGENATED METHYL ABIETATE (UNII: A23O709X8O)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
CASTOR OIL (UNII: D5340Y2I9G)	
STEVIA LEAF (UNII: 6TC6NN0876)	
CORN OIL (UNII: 8470G57WFM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71585-103-21	4.25 g 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)

