SUNSCREEN SPF-50 TINTED- zinc oxide stick 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 FACE STICK SPF-50 TINTED

ACTIVE INGREDIENTS

ZINC OXIDE 22.5%

PURPOSE

SUNSCREEN

USES

• HELPS PREVENT SUNBURN

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

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. REAPPL AFTER 80 MINUTES OF SWIMMING OR SWEATING OR IMMEDIATELY AFTER TOWEL DRYING. REAPPLY 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

* TYROSPERMUM PARKII (SHEA) BUTTER, * BEESWAX (CIRE D'ABIELLE), * COCOS NUCIFERA (COCONUT) OIL, SILICA, * COPERNICIA PRUNIFERA (CARNAUBA) WAX, * HELIANTHUS ANNUUS (SUNFLOWER) OIL, IRON OXIDE, MICA, SILICA, * SIMMONDSIA CHINENSIS (JOJOBA) OIL, * THEOBROMA CACAO (COCOA) BUTTER, VITAMIN E.

* CERTIFIED ORGANIC

OTHER INFORMATION

• PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN

QUESTIONS OR COMMENTS?

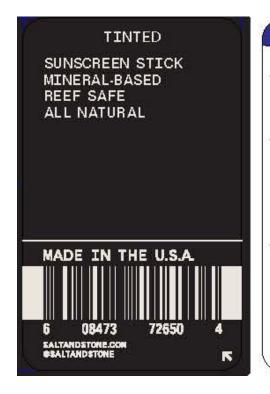
CALL TOLL FREE 1 888 952 4250

BROAD SPECTRUM SPF 50 WATER RESISTANT (80 MIN)

SALT & STONE

SPF 50

0.53 OZ / 15 G



Drug Facts

Active Ingredients Purpose Non-Nano Zinc Oxide 22.5% 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 an damaged or broken skin When using this product keep out of eyes. Rinse with water to remove.
Stop useendaska doctor if rashoosurs Keep out of reach of children.
If product is swalloed, get medical help or contact a poison control center right away.

Direction

- Apply liberally 15 minutes before sun exposure
- Reapply:
- After 80 minutes of swimming or sweating
- Immediately after toweld rying
- At least every 2 hours
- Sun Protection Measures.
 Spending time in the sun increases your risk of skin cancer and early skin.

HINGE - NO TEXT

Drug Facts (Continued)

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:
 Aska doctor

Other Information

 Protect this product from excess heat and direct sun.

Inactive Ingredients

Helanthus Annuus (Sunflower) Seed Oil*, Cooos Nusifera (Coconut) Oil*, Cera Alba (Beeswax)*, Butyros permum Parkii (Shea) Butter*, Silica, Copernica Cerifera (Carrauba) Wax*, Theobroma Cacao (Cocoa) Seed Butter*, Mica, Simmonds'a Chinensis (Jojoba) Seed Oil*, Tocopherol (Vitamin B, Iron Oxides, *Organic

Distributed by SALT & STONE



SUNSCREEN SPF-50 TINTED

zinc oxide stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71585-106

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients				
Ingredient Name	Strength			
SHEA BUTTER (UNII: K49 155WL9 Y)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
COCONUT OIL (UNII: Q9L0O73W7L)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
MICA (UNII: V8A1AW0880)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
JOJOBA OIL (UNII: 724GKU717M)				
COCOA BUTTER (UNII: 5120 YT1CRR)				
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)				
FERROUS OXIDE (UNII: G7036 X8 B5H)				

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:71585-106-11 15 g in 1 TUBE; Type 0: Not a Combination Product 08/29/2017							
Marketing Information							
	Marketing Categor	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
O	TC monograph not fir	nal part352	08/29/2017				

Labeler - SALT AND STONE (080683697)

Establishment						
Name	Address	ID/FEI	Business Operations			
Filltech USA, LLC		926433855	manufacture(71585-106)			

Revised: 5/2019 SALT AND STONE