

**SUNSCREEN SPF-50- 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

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



SUNSCREEN SPF-50

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71585-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	
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 DIOXIDE (UNII: ETJ7Z6XBU4)	
JOJOBA OIL (UNII: 724GKU717M)	

COCOA BUTTER (UNII: 512OYT1CRR)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71585-104-11	15 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)

Establishment

Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		926433855	manufacture(71585-104)

Revised: 4/2019

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