PREMIUM SUNSCREEN 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 PREMIUM SUNSCREEN SPF-30

ACTIVE INGREDIENTS

ZINC OXIDE 20%

PURPOSE

SUNSCREEN

USE

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 Protection 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

*Aloe Barbadensis Juice, *Cera Alba (Beeswax), Cetearyl Alcohol, Citric Acid, *Cocos Nucifera (Coconut) Oil, Glyceryl Stearate, *Helianthus Annuus (Sunflower) Seed Oil, Hydroxyethylcellulose, Phenoxyethanol, *Simmondsia Chinesnsis (Jojoba) Oil, Sodium Citrate, Sodium Stearoyl Lactylate, Stearic Acid, *Theobroma Cacao (Cocoa) Butter, *Tocopherol (Vitamin E), *Vanilla, *Vitellaria Paradox (Shea) Butter, Xanthan Gum

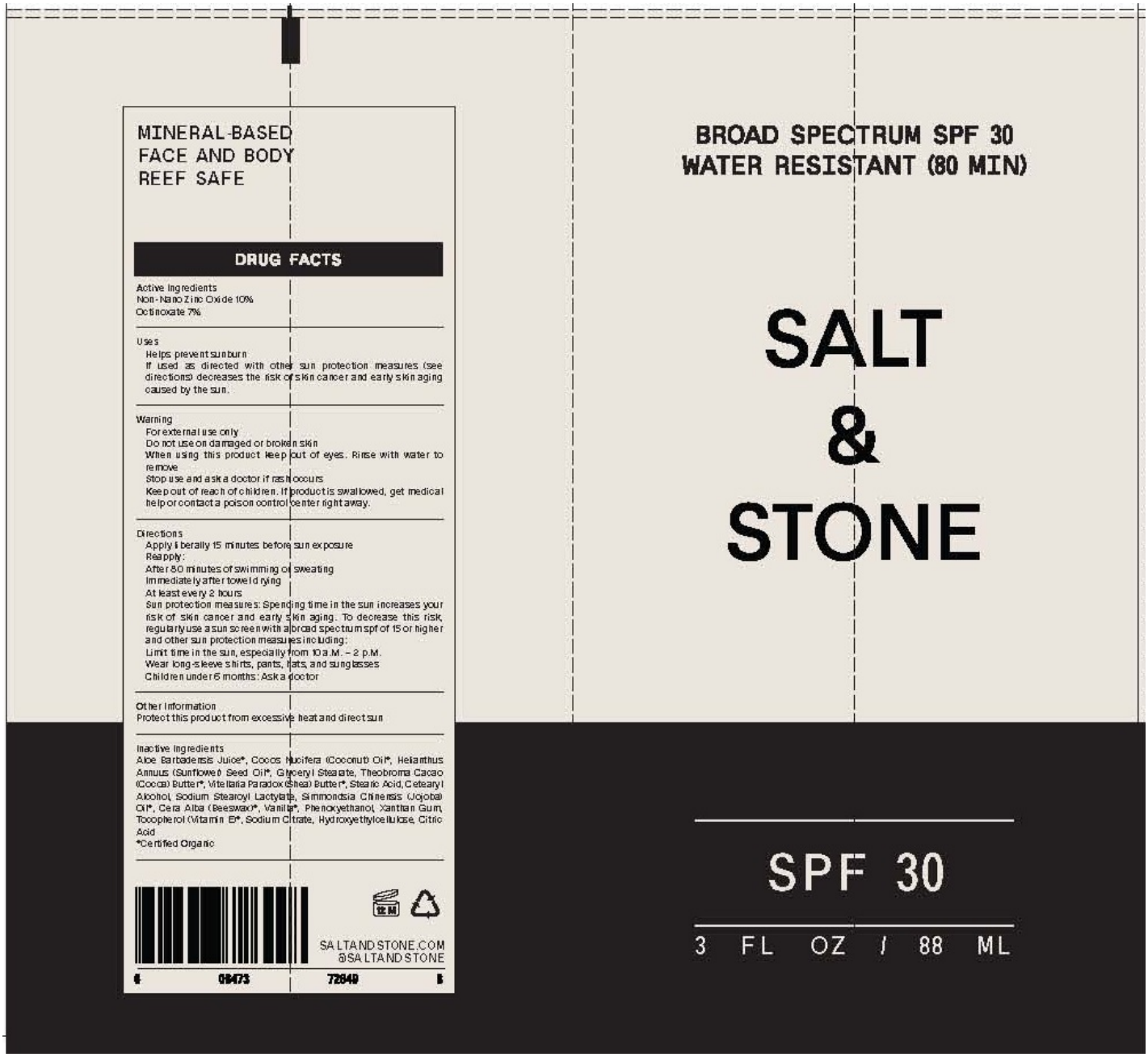
*Certified Organic

OTHER INFORMATION

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN

QUESTIONS OR COMMENTS?

CALL TOLL FREE 888 952 4250



PREMIUM SUNSCREEN SPF-30

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71585-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
JOJOBA OIL (UNII: 724GKU717M)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VANILLA (UNII: Q74T35078H)	
SHEA BUTTER (UNII: K49155WL9Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71585-105-21	88 mL 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)

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