## MINERAL DEFENSE SPORT CERAMIDE SPF-30- zinc oxide stick SOLARA SUNCARE, INC.

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.

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## SOLARA SUNCARE - GO! MINERAL DEFENSE SPORT CERAMIDE SUNSCREEN STICK (73054-108)

#### **ACTIVE INGREDIENTS**

Zinc Oxide 20%

#### **PURPOSE**

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

Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away.

#### **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

#### **DIRECTIONS**

- keep out of direct heat or sunlight
- apply generously and evenly 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 asunscreen with a Broad

Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

#### **INACTIVE INGREDIENTS**

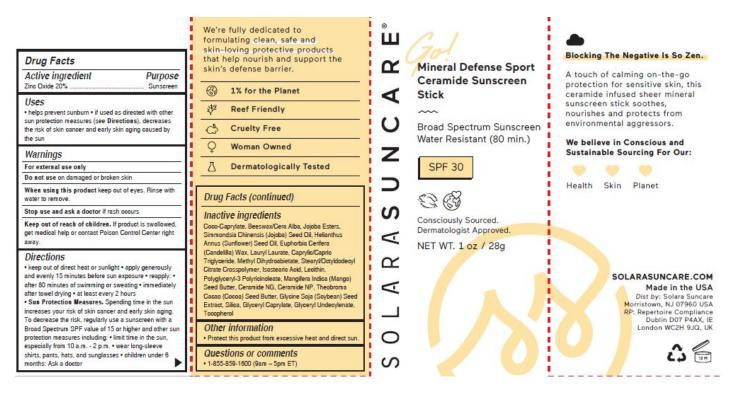
Coco-Caprylate, Beeswax/Cera Alba, Jojoba Esters, Simmondsia Chinensis (Jojoba) Seed Oil, Helianthus Annus (Sunflower) Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Lauryl Laurate, Caprylic/Capric Triglyceride, Methyl Dihydroabietate, Stearyl/Octyldodecyl Citrate Crosspolymer, Isostearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Mangifera Indica (Mango) Seed Butter, Ceramide NG, Ceramide NP, Theobroma Cacao (Cocoa) Seed Butter, Glycine Soja (Soybean) Seed Extract, Silica, Glyceryl Caprylate, Glyceryl Undecylenate, Tocopherol

#### OTHER INFORMATION

• Protect this product from excessive heat and direct sun.

#### **QUESTIONS OR COMMENTS**

• 1-855-859-1600 (9am – 5pm ET)



# MINERAL DEFENSE SPORT CERAMIDE SPF-30 zinc oxide stick Product Information Product Type HUMAN OTC DRUG Route of Administration HUMAN OTC DRUG TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q00K5D0T4)	
MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)	
CERAMIDE NG (UNII: C04977SRJ5)	
CERAMIDE NP (UNII: 4370DF050B)	
COCOA BUTTER (UNII: 5120YT1CRR)	
SOYBEAN (UNII: L7HT8F1ZOD)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZ D4G4A)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
TOCOPHEROL (UNII: ROZB2556P8)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
WHITE WAX (UNII: 7G1J5DA97F)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CANDELILLA WAX (UNII: WL0328HX19)	
LAURYL LAURATE (UNII: GPW77G0937)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)	
ISOSTEARIC ACID (UNII: X33R8U0062)	

F	Packaging						
#	tem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:73054- 108-11	1 in 1 BOX	10/17/2021				
1		28 g in 1 APPLICATOR; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M020	10/17/2021		

### Labeler - SOLARA SUNCARE, INC. (040998319)

Revised: 2/2023 SOLARA SUNCARE, INC.