

# **MINERAL SUNSCREEN STICK SPF 50 FRAGRANCE-FREE- zinc oxide stick COOLA LLC**

*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.*

-----  
**COOLA Mineral Sunscreen Stick SPF 50**

## ***Drug Facts***

### ***Active Ingredients***

Zinc Oxide 13.63%

### ***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

### ***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 doctor** if skin rash occurs

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

### ***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

**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: 10 a.m. - 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

***Inactive Ingredients***

Helianthus Annus (Sunflower) Seed Oil (ORGANIC), caprylic/Capric Triglyceride (ORGANIC), Copernicia Cerifera (Carnauba) Wax (ORGANIC), Ozokerite, Polymethylsilsesquioxane, Capryloyl Glycerin/Sebacic Acid Copolymer, Silica, Trimethoxybenzylidene Pentanedione, Butyrospermum Parkii (Shea) Butter (ORGANIC), 1,2-Heenediol Dimethicone, Ethyl Ferulate, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Limnanthese Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa Fruit Oil (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Optuntia Ficus-Indica Seed Oil (ORGANIC)

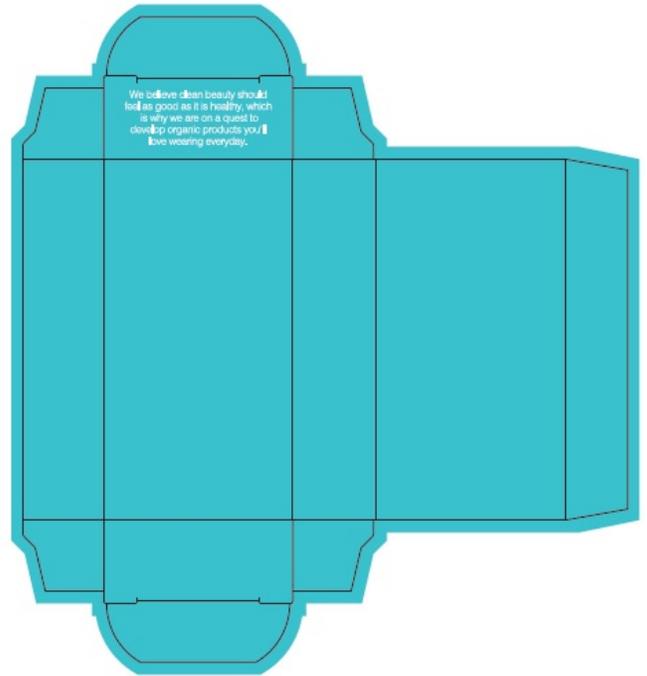
***Other information***

- may stain fabrics
- protect this product from excessive heat and direct sun

***Questions or comments?***

Call 760-940-2125

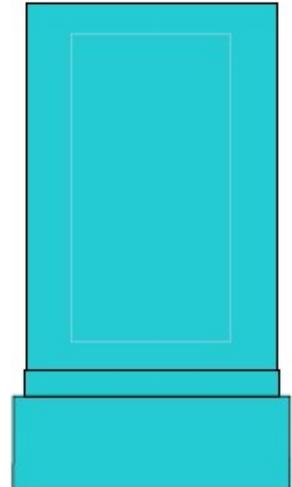
**COOLA Label****SPF****50****70%+*****Organic*****COOLA®****Classic****Sunscreen Stick*****Fragrance-Free*****Broad Spectrum SPF 50****Water-Resistant (80 Minutes)****+Plant Protection®****Net Wt. 0.6 OZ / 17.0 g****©2022 COOLA. Manufactured in the USA for COOLA, located in****Sunny & Cool San Diego, CA 92010. All Rights Reserved. Questions or****Comments? Call 760-940-2125. [www.coola.com](http://www.coola.com)**



Front



Back



res

# MINERAL SUNSCREEN STICK SPF 50 FRAGRANCE-FREE

zinc oxide stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79753-032
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	13.63 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
SUNFLOWER OIL (UNII: 3W1JG795YI)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CERESIN (UNII: Q1LS2UJ03A)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIMETHOXYBENZYLIDENE PENTANEDIONE (UNII: 322V0ACF25)	
SHEA BUTTER (UNII: K49155WL9Y)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYL FERULATE (UNII: 5B8915UELW)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
OPUNTIA FICUS-INDICA WHOLE (UNII: 23Z87HTQ6P)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-032-01	1 in 1 CARTON	01/16/2023	
1		17 g in 1 CANISTER; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part352	01/16/2023	

