

**MINERAL SUN SILK MOISTURIZER SUNSCREEN SPF 30- zinc oxide
13.5% cream
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 Sun Silk Moisturizer Sunscreen SPF 30

DRUG FACTS

Active ingredients

Zinc Oxide 13.5%

Purpose

Sunscreen

Warnings

For external use only

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

* shake well * apply liberally 15 minutes before sun exposure

* **reapply:** * after swimming or sweating * immediately after towel drying * at least every 2 hours

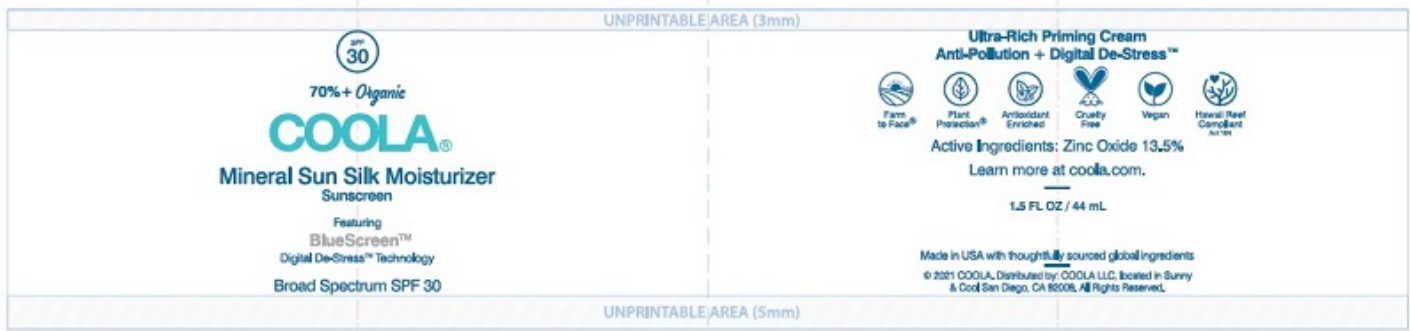
* **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: * limit time in the sun, especially from: 10 a.m. – 2 p.m.

* wear long-sleeve shirts, pants, hats, and sunglasses

* children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Juice (ORGANIC), Cocos Nucifera (Coconut) Oil (ORGANIC), Simmondsia Chinensis (Jojoba) Seed Oil (ORGANIC), Caprylic/Capric Triglyceride, Water/Aqua/Eau, Olive Oil Polyglyceryl-6 Esters, Polyhydroxystearic Acid, Cetearyl Alcohol, Jasminum Sambac (Jasmine) Leaf Cell Extract, Theobroma Cacao (Cocoa) Seed Extract, Schinus Molle Extract, Nymphaea Caerulea Flower Extract, Paeonia Lactiflora Leaf Cell



MINERAL SUN SILK MOISTURIZER SUNSCREEN SPF 30

zinc oxide 13.5% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-078
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	135 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCONUT OIL (UNII: Q9L0O73W7L)	
JOJOBA OIL (UNII: 724GKU717M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
OLIVE OIL POLYGLYCERYL-6 ESTERS (UNII: 4KDO9AFM9I)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
JASMINUM SAMBAC FLOWER (UNII: 2S686I937F)	
COCOA (UNII: D9108TZ9KG)	
SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)	
NYMPHAEA CAERULEA FLOWER (UNII: S9560USZ74)	
PAEONIA LACTIFLORA FLOWER (UNII: R73687A534)	
NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
XANTHAN GUM (UNII: TTV12P4NEE)	

METHYLPROPANEDIOL (UNII: N8F53B3R4R)

CAPRYLYL GLYCOL (UNII: 00YIU5438U)

POLYQUATERNIUM-80 (UNII: 3N8LGV97HR)

DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-078-01	1 in 1 CARTON	02/01/2023	
1		44 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2023	

Labeler - COOLA LLC (956990290)

Registrant - Bentley Laboratories, LLC (068351753)

Revised: 4/2023

COOLA LLC