## COOLA 70 PERCENT PLUS ORGANIC MINERAL BODY SUNSCREEN SPF50titanium dioxide, zinc oxide lotion 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.

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## COOLA 70%+ ORGANIC MINERAL BODY SUNSCREEN SPF50

## Active ingredients

Titanium Dioxide 3.5%, Zinc Oxide 7.25%

## 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 a doctor

• if skin rash occurs.

## Keep out of the reach of children

If 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 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-sleeved shirts, pants, hats, and sunglasses

• children under 6 months of age: Ask a doctor

## **Inactive Ingredients**

Aloe Barbadensis Leaf Juice (ORGANIC), Amyris Balsamifera Bark Oil, Blue-Green (Algae) Extract (ORGANIC), Butyloctyl Salicylate, C30-38 Olefin/Isopropyl Maleate/MA Copolymer, Cananga Odorata Flower Oil, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Oleosomes (ORGANIC), Chlorphenesin, Citrus Paradisi (Grapefruit) Peel Oil, Cocos Nucifera (Coconut) Oil (ORGANIC), Ethylhexylglycerin, Glycerin (ORGANIC), Glyceryl Stearate, Limnanthes Alba (Meadowfoam) Seed Oil, Magnesium Sulfate, Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Neopentyl Glycol Diheptanoate, Olive Oil Polyglyceryl-6 Esters, Opuntia Ficus-Indica Flower Extract, Pelargonium Graveolens Flower Oil, Polyglyceryl-6 Pentaoleate, Polymethyl Methacrylate, Rubus Idaeus (Raspberry) Seed Oil, Silica, Simmondsia Chinensis (Jojoba) Seed Oil (ORGANIC), Stearyl/Octyldodecyl Citrate Crosspolymer, Tocopherol, Triethyl Citrate, VP/Hexadecene Copolymer., Water

## Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Label



32 FL OZ / 946 mL

### **Drug Facts**

Uses

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## Warnings

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 Inactive ingredientis
 Aloe Barbadeniss Leaf Juice (ORGANIC), Neopentyl Glycol
 Diheptanoate, Caprylic/Capric Triglycenide, Butylocyl Salicytate, Olive
 Oli Pohytylocych E stars, Glycenin (ORGANIC), Sliaz, Pohytylocyr-Je
 Pertaoleate, Stearyl/Octyldodecyl Citrate Crosspolymer, C30-38
 Olefin/Bospropyl Malaeta/MA Copolymer, W7Hexadocene Copolymer,
 Magnesium: Sulate, Glyceryl Stearate, Polymerityl Methacrylate,
 Ethylhexylgtycerin, Chiorphenesin, Simmondsia Chinensis (Joiota)
 Seed OI (IORGANIC), Cocopheneri, Cocos Nucleriar (Cocontu)
 (ORGANIC), Cartharnus Tinctorius (Safflower) Oleosomes (ORGANIC),
 Mubus Kiaaue, Raspberry) Seed OII, Maurita Revucsa (Burti) Fuit OII
 (ORGANIC), Limmarthes Alba (Meadowfoam) Seed OII, Blue-Green
 (Algae) Extrat. (ToRANIC), Orunita Tuna Flower/Sime Totrata, Triethyl
 Citrate, Othus Paradisi (Grapefruit) PedI OII, Cananga Odorata Flower
 OII, Pelargonium Graveolens Flower OII, Amyris Balsamifera Bark Oil
 Other information

### Other information

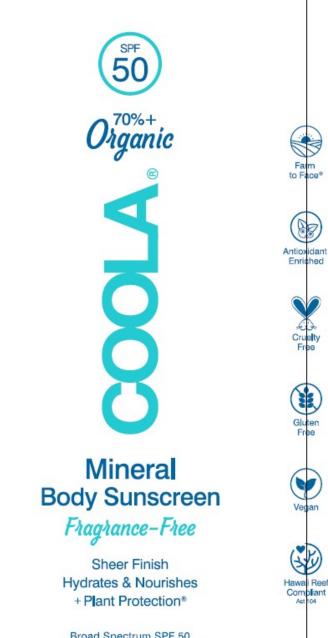
protect this product from excessive heat and direct sun
 may stain fabrics

Questions or comments? Call 760-940-2125

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Enriched

pliant

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Broad Spectrum SPF 50 Water Resistant (80 Minutes)

5 FL OZ / 148 mL

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At COOLA, we're passionate about creating beautiful product experiences that embody a happy, healthy lifestyle.

Our COOLA Mineral Body Sunscreen provides hydrating, chemical-active free sun protection for all skin types, including sensitive skin. We incorporate genre-defying technology to help us disperse mineral actives evenly, for a sheer application with a lightweight and eminently wearable finish.

This Farm-to-Face® formula is supercharged with our proprietary Plant Protection®, which incorporates naturally effective and antioxidant-rich nutrients such as Buriti Oil, Meadowfoam Seed Oil. Raspberry Seed Oil, and Prickly Pear extract to help fight free radicals and nourish and support the skin barrier.

Active Ingredients: Titanium Dioxide 3.5%, Zinc Oxide 7.25%

**Dermatologist Tested** 

This tube is made from sustainably sourced sugar cane resin, Made in USA with thoughtfully sourced global ingredients

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		50 COOLA Mineral Body Sunscreen Ragionae-Res	
<section-header></section-header>	Form to Face*	SPE 50 D70%+ Organic Sheer Finish Hydrates & Nourishes +Plant Protection*	<image/> <section-header><text><text><text><text></text></text></text></text></section-header>
Karle in U.G. with forughting Decision global higher heads 200 colora Bindback (Color.A. U.G. Ariski and Surry 2 Biological Biological (Color.A. U.G. Ariski and Burry Biglan (U.G. Landon WOOL FOR Ariski Alement) www.color.com	feathing piickly pear extract, raspberry seed oil & burill oil	Broad Spectrum SPF 50 Water Resistant (80 Minutes) 34 FL OZ / 100 mL 8 577724 00889 4 8 577724 00889 4 Kitter statute spr	rag your photos #coolasuncare

SPF	COOLA.
30	At COOLA, we're passionate about creating beautiful product experiences that embody a happy, healthy lifestyle.
Organic ®	Our COOLA Mineral Body Sunscreen provides hydrating, chemical-active free sun protection for all skin types, including sensitive
	skin. We incorporate genre-defying technology to help us disperse non-nano minerals evenly, for a sheer application with a lightweight and eminently wearable finish.
	This Farm-to-Face* formula is supercharged with our proprietary Plant Protection*, which incorporates naturally effective and antioxidant-rich nutrients such as Buriti Oil, Meadowfoam Seed Oil, Raspberry Seed Oil, and Prickly Pear extract to help fight free radicals and nourish and support the skin barrier.
	Titanium Dioxide 3.5%, Zinc Oxide 7.25% dermatologist tested & non-gmo
Sheer Finish Hydrates & Nourishes	*Hawaii Reef Friendly Sunscreen Oxybenzone & Octinoxate Free ef andly: Made in USA with thoughtfully sourced global ingredients
Broad Spectrum SPF 50 Water Resistant (80 Minutes) 3_4 FL OZ / 100 mL	© 2020 COOLA. Distributed by: COOLA LLC, located in Sunny & Cool San Diego, CA 92010. BIORIUS / EU: 7170 Manage, Belgium / UK: London WC2H 9JQ. All Rights Reserved. Questions or Comments? Call 760-940-2125 www.coola.com

# COOLA 70 PERCENT PLUS ORGANIC MINERAL BODY SUNSCREEN SPF50

titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	35 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	72.5 mg in 1 mL
Inactive Ingredients		
Ingredient Name		Strength
OLIVE OIL POLYGLYCERYL-6 ESTERS (UNII: 4KDO9AFM9I)		
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)		
COCONUT OIL (UNII: Q9L0O73W7L)		
AMYRIS BALSAMIFERA OIL (UNII: I1BJ961J2E)		
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)		
GRAPEFRUIT OIL (UNII: YR377U58W9)		
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)		
CANANGA OIL (UNII: 8YOY78GNNX)		
CHLORPHENESIN (UNII: I670DAL4SZ)		
APHANIZOMENON FLOSAQUAE (UNII: 49VG1X560X)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		
RASPBERRY SEED OIL (UNII: 9S8867952A)		
JOJOBA OIL (UNII: 724GKU717M)		
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)		
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)		
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)		
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)		
GLYCERIN (UNII: PDC6A3C0OX)		
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK	()	
SAFFLOWER OIL (UNII: 65UEH262IS)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)		
OPUNTIA TUNA FLOWERING TOP (UNII: R4AS833302)		

## Packaging

#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-040- 01	148 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2019	
2	NDC:79753-040- 02	100 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2019	
3	NDC:79753-040- 72	946 mL in 1 TUBE; Type 0: Not a Combination Product	01/18/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/01/2019	

# Labeler - COOLA, LLC (956990290)

Revised: 6/2023

COOLA, LLC