

## **COOLA SPF 30 MINERAL SUNSCREEN FRAGRANCE FREE- zinc oxide spray 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 Spray SPF 30 - Unscented**

Zinc Oxide - 14.5%

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.
  - **For external use only**
  - **Flammable:** Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120° F. Do not use in the presence of a flame or spark, or while smoking.
  - **Do not use** on damaged or broken skin
  - **When using this product** keep away from face to avoid breathing in • Keep out of eyes. Rinse with water to remove. Apply outdoors. Avoid overspray as could cause surface to become slippery. Do not apply in windy conditions. Use in a well ventilated area.
  - **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. Hold container 4 to 6 inches from skin to apply. Rub in. Do not spray directly on face. Spray onto hands and apply to face. • When properly used, mineral sunscreens will leave a whitish tint when first applied.
- 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
- May stain fabrics

- Protect this product from excessive heat and direct sun

Citrus Aurantium Dulcis (Orange) Fruit Water (ORGANIC), Water Simmondsia Chinensis (Jojoba) Seed Oil (ORGANIC), Butyloctyl Salicylate, Cocos Nucifera (Coconut) Oil (ORGANIC), Methyl Dihydroabietate, Bentonite, Cetearyl Alcohol, Aloe Barbadensis Leaf Juice (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Limnanthes Alba (Meadowfoam) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract (ORGANIC), Helianthus Annuus (Sunflower) Seed Oil (ORGANIC), Bisabolol (ORGANIC), Brassica Campestris (Rapeseed) Seed Oil, Camelina Sativa Seed Oil, Opuntia Ficus-Indica Flower Extract, Carthamus Tinctorius (Safflower) Oleosomes, Shea Butter Ethyl Esters, Propanediol, Glycerin (ORGANIC), Coco-Glucoside, Laminaria Digitata (Algae) Extract (ORGANIC), Microcrystalline Cellulose, Cellulose Gum, Sodium Stearoyl Glutamate, Caprylhydroxamic Acid, Caprylyl Glycol, Capryloyl Glycerin/Sebacic Acid Copolymer, Citric Acid

Call 760-940-2125

SPF 30

70%+ Organic

**COOLA**

Mineral Sunscreen Spray

Fragrance-Free

Sheer Finish  
Hydrates & Nourishes  
+ Plant Protection\*

Broad Spectrum SPF 30  
Water Resistant (80 Minutes)

5 FL OZ / 148 mL

Shake Well

Farm to Face®

Antioxidant Enriched

Cruelty Free

Gluten Free

Vegan

Hawaii Reef Compliant Act 104

8 57724 00874 0

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

Our easy-to-apply COOLA Mineral Sunscreen Spray 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 Zinc Oxide evenly, for a sheer application with a lightweight and eminently wearable matte 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.

Drug Facts	
<b>Active ingredients</b>	<b>Purpose</b>
Zinc Oxide 14.5%	Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> For external use only	
<b>Flammable:</b> Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120° F. Do not use in the presence of a flame or spark, or while smoking.	
<b>Do not use on damaged or broken skin</b>	
<b>When using this product</b> keep away from face to avoid breathing. Keep out of eyes. Rinse with water to remove. Apply outdoors. Avoid overspray as it could cause surface to become slippery. Do not apply in windy conditions. Use in a well-ventilated area.	
<b>Stop use and ask doctor</b> if skin rash occurs	
<b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • Shake Well. Apply liberally 15 minutes before sun exposure. Hold container 4 to 6 inches from skin to apply. Rub in. Do not spray directly on face. Spray onto hands and apply to face. • When properly used, mineral sunscreens will leave a whitish tint when first applied. • reapply. • after 80 minutes of swimming or sweating. • immediately after towel drying • at least every 2 hours. • <b>Sun Protection Measures.</b> 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	
<b>Inactive ingredients</b> Citrus Aurantium Dulcis (Orange) Fruit Water (ORGANIC), Water, Simmondsia Chinensis (Jojoba) Seed Oil (ORGANIC), Butyloctyl Salicylate, Cocos Nucifera (Coconut) Oil (ORGANIC), Methyl Dihydroabietate, Bentonite, Cetearyl Alcohol, Aloe Barbadensis Leaf Juice (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Limnanthes Alba (Meadowfoam) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract (ORGANIC), Helianthus Annuus (Sunflower) Seed Oil (ORGANIC), Bisabolol (ORGANIC), Brassica Campestris (Rapeseed) Seed Oil, Camelina Sativa Seed Oil, Opuntia Ficus-Indica Flower Extract, Carthamus Tinctorius (Safflower) Oleosomes, Shea Butter Ethyl Esters, Propanediol, Glycerin (ORGANIC), Coco-Glucoside, Laminaria Digitata (Algae) Extract (ORGANIC), Microcrystalline Cellulose, Cellulose Gum, Sodium Stearoyl Glutamate, Caprylhydroxamic Acid, Caprylyl Glycol, Capryloyl Glycerin/Sebacic Acid Copolymer, Citric Acid	
<b>Other information</b> • may stain fabrics • protect this product from excessive heat and direct sun	
<b>Questions or comments?</b> Call 760-940-2125	

© 2020 COOLA. Distributed by: COOLA LLC, located at 6023 Innovation Way in Sunny & Cool San Diego, CA 92008. All Rights Reserved. [www.coola.com](http://www.coola.com)



**COOLA SPF 30 MINERAL SUNSCREEN FRAGRANCE FREE**

zinc oxide spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79753-049
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.5 g in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>LAMINARIA DIGITATA</b> (UNII: 15E7C67EE8)	
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	
<b>CAMELINA SATIVA SEED OIL</b> (UNII: 12824X01L0)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>BRASSICA RAPA SUBSP. OLEIFERA OIL</b> (UNII: N4G8379626)	
<b>CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES</b> (UNII: 9S60Q72309)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S)</b> (UNII: N7YC58165T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>SHEA BUTTER ETHYL ESTERS</b> (UNII: V2CI786FPG)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>ORANGE</b> (UNII: 5EVU04N5QU)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>METHYL DIHYDROABIETATE</b> (UNII: 7666FJ0J9F)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEADOWFOAM SEED OIL</b> (UNII: 412ZHA4T4Y)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>MAURITIA FLEXUOSA FRUIT OIL</b> (UNII: 48H19MS04L)	
<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
<b>OPUNTIA FICUS-INDICA FLOWER</b> (UNII: 83YSP51SMA)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-049-01	148 mL in 1 CAN; Type 0: Not a Combination Product	01/01/2019	

### Marketing Information

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

**Labeler** - COOLA, LLC (956990290)

Revised: 11/2022

COOLA, LLC