

COOLA MINERAL BODY SPF 30 TROPICAL COCONUT- 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.

COOLA - Mineral Body Lotion SPF 30 - Tropical Coconut

Zinc Oxide - 14.2%

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**
- **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 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 80 minutes of swimming or sweating. • Immediately after towel drying. • At least every 2 hours
- **Sun Protection Measure:** 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. to 2 p.m. • Wear long-sleeved shirts, pants, hats, and sun glasses.

Citrus Aurantium Dulcis (Orange) Fruit Water (ORGANIC), Cocos Nucifera (Coconut) Oil (ORGANIC), Butyloctyl Salicylate, Cetearyl Alcohol, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Methyl Dihydroabietate, Sodium Stearoyl Glutamate, Coco-Glucoside, Acacia Senegal Gum (ORGANIC), Caesalpinia Spinosa Gum (ORGANIC), Sodium Hyaluronate, Glycerin, Laminaria Digitata Extract (ORGANIC), Butyrospermum Parkii (Shea) Butter (ORGANIC), Theobroma Cacao (Cocoa) Seed Butter (ORGANIC), Bisabolol (ORGANIC), Rosmarinus Officinalis (Rosemary) Leaf Extract (ORGANIC), Helianthus Annuus (Sunflower) Seed Oil (ORGANIC), Mauritia Flexuosa Fruit Oil (ORGANIC), Limnanthes Alba (Meadowfoam) Seed Oil, Persea Gratissima (Avocado) Oil (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Brassica Campestris (Rapeseed) Seed Oil, Camelina Sativa Seed Oil, Opuntia Ficus-Indica Flower Extract,

Carthamus Tinctorius (Safflower) Oleosomes, Caprylhydroxamic Acid, Caprylyl Glycol, Sodium Gluconate, Arachidyl Alcohol, Arachidyl Glucoside, Behenyl Alcohol, Capryloyl Glycerin/Sebacic Acid Copolymer, Water, Citric Acid, Gamma-Nonalactone, Gamma-Octalactone, Caprylic/Capric Triglyceride, Trans-2-hexenal, Vanillin, Maltol, Dimethyl Heptenal

- May stain fabrics
- Protect this product from excessive heat and direct sun

Call 760-940-2125

SPF 30

COOLA[®]

Mineral
Body Sunscreen
Tropical Coconut

SPF 30

70%+
Organic

COOLA[®]

Mineral
Body Sunscreen
Tropical Coconut

Sheer Finish
Hydrates & Nourishes
+ Plant Protection[®]

Broad Spectrum SPF 30
Water Resistant (80 Minutes)

5.0 FL. OZ. / 148 mL



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Recycling symbol: Packaging Contains 100% Post Consumer Recycled Material



Drug Facts

Active Ingredients	Purpose
Zinc Oxide 14.2%	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 rash occurs

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

Directions

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- 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 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
 Citrus Aurantium Dulcis (Orange) Fruit Water (ORGANIC), Coco-Nucleus (Coconut) Oil (ORGANIC), Butyltolyl Salicylate, Cetyl Alcohol, Carbomer Triethoxycellulose (Softener) Seed Oil (ORGANIC), Methyl Dihydroxyacetate, Sodium Stearyl Sulfoxylate, Rosmarinus Officinalis (Rosemary) Leaf Extract (ORGANIC), Helianthus Annuus (Sunflower) Seed Oil (ORGANIC), Moutan Flos (Burr) Fruit Oil (ORGANIC), Linum Catharticum (Flaxseed) Seed Oil, Passiflora Incarnata (Passiflora) Seed Oil (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Simmondsia Chinensis (Jojoba) Seed Oil, Camellia Sinesis Seed Oil, Olea Europaea (Olive) Fruit Extract, Carthamus Tinctorius (Safflower) Oleosomes, Theobroma Cacao (Cocoa) Seed Butter (ORGANIC), Sodium Hyaluronate, Glycerin, Butyrospermum Parvum (Shea) Butter (ORGANIC), Acacia Senegal Gum (ORGANIC), Beeswax (ORGANIC), Coco-Benzoate, Cera Alba (Beeswax) Gum (ORGANIC), Laminaria Digitata Extract (ORGANIC), Caprylyl Glycol, Sodium Gluconate, Propylparaben, Acetyl Glucoside, Behenyl Alcohol, Caprylyl Glycol, Citric Acid, Copolymer, Water, Citric Acid, Gamma-Hexactone[®], Gamma-Octactone[®], Caprylyl Capric Triglyceride[®], Benzyl Alcohol, Hexyl Alcohol, Dimethyl Silylate

Other information

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

Questions or comments?
 Call 760-940-2125

*These ingredients contain. See www.coola.com for additional details.



Farm to Face[®]



Antioxidant Enriched



Cruelty Free



Gluten Free



Vegan



Hawaii Reef Compliant Act 104

Dermatologist Tested

Featuring Prickly Pear Extract, Raspberry Seed Oil & Buriti Oil

Healthy Suncare People Love To Wear!

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

Our organic COOLA Mineral Body Sunscreen Lotion provides hydrating, chemical-free sun protection with a natural Tropical Coconut scent. We incorporate gene-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, Meadowbloom Oil, Raspberry Seed Oil, and Prickly Pear extract to help fight free radicals and nourish and support the skin barrier.

COOLA MINERAL BODY SPF 30 TROPICAL COCONUT

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ACACIA (UNII: 5C5403N26O)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
VANILLIN (UNII: CHI530446X)	
OPUNTIA FICUS-INDICA FLOWER (UNII: 83YSP51SMA)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
COCO GLUCOSIDE (UNII: ICS790225B)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
.GAMMA.-OCTALACTONE (UNII: UHD6M52X0K)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CAESALPINIA SPINOSA RESIN (UNII: WL3883U2PO)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
.GAMMA.-NONALACTONE (UNII: I1XGH66S8P)	
MALTOL (UNII: 3A9RD92BS4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
LEVOMENOL (UNII: 24WE03BX2T)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
DOCOSANOL (UNII: 9G1OE216XY)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ORANGE (UNII: 5EVU04N5QU)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GLYCERIN (UNII: PDC6A3C0OX)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	

ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
2-HEXENAL, (2E)- (UNII: 69JX3AIR1I)	
ROSEMARY (UNII: IJ67X351P9)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
2,6-DIMETHYL-5-HEPTENAL (UNII: Z331YX9EL9)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-053-01	1 in 1 CARTON	11/01/2019	
1		148 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:79753-053-02	1 in 1 CARTON	11/01/2019	
2		100 mL in 1 TUBE; 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	11/01/2019	

Labeler - COOLA, LLC (956990290)