COOLA CLASSIC SUNSCREEN STICK SPF 30 - TROPICAL COCONUT- avobenzone 3.0%, octis alate 4.0%, octocrytene 7.0% 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 Classic Sunscreen Stick SPF 30 - Tropical Coconut

Drug Facts

Active Ingredients

Avobenzone 3.0%, Octisalate 4.0%, Octocrylene 7.0%

Purpose

Suncreen

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.

Do not use on damaged or broken skin

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 spection 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

1,2-Hexanediol, Bisabolol, Bis-Octyldodecyl Dimer Dilinoleate/Propanediol Copolymer, Brassica Campestris (Rapeseed) Seed Oil, Camelina Sativa Seed Oil, Camellia Oleifera

Seed Oil (ORGANIC), Caprylic/Capric Triglyceride (ORGANIC), Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Dimethyl Heptenal*, Gamma-Nonalactone*, Gamma-Octalactone*, Hydroxystearic Acid, Limnanthes Alba (Meadowfoam) Seed Oil, Maltol*, Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Opuntia Ficus-Indica Flower Extract, Polyester-8, Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Silica Dimethyl Silylate, Trans-2-Hexenal*, Triethyl Citrate*, *VANILLIN* OR VANADIUM*???**

Other information

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

Questions or comments?

Call 760-940-2125

COOLA Label

SPF

30

70%+

Organic

 $COOLA_{|R|}$

Classic

Sunscreen Stick

Tropical Coconut

Broad Spectrum SPF 30

Water Resistant (80 Minutes)

+Plant Protection®

0.6 OZ / 17.0 g

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Cool San Diego, CA 92010. All Rights Reserved. www.coola.com

Hawaii Reef Friendly Sunscreen Oxybenzone & Octinoxate Free *Plant-derived scent constituent. See coola.com for additional detail.

Carton



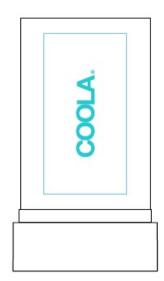
Canister

Front



Back





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COOLA CLASSIC SUNSCREEN STICK SPF 30 - TROPICAL COCONUT

avobenzone 3.0%, octisalate 4.0%, octocrytene 7.0% stick

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-016	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4.0 g in 100 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.0 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)	
LEVOMENOL (UNII: 24WE03BX2T)	
BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER (UNII: TY3J98ZR7R)	
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	
CAMELLIA O IL (UNII: T1PE06G0VE)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
2,6-DIMETHYL-5-HEPTENAL (UNII: Z331YX9EL9)	
.GAMMANONALACTONE (UNII: I1XGH66S8P)	
.GAMMAO CTALACTO NE (UNII: UHD6 M52X0 K)	

10-HYDRO XYSTEARIC ACID (UNII: 384M5B7IFL)
MEADO WFO AM SEED O IL (UNII: 412ZHA4T4Y)
MALTOL (UNII: 3A9RD92BS4)
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48 H19 MS 0 4L)
OPUNTIA FICUS-INDICA LEAF (UNII: 5VM709H93V)
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)
RASPBERRY SEED OIL (UNII: 9S8867952A)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
2-HEXENAL, (2E)- (UNII: 69JX3AIR1I)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
VANILLIN (UNII: CHI530446X)

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:79753-016-01	1 in 1 CARTON	02/08/2021	
1	17 g in 1 CANISTER; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	02/08/2021		

Labeler - COOLA LLC (956990290)

Revised: 1/2021 COOLA LLC