

COOLA CLASSIC BODY SUNSCREEN TROPICAL COCONUT SPF 30- avobenzone, homosalate, octisalate, octocrylene 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 Classic Body Sunscreen Tropical Coconut SPF 30

Active Ingredients

AVOBENZONE 1.75%, HOMOSALATE 2.25%, OCTISALATE 1.5%, OCTOCRYLENE 3.75%

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 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 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), Brassica Campestris (Rapeseed) Seed Oil,

Butylene Glycol, Camelina Sativa Seed Oil, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Carthamus Tinctorius (ORGANIC Safflower) Seed Oil, Carthamus Tinctorius (Safflower) Seedcake Extract, Decyl Glucoside, Dimethicone, Gamma-Nonalactone, Glycerin (ORGANIC), Hydrogenated Methyl Abietata, Hydrolyzed Jojoba Esters, Jojoba Esters, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa Fruit Oil, 1,2 Hexanediol, Opuntia Ficus-Indica Flower Extract, Polyacrylate Crosspolymer-6, Polysilicone-11, Rubus Idaeus (Raspberry) Seed Oil, Silica, Sodium Phytate, Tropolone, Vanillin, Xanthan Gum

Other Information

*** protect this product from excessive heat and direct sun**

Questions or comments? Call 760-940-2125

Product Labeling

COOLA

Classic

Body Sunscreen

Tropical Coconut

Broad Spectrum SPF 30

Water Resistant (80 Minutes)

5.0 FL OZ / 148 mL

**© 2022 COOLA. Manufactured in the USA for COOLA LLC,
located in Sunny & Cool San Diego, CA 92009.**

All Rights Reserved. www.coola.com

res

COOLA CLASSIC BODY SUNSCREEN TROPICAL COCONUT SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	15 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	37.5 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	22.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	17.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
TROPOLONE (UNII: 7L6DL16P1T)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
OPUNTIA FICUS-INDICA (UNII: 23Z87HTQ6P)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CARTHAMUS TINCTORIUS SEEDCAKE (UNII: DHQ13F4N2W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	
CANOLA OIL (UNII: 331KBJ17RK)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	NDC:79753-076-01	1 in 1 CARTON	02/01/2023	
1		148 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	part352	02/01/2023	

Labeler - COOLA LLC (956990290)

Registrant - Bentley Laboratories, LLC (068351753)

Revised: 4/2023

COOLA LLC