COOLA CLASSIC BODY SUNSCREEN GUAVA MANGO BROAD SPECTRUM SPF 50- 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 Guava Mango Broad Spectrum SPF 50

DRUG FACTS

Active Ingredients

Avobenzone 1.75%Homosalate 5.0%Octisalate 2.0%Octocrylene 5.0%

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 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

- 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 of 15 or higher and after 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 (Safflower) Seed Oil (ORGANIC), Cetearyl Alcohol, Cetyl Palmitate, Decyl Glucoside, Dimethicone, Flavor*, Glycerin (ORGANIC), 1,2-Hexanediol, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa (Buriti) Fruit Oil, Methyl Dihydroabietate, Opuntia Ficus-Indica Flower Extract, Polyacrylate Crosspolymer-6, Polysilicone-11, Rubus Idaeus (Raspberry) Seed Oil, Silica, Sodium Hydroxide, Sodium Phytate, Sorbitan Oleate, Sorbitan Palmitate, Tropolone, Water, Xanthan Gum

Other Information

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

Questions or Comments? Call 760-940-2125

Package Label

SPF 50 70% + Organic

COOLA

Classic Body Sunscreen *Guava Mango*

Ultra Lightweight Hydrates & Nourishes +Plant Protection®

Broad Spectrum SPF 50 Water Resistant (80 Minutes)

3.4 FL OZ / 100 mL

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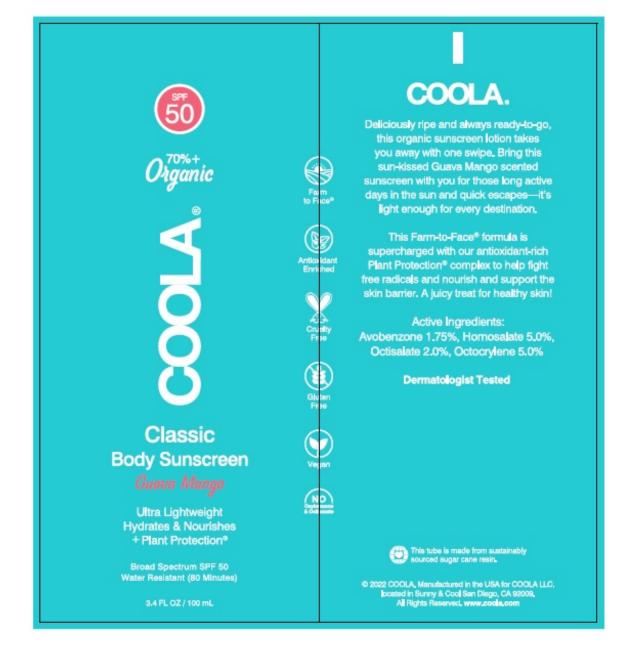
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COOLA CLASSIC BODY SUNSCREEN GUAVA MANGO BROAD SPECTRUM SPF 50

avobenzone homosalate octisalate octocrylene lotion

Product Information								
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC:79753-075				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingred	ient Name		Basis of Strengt	h Strength				
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZONE	1.75 g in 100 mL				
HOMOSALATE (UNII: V06SV4M95S	SV4M95S)	HOMOSALATE	5.0 g in 100 mL					

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.0 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5.0 g in 100 mL

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
MEADOWFOAM SEED OIL (UNII: 412Z HA4T4Y)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
OPUNTIA FICUS-INDICA FLOWER (UNII: 83YSP51SMA)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	1
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
TROPOLONE (UNII: 7L6DL16P1T)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

# Item Code Package Description Date Date 1 NDC:79753-075- 02 1 in 1 CARTON 02/01/2023 1 100 mL in 1 TUBE; Type 0: Not a Combination Product 100 mL in 1 TUBE; Type 0: Not a Combination								
1 02 100 mL in 1 TUBE; Type 0: Not a Combination Product Product Marketing Information Marketing Application Number or Monograph Marketing Start Marketing Er	#	ltem Code	Package Description	-	Marketing End Date			
Product Marketing Information Marketing Application Number or Monograph Marketing Start Marketing Er	1		1 in 1 CARTON	02/01/2023				
Marketing Application Number or Monograph Marketing Start Marketing Er	1							
Marketing Application Number or Monograph Marketing Start Marketing Er								
	Marketing Information							
				-	Marketing End Date			

Labeler - COOLA LLC (956990290)

Revised: 4/2023

COOLA LLC