# COOLA CLASSIC FACE SUNSCREEN FRAGRANCE-FREE 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.

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#### COOLA Classic Face Sunscreen Fragrance-Free SPF 50

#### **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 rise 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-sleve shirts, pants, hats, and sunglasses
- \* children under 6 months: Ask a doctor

### **Inactive ingredients**

Aloe Barbadensis Leaf Juice (ORGANIC). Carthamus Tinctorius (Safflower) Oleosomes, Water, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Glycerin (ORGANIC), Polyacrylate Crosspolymer-6, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa (Buriti) Fruit Oil, Rubus Idaeus (Raspberry) Seed Oil, Squalane, Brassica Campestris (Rapeseed) Seed Oil, Opuntia Ficus-Indica Flower Extract, Camelina Sativa Seed Oil, Tropolone, Cetyl Palmitate, Sodium Hydroxide, Citric Acid, Cetearyl Alcohol, Caprylyl Glycol, 1,2-Hexanediol, Sorbitan Palmitate, Methyl Dihydroabietate, Xanthan Gum, Dimethicone, Sorbitan Oleate, Gluconolactone, Silica, Sodium Phytate, Sodium Benzoate, Polysilicone-11, Butylene Glycol, Decyl Glucoside

#### Other Information

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

Questions or comments? Call 760-940-2125

## **Product Labeling - COOLA Classic Face Sunscreen Fragrance-Free SPF 50**

SPF 50

**70**% +

Organic

COOLA

Classic Face Sunscreen *FragranceiFree* 

Broad Spectrum SPF 50 Water Resistant (80 Minutes)

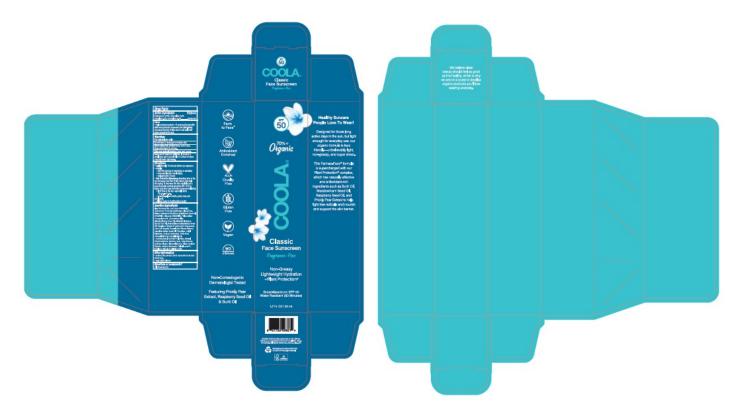
1.7 FL OZ / 50 mL

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Carton



Tube



### COOLA CLASSIC FACE SUNSCREEN FRAGRANCE-FREE SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-074	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)HOMOSALATE50 mg in 1 mLAVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)AVOBENZONE17.5 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)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
SQUALANE (UNII: GW89575KF9)	
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
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)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CARTHAMUS TINCTORIUS SEEDCAKE (UNII: DHQ13F4N2W)	
DIMETHICONE (UNII: 92RU3N3Y10)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79753-074- 01	1 in 1 CARTON	02/01/2023		
1		50 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