# COOLA BARE REPUBLIC CLEARSCREEN SPF100- 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 BARE REPUBLIC CLEARSCREEN SPF100 LOTION

## **Active ingredients**

Avobenzone 3.0%

Homosalate 15.0%

Octisalate 5.0%

Octocrylene 10.0%

## **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 a doctor if

rash occurs.

## Keep out of the reach of children

If 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
- children under 6 months of age: Ask a doctor
- 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 value 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-sleeved shirts, pants, hats, and sunglasses

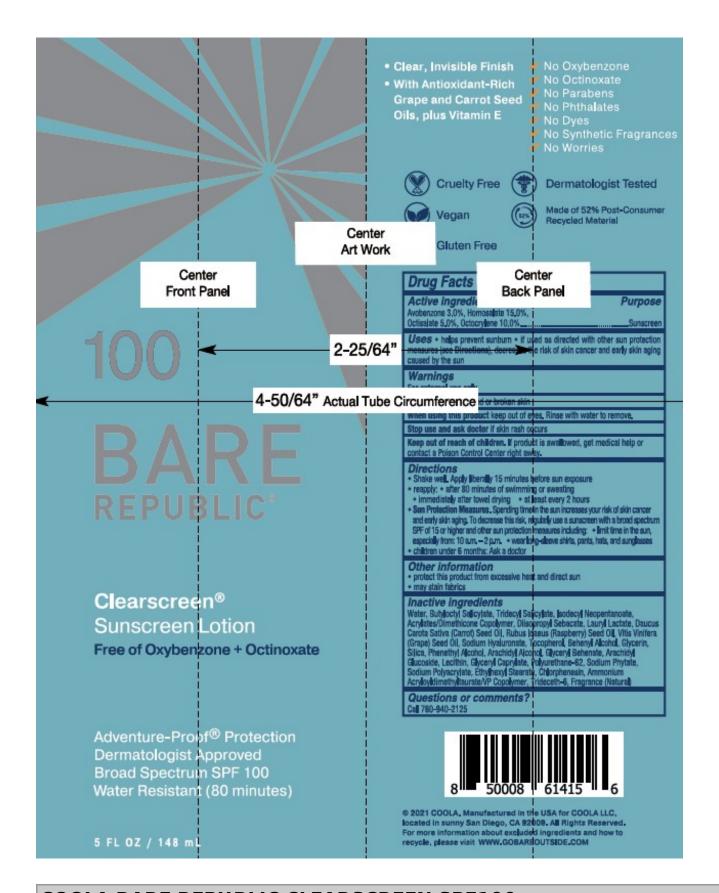
#### Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

## **Inactive Ingredients**

Water, Butyloctyl Salicylate, Tridecyl Salicylate, Isodecyl Neopentanoate, Acrylates/Dimethicone Copolymer, Diisopropyl Sebacate, Lauryl Lactate, Daucus Carota Sativa (Carrot) Seed Oil, Rubus Idaeus (Raspberry) Seed Seed Oil, Vitis Vinifera (Grape) Seed Oil, Sodium Hyaluronate, Tocopherol, Behenyl Alcohol, Glycerin, Silica, Phenethyl Alcohol, Arachidyl Alcohol, Glyceryl Behenate, Arachidyl Glucoside, Lecithin, Glyceryl Caprylate, Polyurethane-62, Sodium Phytate, Sodium Poluacrylate, Ethylhexyl Stearate, Chlorphenesin, Ammonium Acryloyldimethyltaurate/VP Copolymer, Trideceth-6, Fragrance (Natural)

#### Label



### COOLA BARE REPUBLIC CLEARSCREEN SPF100

avobenzone, homosalate, octisalate, octocrylene lotion

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-022

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	150 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	30 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CARROT SEED OIL (UNII: 595AO13F11)	
.ALPHATOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)	
DOCOSANOL (UNII: 9G10E216XY)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
POLYURETHANE-62 (UNII: TBK645J3J8)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
2-ETHYLHEXYL ACRYLATE, METHACRYLATE, METHYL METHACRYLATE, OR BUTYL METHACRYLATE/HYDROXYPROPYL DIMETHICONE COPOLYMER (30000-300000 MW) (UNII: S7ZA3CCJ4M)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GLYCERYL CAPRYLATE (UNII: TM2TZ D4G4A)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	

	Packaging			
7	tem Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:79753-022- 01	148 mL in 1 TUBE; Type 0: Not a Combination Product	10/21/2021	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	10/21/2021			

## **Labeler -** COOLA, LLC (956990290)

Revised: 1/2023 COOLA, LLC