

**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

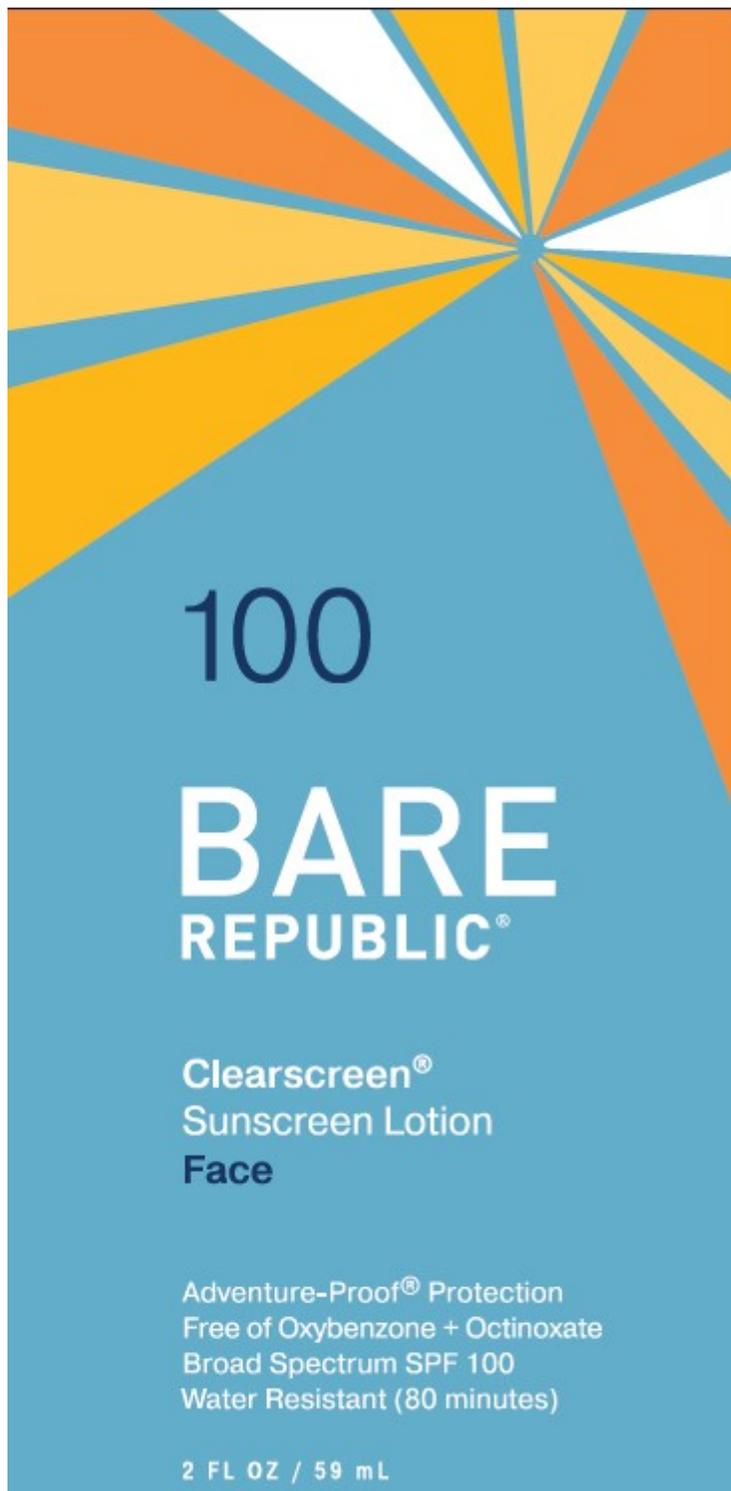
## **Other information**

- 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, Behenyl Alcohol, Diisopropyl Sebacate, Lauryl Lactate, Glyceryl Behenatae, Vitis Vinifera (Grape) Seed Extract, Daucus Carota Sativa (Carrot) Extract, Rubus Idaeus (Raspberry) Seed Extract, Sodium Hyaluronate, Glycerin, Ethylhexylglycerin, Chlorphenesin, Polyurethane-62, Silica, Ammonium Acryloyldimethyltaurate/VP Copolymer, Trideceth-6, Tocopherol, Arachidyl Alcohol, Arachidyl Glucoside, Lecithin, Sodium Phytate

## **Label**



- Clear, Invisible Finish
- Non-Comedogenic
- Enriched with Antioxidants and Vitamin E

- ✓ No Oxybenzone
- ✓ No Octinoxate
- ✓ No Parabens
- ✓ No Phthalates
- ✓ No Dyes
- ✓ No Synthetic Fragrances
- ✓ No Gluten
- ✓ No Worries



### Drug Facts

Active Ingredients	Purpose
Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 10.0%	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

- Shake well. 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 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

### Other information

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

### Inactive ingredients

Water, Butyloctyl Salicylate, Tridecyl Salicylate, Isodecyl Neopentanoate, Acrylates/Dimethicone Copolymer, Behenyl Alcohol, Diisopropyl Sebacate, Lauryl Lactate, Glycerol Behenates, Vitis Vinifera (Grape) Seed Extract, Daucus Carota Sativa (Carrot) Extract, Rubus Idaeus (Raspberry) Seed Extract, Sodium Hyaluronate, Glycerin, Ethylhexylglycerin, Chlorphenesin, Polyurethane-62, Silica, Ammonium Acryloyldimethyltaurate/VP Copolymer, Trideceth-6, Tocopherol, Arachidyl Alcohol, Arachidyl Glucoside, Lecithin, Sodium Phytate

### Questions or comments?

Call 760-840-2125



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## COOLA BARE REPUBLIC CLEARSCREEN SPF100

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-021
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>CARROT SEED OIL</b> (UNII: 595AO13F11)	
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>GLYCERYL MONOBEHENATE</b> (UNII: A626UU0W2A)	
<b>PHYTATE SODIUM</b> (UNII: 88496G1ERL)	
<b>POLYURETHANE-62</b> (UNII: TBK645J3J8)	
<b>LAURYL LACTATE</b> (UNII: G5SU0BFK7O)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVV35J00J)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER</b> (UNII: W59H9296Z G)	
<b>ISODECYL NEOPENTANOATE</b> (UNII: W60VYE24XC)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>2-ETHYLHEXYL ACRYLATE, METHACRYLATE, METHYL METHACRYLATE, OR BUTYL METHACRYLATE/HYDROXYPROPYL DIMETHICONE COPOLYMER (30000-300000 MW)</b> (UNII: S7ZA3CCJ4M)	
<b>TRIDECETH-6</b> (UNII: 3T5PCR2H0C)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-021-01	59 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