

**COOLA BARE REPUBLIC CLEARSCREEN SUNSCREEN SPF100- avobenzone, homosalate, octisalate, octocrylene spray**  
**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 NON-AEROSOL SUNSCREEN SPRAY**

**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**

**FLAMMABLE:**

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)

**Do not use**

- on damaged or broken skin

**When using this product**

- keep out of eyes. Rinse with water to remove.
- do not puncture or incinerate. Contents under pressure.
- do not store at temperatures above 120° F.

**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**

- spray liberally and spread evenly 15 minutes before sun exposure
- hold can 4-6 inches away from skin to apply
- do not spray into face. Spray into hand and apply to face.
- Do not apply in windy conditions
  
- use in well ventilated, but not windy areas

reapply:

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
  
- children under 6 months: 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 the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

## **Inactive ingredients**

SD Alcohol 40-B, Butyloctyl Salicylate, Tridecyl Salicylate, Isodecyl Neopentanoate, Acrylates/Octylacrylamide Copolymer, Diisopropyl Sebacate, Lauryl Lactate, Fragrance (Natural Fragrance), Caprylic/Capric Triglyceride, Glycerin, Rubus Idaeus (Red Raspberry) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Daucus Carota Sativa (Carrot) Seed Oil

## **Label**

Encouraging adventure and connection under the sun with healthy, high-performance sunscreen

- Clear, Invisible Finish
- Non-Greasy, Fast-Absorbing
- With Antioxidant-Rich Grape and Carrot Seed Oils, plus Vitamin E

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

Cruelty Free Vegan Gluten Free Dermatologist Tested

Drug Facts	
<b>Active ingredients</b> Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 10.0%	<b>Purpose</b> Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> For external use only	
<b>Flammable:</b> Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120° F. Do not use in the presence of a flame or spark, or while smoking.	
Do not use on damaged or broken skin	
When using this product keep away from face to avoid breathing in • Keep out of eyes. Rinse with water to remove. Apply outdoors. Avoid overspray as could cause surface to become slippery. Do not apply in windy conditions. Use in a well-ventilated area.	
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.	
<b>Directions</b> • Shake well. Apply liberally 15 minutes before sun exposure. Hold container 4 to 6 inches from skin to apply. Rub in. Do not spray directly on face. Spray onto hands and apply to face. • 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	
<b>Other information</b> • may stain fabrics • protect this product from excessive heat and direct sun	
<b>Inactive ingredients</b> SD Alcohol 40-B, Butylacetyl Salicylate, Tridecyl Salicylate, Isodecyl Neopentanoate, Acrylates/Octylacrylamide Copolymer, Diisopropyl Sebacate, Lauryl Lactate, Fragrance (Natural Fragrance), Caprylic/Capric Triglyceride, Glycerin, Rubus Idaeus (Red Raspberry) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Daucus Carota Sativa (Carrot) Seed Oil	
<b>Questions or comments?</b> Call 760-940-2125	

Adventure-Proof® Protection  
Dermatologist Approved  
Broad Spectrum SPF 100  
Water Resistant (80 minutes)

Net Wt 6 OZ / 170 g

## COOLA BARE REPUBLIC CLEARSCREEN SUNSCREEN SPF100

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79753-023
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW)</b> (UNII: JU3XHR8VWK)	
<b>ISODECYL NEOPENTANOATE</b> (UNII: W60VYE24XC)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
<b>LAURYL LACTATE</b> (UNII: G5SU0BFK7O)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>CARROT SEED OIL</b> (UNII: 595AO13F11)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-023-01	170 g in 1 CAN; Type 0: Not a Combination Product	09/23/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/23/2021	

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

Revised: 1/2023

COOLA, LLC