

**COOLA CLASSIC SUNSCREEN FRAGRANCE FREE- 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 SUNSCREEN LOTION FRAGRANCE-FREE**

**Active ingredients**

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 4.5%

Octocrylene 8.0%

**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**

Alkyl Heptoate, Behenyl Alcohol, Butylated PVP, Butylene Glycol, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Cellulose Gum, Cetyl Alcohol, Citrus Aurantium Bergamia (Bergamot) Leaf Extract, Disodium EDTA, Ethylhexylglycerin, Gamma-Decalactone, Gamma-Nonalactone, Glycerin, Glyceryl Stearate, Heliotropine, Lauryl Alcohol, Lecithin, Linum Usitatissimum (Linseed) Seed Oil, Lycium Barbarum Fruit Extract, Microcrystalline Cellulose, Myristyl Alcohol, Palmitic Acid, Phenoxyethanol, Propylene Glycol, Raspberry Ketone, Rubus Idaeus (Raspberry) Seed Extract, Sodium Ascorbyl Phosphate, Stearic Acid, Tocopherol, Triethyl Citrate, Vanillin, Water (Aqua)

## **Label**



SPF 50



# COOLA

## Classic Face Sunscreen Fragrance-Free

+ Plant Protection\*

Broad Spectrum SPF 50  
Water Resistant (80 Minutes)

32 FL OZ / 946 mL

\* Hawaii Reef Friendly, Oxybenzone and Octinoxate Free Sunscreen



8 50008 61410 1

### Drug Facts

Active Ingredients	Purpose
Homosalate 10%, Octocrylene 8%, Octisalate 4.5%, Avobenzone 3%	Sunscreen

**Uses**

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Stop use and ask doctor if skin rash occurs

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  - wear long-sleeve shirts, pants, hats, and sunglasses
  - children under 6 months. Ask a doctor

**Inactive ingredients**

Allyl Heptanoate, Behenyl Alcohol, Butylated PVP, Butylene Glycol, Butylacetyl Salicylate, Caprylic/Capric Triglyceride, Cellulose Gum, Cetyl Alcohol, Citrus Aurantium Bergamita (Bergamot) Leaf Extract, Decylum EDTA, Ethylhexylglycerin, Gamma-Decalactone, Gamma-Nonolactone, Gamma-Octalactone, Glycerin, Glyceryl Stearate, Heliotropine, Lauryl Alcohol, Lecithin, Linum Usitatissimum (Linseed) Seed Oil, Lycium Barbarum Fruit Extract, Microcrystalline Cellulose, Myristyl Alcohol, Palmitic Acid, Phenoxethanol, Propylene Glycol, Raspberry Ketone, Rubus Idaeus (Raspberry) Seed Extract, Sodium Ascorbyl Phosphate, Stearic Acid, Tocopherol, Triethyl Citrate, Vanillin, Water (Aqua)

**Other information**

- protect this product from excessive heat and direct sun

**Questions or comments?**  
Call 760-940-2125

Made in USA with thoughtfully sourced global ingredients

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SPF 50



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COOLA®

classic  
sunscreen

Unscented

+ plant protection®

water resistant (80 minutes)



Drug Facts	
Active Ingredients	Purpose
Homosalate 10%, Octocrylene 8%, Octisalate 4.5%, Avobenzone 3%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Helps prevent sunburn</li> <li>If used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun.</li> </ul>	
<b>Warnings</b>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Apply liberally 15 minutes before sun exposure.</li> <li>Reapply:               <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li>Sun Protection Messages: 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:               <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m.–2 p.m.</li> <li>wear long-sleeved shirts, pants, hats, and sunglasses</li> <li>children under 6 months: Ask a doctor.</li> </ul> </li> </ul>	
<b>Inactive ingredients</b>	
All: Hydroxystyrene, Behenyl Alcohol, Butylated PVP, Butylene Glycol, Butylacrylate/Silicone Copolymer, Cetyl Alcohol, Cellulose Gum, Cetyl Alcohol, Citrus Aurantium Bergamot (Essential Oil Extract), Cocamidopropyl Dimethylamine, Gamma-Hydroxybutyrate, Gamma-Hydroxybutyrate, Gamma-Octalactone, Glyceryl Stearate, Hydroquinone, Isobutyl Alcohol, Lactic Acid, Linum Catharticum (Linen Seed Oil), Lycopodium Plant Extract, Microcrystalline Cellulose, Myristyl Alcohol, Palmitic Acid, Phenoxethanol, Propylene Glycol, Propylene Glycol Stearate, Stearic Acid, Tocopheryl Acetate, Vanillin, Water (Aqua)	
<b>Other information</b>	
protects the product from excessive heat and direct sun	
<b>Questions or comments?</b>	
Call 1-800-949-2123	

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ECO-FRIENDLY SUNCARE



Broad Spectrum SPF 30

\* Hawaii Reef Friendly, Oxybenzone and Octinoxate Free Sunscreen

32 FL OZ / 946 mL



## COOLA CLASSIC SUNSCREEN FRAGRANCE FREE

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79753-045
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 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	80 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
<b>GLYCERYL 1-STEARATE</b> (UNII: 258491E1RZ)	
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)	
<b>GLYCERIN</b> (UNII: PDC6A3COOX)	

<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>MONARDA DIDYMA LEAF</b> (UNII: JY15982UBB)
<b>.GAMMA.-NONALACTONE</b> (UNII: I1XGH66S8P)
<b>.GAMMA.-DECALACTONE</b> (UNII: 7HLS05KP9O)
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)
<b>ALLYL HEPTANOATE</b> (UNII: AU4CYG9V68)
<b>4-(P-HYDROXYPHENYL)-2-BUTANONE</b> (UNII: 7QY1MH15BG)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)
<b>LAURYL ALCOHOL</b> (UNII: 178A96NLP2)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>PIPERONAL</b> (UNII: KE109YAK00)
<b>MYRISTYL ALCOHOL</b> (UNII: V42034O9PU)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 1200 MPAS AT 1%)</b> (UNII: 4J4P6L645M)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)
<b>VANILLIN</b> (UNII: CHI530446X)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>LINSEED OIL</b> (UNII: 84XB4DV00W)
<b>.GAMMA.-OCTALACTONE</b> (UNII: UHD6M52X0K)
<b>LYCIUM BARBARUM FRUIT</b> (UNII: 930626MWDL)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-045-72	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2018	

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