

**COOLA CLASSIC BODY SUNSCREEN FRAGRANCE-FREE SPF 50- avobenzone  
homosalate octisalate octocrylene lotion  
Bentley Laboratories, LLC**

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**COOLA CLASSIC BODY SUNSCREEN Fragrance-Free SPF 50**

***DRUG FACTS***

***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 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 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 skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and after 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

***Inactive Ingredients***

Aloe Barbadensis Leaf Juice (ORGANIC), Brassica Campestris (Rapeseed) Seed Oil, Butylene Glycol, Camellina Sativa Seed Oil, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Carthamus Tinctorius

(Safflower) Seed Oil (ORGANIC), Cetearyl Alcohol, Cetyl Palmitate, Decyl Glucoside, Dimethicone, Glycerin (ORGANIC), 1,2-Hexanediol, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa (Buriti) Fruit Oil, Methyl Dihydroabietate, Opuntia Ficus-Indica Flower Extract, Polyacrylate Crosspolymer-6, Polysilicone-11, Rubus Idaeus (Raspberry) Seed Oil, Silica, Sodium Hydroxide, Sodium Phytate, Sorbitan Oleate, Sorbitan Palmitate, Tropolone, Water, Xanthan Gum

### **Other Information**

- protect this product from excessive heat and direct sun

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

### **Package Label**

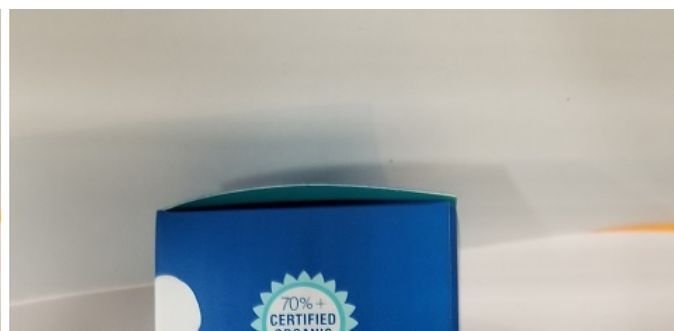
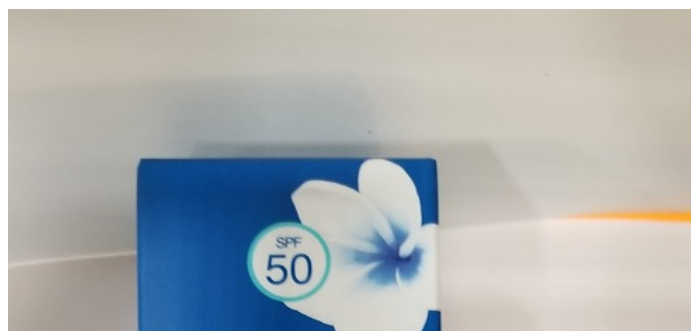
SPF  
**50**  
70% +  
**Organic**  
**COOLA®**  
**Classic**  
**Body Sunscreen**  
**Fragrance-Free**  
**Ultra Lightweight**  
**Hydrates & Nourishes**  
**+Plant Protection®**  
**Broad Spectrum SPF 50**  
**Water Resistant (80 Minutes)**  
**5 FL OZ / 148 mL**

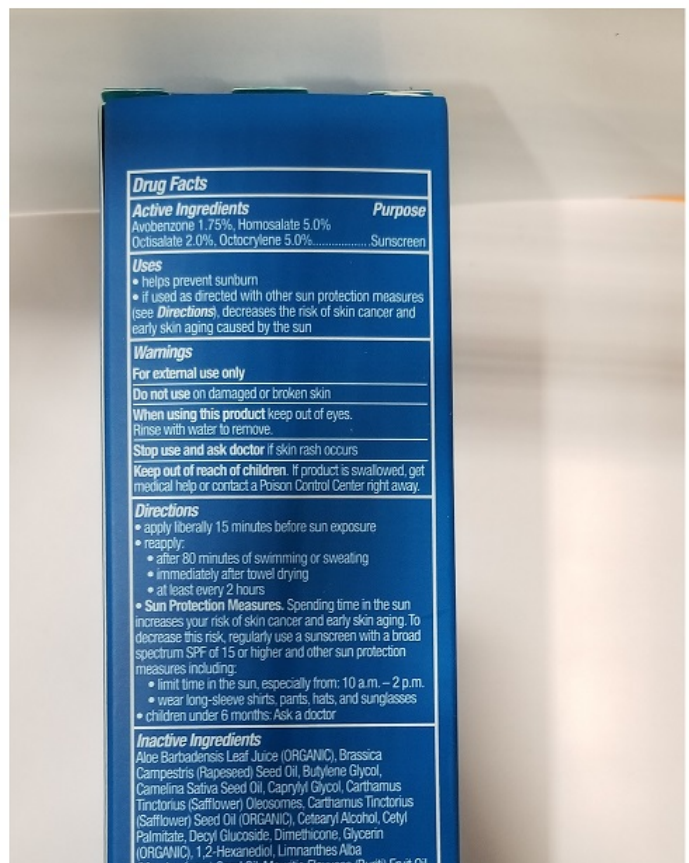
\*Hawaii Reef Friendly Sunscreen Oxybenzone & Octinoxate Free

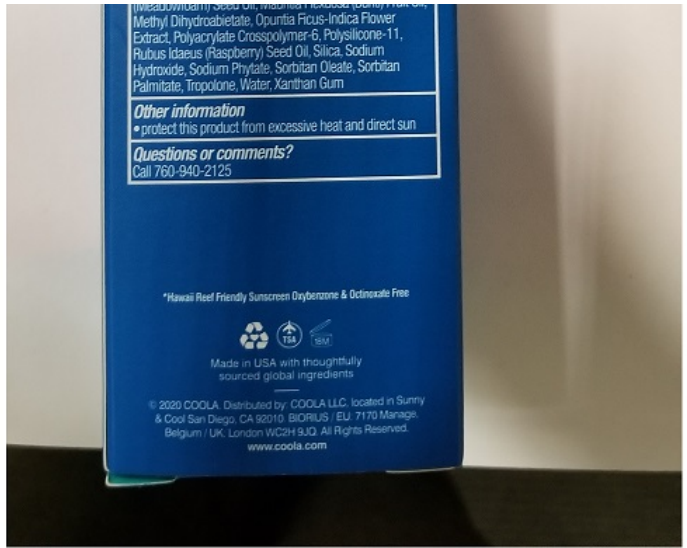
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## COOLA CLASSIC BODY SUNSCREEN FRAGRANCE-FREE SPF 50

avobenzone homosalate octisalate octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54111-145
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.75 g in 100 mL

<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.0 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.0 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5.0 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BRASSICA RAPA SUBSP. OLEIFERA OIL</b> (UNII: N4G8379626)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>CAMELINA SATIVA SEED OIL</b> (UNII: 12824X01L0)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CARTHAMUS TINCTORIUS SEED OLEOSOMES</b> (UNII: 9S60Q72309)	
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>MEADOWFOAM SEED OIL</b> (UNII: 412ZHA4T4Y)	
<b>MAURITIA FLEXUOSA FRUIT OIL</b> (UNII: 48H19MS04L)	
<b>METHYL DIHYDROABIETATE</b> (UNII: 7666FJ0J9F)	
<b>OPUNTIA FICUS-INDICA WHOLE</b> (UNII: 23Z87HTQ6P)	
<b>AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S)</b> (UNII: Q7UI015FF9)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>RASPBERRY SEED OIL</b> (UNII: 9S8867952A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>DISODIUM PHTHALATE</b> (UNII: QB14YV193C)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>SORBITAN MONOPALMITATE</b> (UNII: 77K6Z421KU)	
<b>TROPOLONE</b> (UNII: 7L6DL16P1T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54111-145-51	1 in 1 BOX	11/06/2019	
1		148 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M020	11/06/2019	

**Labeler** - Bentley Laboratories, LLC (068351753)

Revised: 12/2023

Bentley Laboratories, LLC