# COOLA CLASSIC BODY SPF 50 FRAGRANCE FREE- 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.

-----

#### Coola Classic Body Spray SPF 50 - Unscented

Avobenzone - 2.9%

Homosalate - 4.3%

Octisalate - 4.9% Octocrylene - 9.5%

Sunscreen

#### Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the nsk of skin cancer and early skin aging caused by the sun
- For external use only
- **Flammable:** Contents under pressure. Do not puncture or incinerat. 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. Keep out of eyes. Rinse with water to remove. Apply outdoors. Avoid overspray as it could cause surface to become slippery. Do not apply in windy conditions. Use in a well-ventilated area.
- Stop use and ask a 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

- 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 value of 15 or higher and other sun protection measures

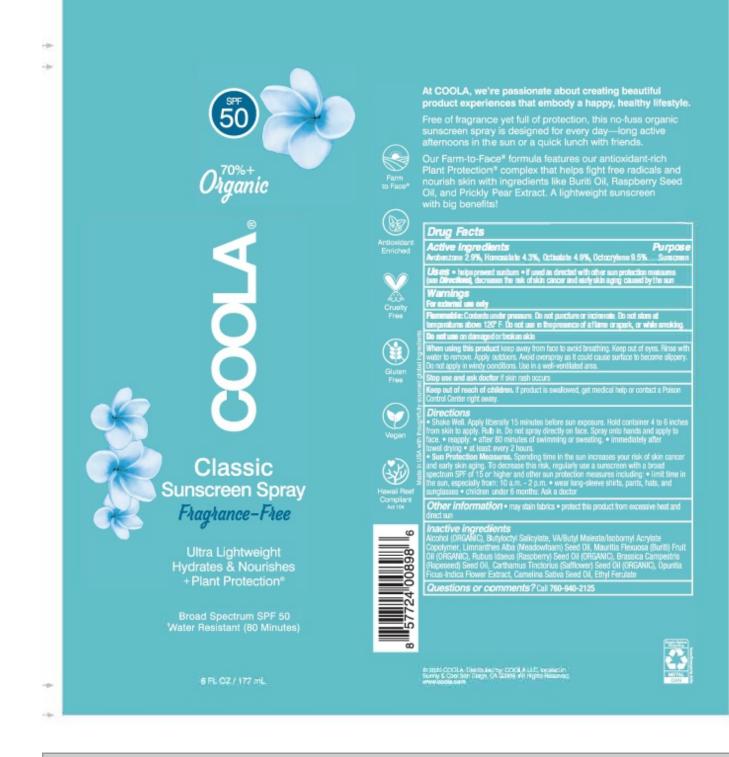
including: • Limit time in the sun especially from 10 a.m. – 2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses.

• Children under six months: Ask a doctor.

Alcohol (ORGANIC), Butyloctyl Salicylate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Brassica Campestris (Rapeseed) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Opuntia Ficus-Indica Flower Extract, Camelina Sativa Seed Oil, Ethyl Ferulate

- May stain fabrics
- Protect this product from excessive heat and direct sun

Call 760-940-2125



### **COOLA CLASSIC BODY SPF 50 FRAGRANCE FREE**

avobenzone, homosalate, octisalate, octocrylene spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-060	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.9 g in 100 mL		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.5 g in 100 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.3 g in 100 mL		
Inactive Ingredients				
Ingredient Name				
OPUNTIA FICUS-INDICA FLOWER (UNII: 83YSP51SMA)				
VINYL ACETATE (UNII: L9MK238N77)				
DIBUTYL MALEATE (UNII: 4X371TMK9K)				
ISOBORNYL ACRYLATE (UNII: IXOPRH184P)				
ETHYL FERULATE (UNII: 5B8915UELW)				
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)				
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)				
ALCOHOL (UNII: 3K9958V90M)				
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)				
SAFFLOWER OIL (UNII: 65UEH262IS)				
MEADOWFOAM SEED OIL (UNII: 412Z HA4T4Y)				
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)				

RASPBERRY SEED OIL (UNII: 9S8867952A)

#### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:79753-060- 01	177 mL in 1 CAN; Type 0: Not a Combination Product	10/01/2019	
	NDC:79753-060- 02	60 mL in 1 CAN; Type 0: Not a Combination Product	07/01/2020	

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	M020	10/01/2019	

# Labeler - COOLA, LLC (956990290)

Revised: 11/2022

COOLA, LLC