COOLA CLASSIC BODY SPF 30 TROPICAL COCONUT- avobenzone, 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 30 - Tropical Coconut

Avobenzone - 2.8% Octisalate - 4.9% Octocrylene - 7.6%

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

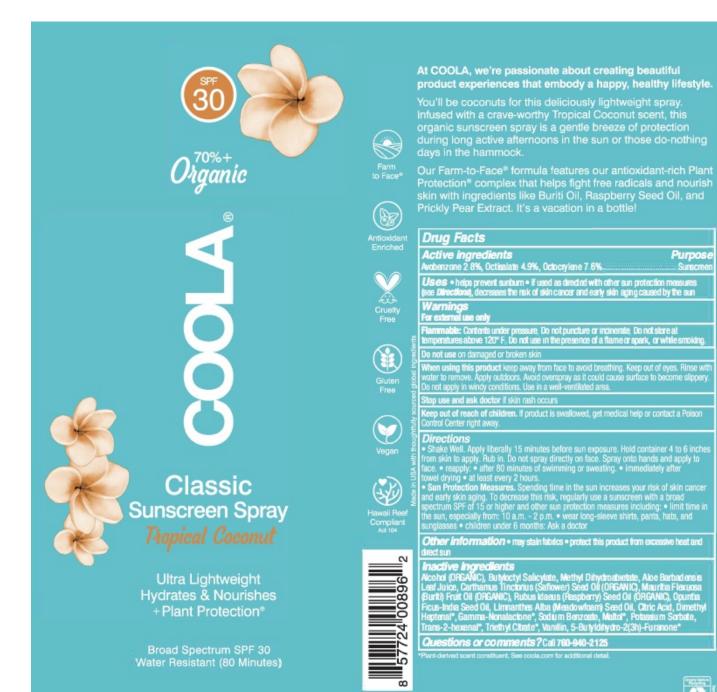
- Shake Well
- Apply liberally 15 minutes before sun exposure.
- Hold container 4 to 6 inches from skin to apply.
- Rub in. Do not spray directly on face.
- Spray onto hands and apply to face.
- Reapply: After 80 minutes of swimming or sweating. Immediately after towel drying. At least every 2 hours.
- 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, Methyl Dihydroabietate, Aloe Barbadensis Leaf Juice, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Opuntia Ficus-Indica Seed Oil, Limnanthes Alba (Meadowfoam) Seed Oil, Citric Acid, Dimethyl Heptenal, Gamma-Nonalactone, Sodium Benzoate, Maltol, Potassium Sorbate, Trans-2-hexenal, Triethyl Citrate, Vanillin, 5-Butyldihydro-2(3H)-Furanone

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

Call 760-940-2125





Purpose

COOLA CLASSIC BODY SPF 30 TROPICAL COCONUT

avobenzone, octisalate, octocrylene spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-062	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.8 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.6 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
MALTOL (UNII: 3A9RD92BS4)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
2-HEXENAL, (2E)- (UNII: 69JX3AIR1I)	
.GAMMAOCTALACTONE (UNII: UHD6M52X0K)	
.GAMMANONALACTONE (UNII: 11XGH66S8P)	
2,6-DIMETHYL-5-HEPTENAL (UNII: Z331YX9EL9)	
VANILLIN (UNII: CHI530446X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
OPUNTIA FICUS-INDICA SEED OIL (UNII: 1XGW49AK2J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
RASPBERRY SEED OIL (UNII: 958867952A)	
MEADOWFOAM SEED OIL (UNII: 412Z HA4T4Y)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
Packaging	

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-062- 01	177 mL in 1 CAN; Type 0: Not a Combination Product	10/01/2019	

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

Labeler - COOLA, LLC (956990290)

Revised: 11/2022