COOLA SPF 50 CLASSIC- sunscreen face mist 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 Face Sunscreen Mist SPF 50 (07-OC-013)

Active Ingredients

Avobenzone 2.9%, Octisalate 4.9%, Octocrylene 9.5%

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 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 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.

Directions

SHAKE WELL before use.

With your eyes completely closed, mist face evenly, holding bottle 10-12 inches away from face.

Wait until dry.

Apply liberally 15 minutes before sun exposure.

Reapply:

-After 80 minutes 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 the risk, regularly use a sunscreen with a broadspectrum SPF of 15 or higher and other protection measures including:

-Limit time in the sun, especially from 10 a.m. - 2 p.m.

-Wear long sleeves shirts, pants, hats, and sunglasses.

Children under 6 months: Ask a doctor.

Inactive Ingredients

Alcohol (ORGANIC), Butyloctyl Salicylate, Ethylhexyl Methoxycrylene, Polyester-8, Fragrance (Natural), VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Limnanthes Alba (Meadowfoam) Seed Oil, Brassica Campestris (Rapeseed) Seed Oil, Camellia Sinensis Leaf Extract (ORGANIC),Glycyrrhiza Glabra (Licorice) Root Extract (ORGANIC), Opuntia Ficus-Indica Flower Extract, Camelina Sativa Seed Oil, Bisabolol (ORGANIC), Glycerin (ORGANIC), Water, Ethyl Ferulate, Diisooctyl Succinate

Other Information

Protect this product from excessive heat and direct sun

Questions or Comments

Call 760-940-2125

Package Label



COOLA SPF 50 CLASSIC

sunscreen face mist spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-033	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL (UNII: 3K9958V90M)		
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)		
SAFFLOWER OIL (UNII: 65UEH262IS)		
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)		
VINYL ACETATE (UNII: L9MK238N77)		

ISOBORNYL ACRYLATE (UNII: IXOPRH184P)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	
DICAPRYL SUCCINATE (UNII: 8XD1ZF2M1M)	
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
LEVOMENOL (UNII: 24WE03BX2T)	
ETHYL FERULATE (UNII: 5B8915UELW)	
MEADOWFOAM SEED OIL (UNII: 412Z HA4T4Y)	
OPUNTIA FICUS-INDICA FLOWER (UNII: 83YSP51SMA)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:79753- 033-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/02/2021	

Labeler - COOLA LLC (956990290)

Revised: 4/2023

COOLA LLC