

**COOLA REFRESHING WATER MIST SUNSCREEN SPF 30- avobenzone, homosalate, octisalate, octocrylene liquid
GORDON LABORATORIES, INC**

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 Refreshing Water Mist Sunscreen SPF 30

Active ingredients

Avobenzone 2.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 5.5%

Purpose

Sunscreen

Uses

* helps prevent sunburn

* if used as directed with other sun protection measures (see **Directions**), decreases the rise 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 skin rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away.

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 * apply liberally 15 minutes before sun exposure

* reapply: * after 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 aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses

* children under 6 months: Ask a doctor

Inactive ingredients

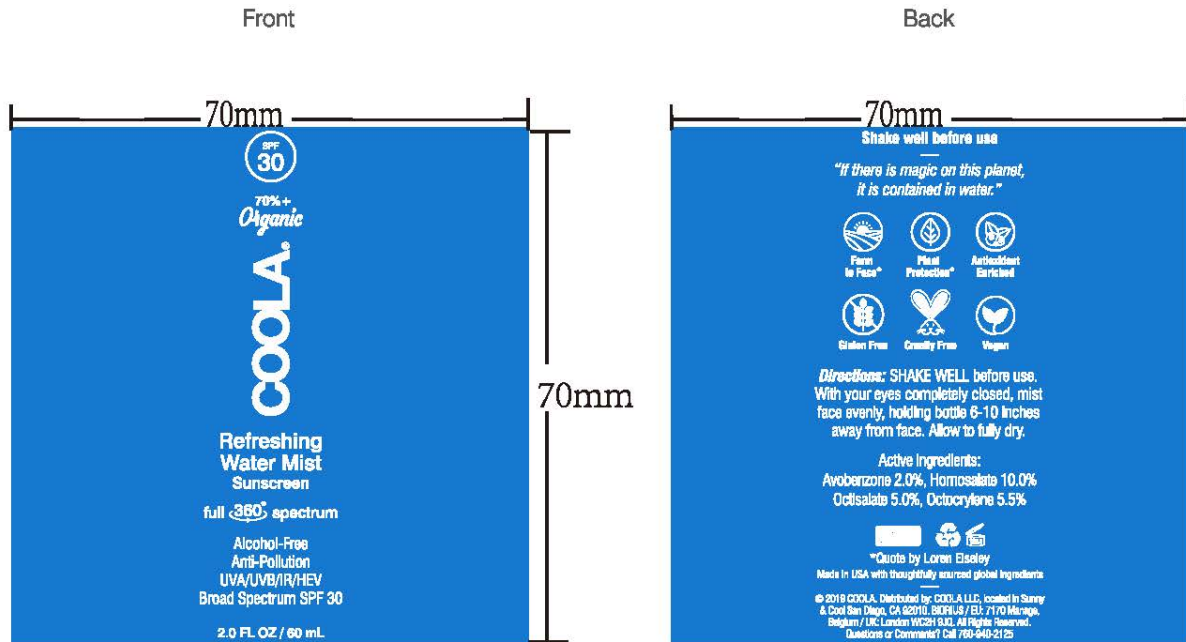
Aloe Barbadensis Leaf Juice (ORGANIC), Butylene Glycol, Caprylyl Glycol, Cetareth-12, Cetareth-20, Cetearyl Alcohol, Cetearyl Isononanoate, Cetyl Palmitate, Citronellyl Acetate, Cocos Nucifera (ORGANIC Coconut) Water, Cyclamen Aldehyde, Ethylene Brassylate, Glycerin (ORGANIC), Glyceryl Stearate, Glycine Soja (Soybean) Extract, Hyaluronic Acid, Jasminum Sambac Leaf Cell

Extract, Lauryl Glucoside, Methyl Dihydrojasmonate, Methylenedioxyphenyl Methylpropanal, Olive Oil Polyglyceryl-6 Esters, 1,2-Hexanediol, Propanediol, Schinus Molle Extract, Sodium Phytate, Sodium Stearoyl Glutamate, Theobroma Cacao (Cocoa) Seed Extract, Tropolone

Other information

* protect this product from excessive heat and direct sun

Questions or comments? Call 760-940-2125





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avobenzone, homosalate, octisalate, octocrylene liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21839-570
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	55 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
JASMINUM SAMBAC FLOWER (UNII: 2S686I937F)	
SOYBEAN (UNII: L7HT8FIZOD)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
TROPOLONE (UNII: 7L6DL16P1T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCOA (UNII: D9108TZ9KG)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)	
ETHYL OLIVATE (UNII: KKJ108Y20W)	
COCONUT WATER (UNII: 267F5Y81NT)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPANEDIOL (UNII: 5965N8W85T)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21839-570-11	1 in 1 CARTON	12/31/2018	
1	NDC:21839-570-12	60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/31/2018	

Labeler - GORDON LABORATORIES,INC (008328619)

Registrant - GORDON LABORATORIES,INC (008328619)

Establishment

Name	Address	ID/FEI	Business Operations
GORDON LABORATORIES,INC		008328619	manufacture(21839-570)

Revised: 12/2019

GORDON LABORATORIES,INC