# COOLA REFRESHING WATER MIST SUNSCREEN SPF 30- avobenzone, homosalate, octis alate, 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.

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#### 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 a Poison Control Center right away.

- \* 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 othersunprotection measures including: limit time in the sun, especially from: 10 a.m. 2 p.m. \* wear long-sleve shirts, pants, hats, and sunglasses \* children under 6 months: Ask a doctor

#### **Inactive ingredients**

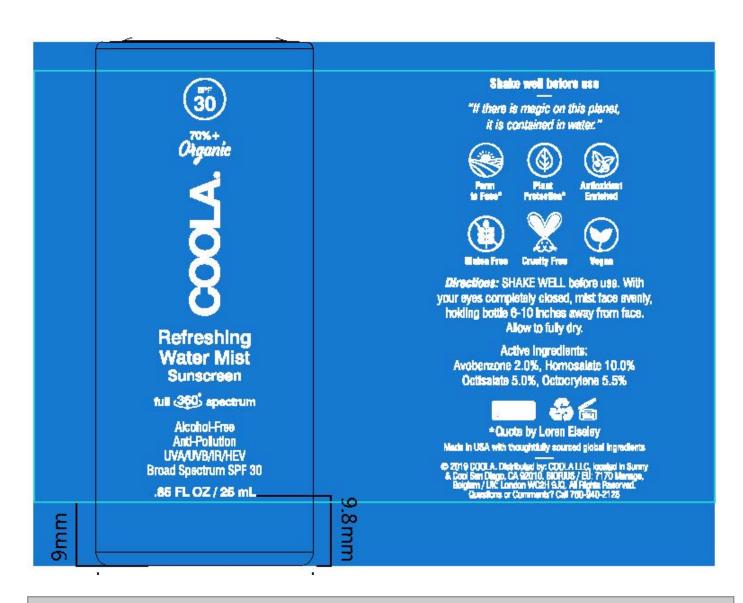
Aloe Barbadensis Leaf Juice (ORGANIC), Butylene Glycol, Caprylyl Glycol, Ceteareth-12, Ceteareth-20, Cetearyl Alcohol, Cetearyl Isononanoate, Cetyl Palmitate, Citronellyl Acetate, Cocos Nucifera (ORGANIC Coconut) Water, Cyclamen Aldehyde, Ethylene Brassylate, Glycerin (ORGANIC), Glyceryl Stearate, Glycine 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





#### COOLA REFRESHING WATER MIST SUNSCREEN SPF 30

avobenzone, homosalate, octisalate, octocrylene liquid

Product Information				
Product Type HUMAN OTC DRUG		Item Code (Source)	NDC:21839-590	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	100 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	55 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			

ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
SO YBEAN (UNII: L7HT8F1ZOD)	
WATER (UNII: 059QF0KO0R)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)	
ETHYL OLIVATE (UNII: KKJ108Y20W)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
TROPOLONE (UNII: 7L6DL16P1T)	
LAURYL GLUCO SIDE (UNII: 76LN7P7UCU)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)	
CETEARYL ISONONANOATE (UNII: P5001U99NI)	
COCONUT WATER (UNII: 267F5Y81NT)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
PROPANEDIOL (UNII: 5965N8W85T)	
JASMINUM SAMBAC FLOWER (UNII: 2S686I937F)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
ALCOHOL (UNII: 3K9958V90M)	
1,2-HEXANEDIOL (UNII: TR046 Y3K1G)	
COCOA (UNII: D9 10 8 TZ9 KG)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
GLYCERIN (UNII: PDC6A3C0OX)	

F	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:21839-590-02	1 in 1 CARTON	12/31/2018		
1	NDC:21839-590-01	25 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	<b>Business Operations</b>	
GORDON LABORATORIES,INC		008328619	manufacture(21839-590)	

Revised: 12/2019 Gordon Laboratories, Inc.