COOLA FULL SPECTRUM 360 SUN SILK DROPS 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 Full Spectrum 360 Sun Silk Drops SPF 30

DRUG FACTS

Active ingredients

Avobenzone 2.0%, Homosalate 10.0%

Octisalate 5.0%, Octocrylene 6.0%

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 prodcut 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

Aloe Barbadensis Leaf Extract (Organic), Anthemis Nobilis (Chamomile) Flower Oil, Butylene Glycol, Butyloctyl Salicylate, Calcium Gluconate, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Organic Safflower) Seed Oil, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Citrus Aurantium Amara (Bitter Orange) Leaf/Twig Extract, Dicaprylyl Carbonate, Glycerin (Organic), Glyceryl Stearate Se, Jasminum Sambac (Jasmine) Leaf Cell Extract, Nylon-12, Olea Europaea (Organic Olive) Fruit Oil, Plankton Leaf Extract, Propanediol, Schinus Molle Extract, Simmondsia Chinensis (Organic Jojoba) Seed Oil, Sodium Benzoate, Sodium Hyaluronate, Sodium Stearoyl Glutamate, Theobroma Cacao (Cocoa) Seed Extract, Tocopheryl Acetate, Water (Aqua), Xanthan Gum

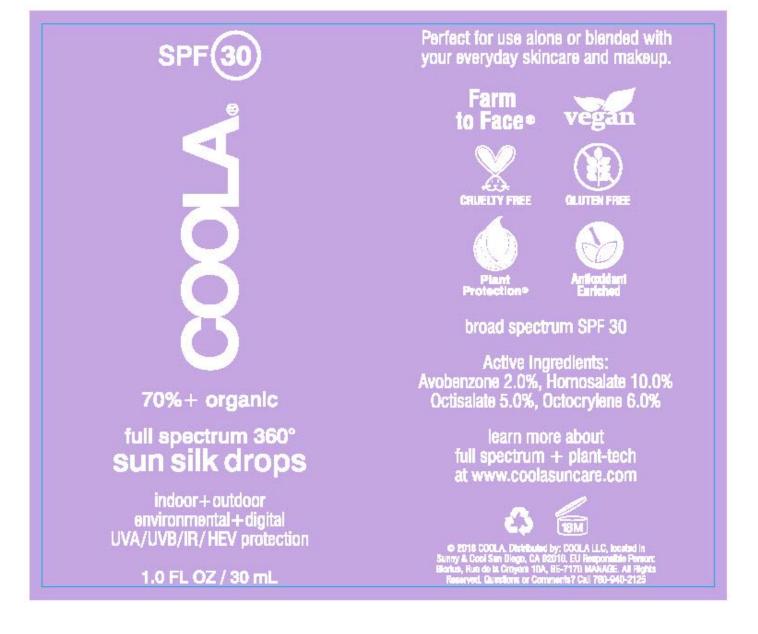
Other information

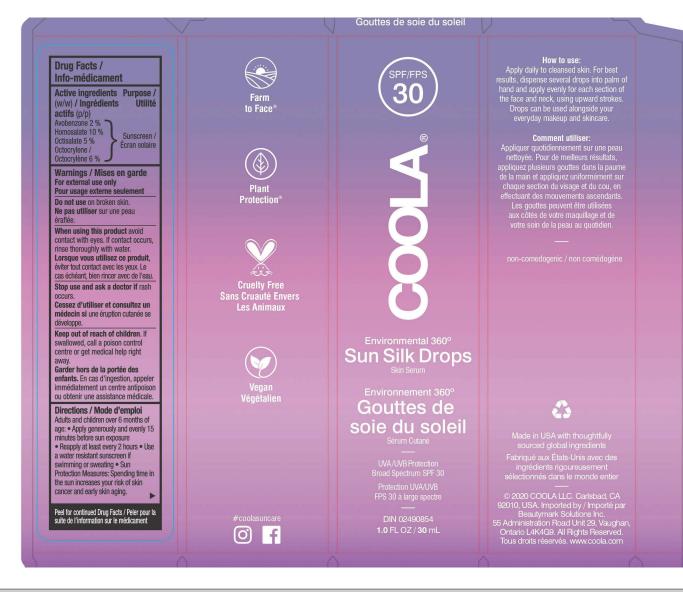
* protect this product from excessive heat and direct sun

Questions or comments? Call 760-940-2125

How to use:

Apply daily to cleansed skin. For best results, dispense several drops as needed into palm of hand and apply evenly across face and neck using upward strokes. Drops are perfect for use alone or blended with your everyday skincare and makeup.





COOLA FULL SPECTRUM 360 SUN SILK DROPS SPF 30

avobenzone, homosalate, octisalate, octocrylene liquid

Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source) NDC		NDC:2	:21839-620	
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	ety					
Ing	redient Name		Basis of Stre	ength	Strength	
VOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZONE		$20\ mg$ in $1\ mL$	
HOMOSALATE (UNII: V06SV4M95S)	ALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)			HOMOSALATE		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)			OCTISALATE		50 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) OCTOCRYLENE			E	60 mg in 1 mL		
Inactive Ingredients						
	Ingredient Name				Strength	
WATER (UNII: 059QF0KO0R)						

ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)			
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
PROPANEDIOL (UNII: 5965N8W85T)			
OLIVE OIL (UNII: 6UYK2W1W1E)			
GLUCONOLACTONE (UNII: WQ29KQ9POT)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
COCOA (UNII: D9108TZ9KG)			
SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)			
JASMINUM SAMBAC FLOWER (UNII: 2S6861937F)			
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)			
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)			
SAFFLOWER OIL (UNII: 65UEH262IS)			
NYLON-12 (UNII: 446U8J075B)			
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)			
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)			
XANTHAN GUM (UNII: TTV12P4NEE)			
JOJOBA OIL (UNII: 724GKU717M)			
GLYCERIN (UNII: PDC6A3C0OX)			
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21839-620-02	1 in 1 NOT APPLICABLE	12/20/2018	
1	NDC:21839-620-01	5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21839-620-04	1 in 1 CARTON	12/20/2018	
2	NDC:21839-620-03	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
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Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	12/20/2018		

Labeler - Gordon Laboratories, Inc. (008328619)

Registrant - Gordon Laboratories, Inc. (008328619)

Establishment

Name	Address	ID/FEI	Business Operations
GORDON LABORATORIES, INC		008328619	manufacture(21839-620)