COOLA CLASSIC FACE SUNSCREEN FRAGRANCE-FREE SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion 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 Classic Face Sunscreen Fragrance-Free SPF 50

Active Ingredients

AVOBENZONE 1.75%, HOMOSALATE 5.0%, OCTISALATE 2.0%, OCTOCRYLENE 5.0%

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.

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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

- * apply liberally 15 minutes before sun exposure
- * 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 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-sleve shirts, pants, hats, and sunglasses
- * children under 6 months: Ask a doctor

Inactive ingredients

Aloe Barbadensis Leaf Juice (ORGANIC), Brassica Campestris (Rapeseed) Seed Oil, Butylene Glycol, Camelina Sativa Seed Oil, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Carthamus Tinctorius (Safflower) Seedcake Extract, Decyl Glucoside, Dimethicone, Glycerin (ORGANIC), Hydrogenated Methyl Abietata, Hydrolyzed Jojoba Esters, Jojoba Esters, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa Fruit Oil, 1,2 Hexanediol, Opuntia Ficus-Indica Flower Extract, Polyacrylate Crosspolymer-6, Polysilicone-11, Rubus Idaeus (Raspberry) Seed Oil, Silica, Sodium Phytate, Tropolone, Xanthan Gum

Other Information

* protect this product from excessive heat and direct sun

Questions or comments? Call 760-940-2125





Classic Face Sunscreen Fragrance-Free

Non-Greasy Lightweight Hydration + Plant Protection*

Broad Spectrum SPF 50 Water Resistant (80 Minutes)

1.7 FL O/Z / 50 mL

COOLA.

This organic COOLA Classic Face Sunscreen Lotion SPF 50 is an enhanced version of our award-winning classic - designed to withstand those long active days in the sun but light enough for everyday use. This Farm-to-Face® formula is supercharged with our proprietary Plant Protection®, which incorporates naturally effective and antioxidant-rich ingredients such as Buriti Oil. Meadowfoarn Oil, Raspberry Seed Oil, and Prickly Pear extract, to help fight











Active ingredients: Avobenzone 1.75%, Hornosalate 5.0% Octisalate 2.0%, Octobrylene 5.0%

free radicals and nourish and strengthen the skin barrier, all year long.

> detreatologist tested, ghiten free, non-gino & non-comedogenic

> > "Hawaii Reaf Friendly Sunscrean Oxybenzone & Octinosate Free





Made in USA with thoughtfully sourced global ingredients

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COOLA CLASSIC FACE SUNSCREEN FRAGRANCE-FREE SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21839-452	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	20 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	17.5 mg in 1 mL

SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TTV12P4NEE) WATER (UNII: 059QF0KO0R) TROPOLONE (UNII: 7L6DL16P1T)	trength
XANTHAN GUM (UNII: TTV12P4NEE) WATER (UNII: 059QF0KO0R) TROPOLONE (UNII: 7L6DL16P1T)	
WATER (UNII: 059QF0KO0R) TROPOLONE (UNII: 7L6DL16P1T)	
TROPOLONE (UNII: 7L6DL16P1T)	
DILYTATE CO DIIM (UNII, 00 40 C C 1EDI)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
1,2-HEXANEDIO L (UNII: TR046 Y3K1G)	
PHENO XYETHANOL (UNII: HIE49 2ZZ3T)	
METHYL DIHYDRO ABIETATE (UNII: 7666FJ0J9F)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
DIMETHICO NE/VINYL DIMETHICO NE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
AMMO NIUM ACRYLO YLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLO LPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI0 15FF9)	
OPUNTIA FICUS-INDICA (UNII: 23Z87HTQ6P)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0 EV20 QYL)	
HYDROGENATED JO JO BA O IL, RANDOMIZED (UNII: Q47ST02F58)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CARTHAMUS TINCTORIUS SEEDCAKE (UNII: DHQ13F4N2W)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48 H19 MS 0 4L)	
MEADO WFO AM SEED OIL (UNII: 412ZHA4T4Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	
CANOLA OIL (UNII: 331KBJ17RK)	

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:21839-452-02	1 in 1 CARTON	12/31/2018	

1 NDC:21839-452-01	148 mL in 1 TUBE; 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		
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Labeler - Gordon Laboratories, Inc. (008328619)

Registrant - Gordon Laboratories, Inc. (008328619)

Establishment				
Name	Address	ID/FEI	Business Operations	
GORDON LABORATORIES,INC		008328619	manufacture(21839-452)	

Revised: 12/2019 Gordon Laboratories, Inc.