

COOLA CLASSIC BODY SUNSCREEN FRAGRANCE-FREE SPF 50- avobenzene,homos alate, 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 Body 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.

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

* 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-sleeve shirts, pants, hats, and sunglasses

* children under 6 months: Ask a doctor

Inactive ingredients

Aloe Barbadensis Leaf Juice (ORGANIC), Blue-Green (Algae) Extract (ORGANIC), Butyloctyl Salicylate, C30-38 Olefin/Isopropyl Maleate/MA Copolymer, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Oleosomes (ORGANIC), Chlorphenesin, Cocos Nucifera (Coconut) Oil (ORGANIC), Ethylhexylglycerin, Glycerin (ORGANIC), Glyceryl Stearate, Limnanthes Alba (Meadowfoam) Seed Oil, Magnesium Sulfate, Mauritia Flexuosa (Buriti) Fruit Oil (ORGANIC), Neopentyl Glycol Diheptanoate, Olive Oil Polyglyceryl-6 Esters, Opuntia Ficus-Indica Flower Extract, Polyglyceryl-6 Pentaoleate, Polymethyl Methacrylate, Rubus Idaeus (Raspberry) Seed Oil, Silica, Simmondsia Chinensis (Jojoba) Seed Oil (ORGANIC), Stearyl/Octyldodecyl Citrate Crosspolymer, Tocopherol, VP/Hexadecene Copolymer.

Other Information

*** protect this product from excessive heat and direct sun**

Questions or comments? Call 760-940-2125



70%+
Organic

COOLA®

**Classic
Body Sunscreen**
Fragrance-Free

Ultra Lightweight
Hydrates & Nourishes
+ Plant Protection*

Broad Spectrum SPF 50
Water Resistant (80 Minutes)

5 FL OZ / 148 mL



COOLA.

At COOLA, we're passionate about creating beautiful product experiences that embody a happy, healthy lifestyle.

New! This organic COOLA Classic Body Sunscreen Lotion SPF 50 is an enhanced version of our award-winning classic – designed for those long active days in the sun but light enough for everyday use. Our advanced plant-based oleosome technology optimizes the performance of our formula, for fortified protection that's unbelievably light, gentle, and sheer on skin.

Our Farm-to-Face® formula is supercharged with our proprietary Plant Protection®, which incorporates naturally effective and antioxidant-rich ingredients such as Buriti Oil, Meadowfoam Seed Oil, Raspberry Seed Oil, and Prickly Pear extract, to help fight free radicals and nourish and strengthen the skin barrier, all year long.

Active Ingredients:
Avobenzone 1.75%, Homosalate 5.0%
Octisalate 2.0%, Octocrylene 5.0 %

*dermatologist tested, non-greasy
gluten free & non-gmo*

**Newell Reef Friendly Sunscreen
Oxybenzone & Octinoxate Free*



Made in USA with thoughtfully sourced global ingredients

© 2019 COOLA. Distributed by: COOLA LLC, located in Sunny & Cool San Diego, CA 92010. BIORIUS / EU: 7170 Manage, Belgium / UK: London WC2H 8JQ. All Rights Reserved. Questions or Comments? Call 780-940-2125 www.coolsuncare.com





COOLA CLASSIC BODY SUNSCREEN FRAGRANCE-FREE SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21839-430
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	17.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	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

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0K00R)	
TROPOLONE (UNII: 7L6DL16P1T)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CANOLA OIL (UNII: 331KBJ17RK)	
ALCOHOL (UNII: 3K9958V90M)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPAS) (UNII: Q7UI015FF9)	
OPUNTIA FICUS-INDICA (UNII: 23Z87HTQ6P)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
CARTHAMUS TINCTORIUS SEEDCAKE (UNII: DHQ13F4N2W)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAURITIA FLEXUOSA FRUIT OIL (UNII: 48H19MS04L)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAMELINA SATIVA SEED OIL (UNII: 12824X01L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21839-430-02	1 in 1 CARTON	02/28/2019	
1	NDC:21839-430-01	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	02/28/2019	

Labeler - Gordon Laboratories, Inc. (008328619)

Registrant - Gordon Laboratories, Inc. (008328619)

Establishment			
Name	Address	ID/FEI	Business Operations
GORDON LABORATORIES,INC		008328619	manufacture(21839-430)

Revised: 12/2019

Gordon Laboratories, Inc.