

COOLA CLASSIC BODY SUNSCREEN GUAVA MANGO SPF 50- avobenzene,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 Body Sunscreen Guava Mango 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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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), Brassica Campestris (Rapeseed) Seed Oil, Butylene Glycol, Camelina Sativa Seed Oil, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Carthamus Tinctorius (Safflower) Seed Oil (ORGANIC), Carthamus Tinctorius (Safflower) Seedcake Extract, Decyl Glucoside, Didecyldimonium Chloride, Dimethicone, Flavor, Glycerin (ORGANIC), Hydrogenated Methyl Abietata, Hydrolyzed Jojoba Esters, Jojoba Esters, Limnanthes Alba (Meadowfoam) Seed Oil, Mauritia Flexuosa Fruit Oil, Methylpropanediol, Opuntia Ficus-Indica Flower Extract, Polyacrylate Crosspolymer-6, Polyquaternium-80, Polysilicone-11, Rubus Idaeus (Raspberry) Seed Oil, Silica, Sodium Phytate, Squalane, Xanthan Gum

Other Information

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

Questions or comments? Call 760-940-2125

SPF
50

70%+
Organic

COOLA®

Classic
Body Sunscreen
Guava Mango

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*

**Hawaii Reef Friendly Sunscreen
Oxybenzone & Octinoxate Free*



Made in USA with thoughtfully
sourced global ingredients

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www.coolasuncare.com

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 Hydrates & Nourishes
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*Healthy Suncare
 People Love To Wear!*

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let's get social!
 tag your photos
 #coolasuncare



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

*featuring prickly pear extract
 raspberry seed oil & buriti oil*

Drug Facts	
Active Ingredients	Purpose
Azobenzene 1.75%, Homosalate 5.0%, Octisalate 2.0%, Octocrylene 5.0%	Sunscreen
Uses	
<ul style="list-style-type: none"> • helps prevent sunburn • if used as directed with other sun protection measures (see Directions), decreases the risk 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.	
Directions	
<ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply: <ul style="list-style-type: none"> • 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 skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> • 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), Brassica Campestris (Rapeseed) Seed Oil, Butylene Glycol, Candelina Saliva Seed Oil, Caprylyl Glycol, Carthamus Tinctorius (Safflower) Oleosomes, Carthamus Tinctorius (ORGANIC) Safflower Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Citric Acid (ORGANIC), Dimethylsiloxane, Ethylhexyl Stearate (ORGANIC), Hydrogenated Methyl Methacrylate, Hydrolyzed Jojoba Esters, Jojoba Esters, Limnanthes Alba (Meadowfoam) Seed Oil, Mearitria Flexuosa Fruit Oil, 1,2 Hexanediol, Quercus Ficus-Indica Flower Extract, Polyethylene Glycol (150), Polysiloxane-11, Rubus Idaeus (Raspberry) Seed Oil, Silica, Sodium Phytate, Tocopherol, Xanthan Gum	
Other information	
• protect this product from excessive heat and direct sun	
Questions or comments? Call 1-800-940-2123	

*Hazard Free: Paraben Free, Phthalate Free, Sulfate Free



Made in USA with thoughtfully sourced global ingredients

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 PEFC Environmentally responsible paper.
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COOLA CLASSIC BODY SUNSCREEN GUAVA MANGO SPF 50

avobenzone,homosalate, octisalate,octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21839-450
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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	20 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	50 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
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)	
ALCOHOL (UNII: 3K9958V90M)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL DIHYDRO ABIETATE (UNII: 7666FJ0J9F)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
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)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21839-450-02	1 in 1 CARTON	01/31/2019	
1	NDC:21839-450-01	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	01/31/2019	

Labeler - Gordon Laboratories, Inc. (008328619)

Registrant - Gordon Laboratories, Inc. (008328619)

Establishment

Name	Address	ID/FEI	Business Operations
GORDON LABORATORIES, INC		008328619	manufacture(21839-450)

Revised: 1/2019

Gordon Laboratories, Inc.