COOLA MINERAL SUN SILK CREME SUNSCREEN SPF 30- zinc oxide 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 Mineral Sun Silk Crème Sunscreen SPF 30

DRUG FACTS

Active ingredients

Zinc Oxide 15%

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.

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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

- * 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

Inactive ingredients

Aloe Barbadensis Leaf Juice (ORGANIC), Butylene Glycol, Caprylyl Glycol, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Didecyldimonium Chloride, Dimethicone, Glyceryl Caprylate,

Glyceryl Stearate Citrate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Jasminum Sambac Leaf Cell Extract, Methylpropanediol, Niacinamide, PEG-7 Trimethylolpropane Coconut Ether, Polyhydroxystearic Acid, Polyisobutene, Polyquaternium-80, Propanediol, Schinus Molle Extract, Theobroma Cacao (Cocoa) Seed Extract.

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, 15 minutes before sun exposure. Dispense into palm of hand and apply evenly across face and neck using upward strokes,



Otganio



Mineral Sun Silk Crème

full 360° spectrum

Oil-Free Anti-Pollution UVA/UVB/IR/HEV Broad Spectrum SPF 30

1.5 FL OZ / 44 mL

Environmental + Digital UV™

We've got you covered from beach to boardroom.

Farm to Face®











Transparent Non-Nano Zinc Oxide

Active Ingredients: Zinc Oxide 15.0%

Learn more about

Full Spectrum + Digital UV™

at www.coolasuncare.com





Made in USA with thoughtfully sourced global ingredients

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Farm to Face*

(1)







Mineral Sun Silk Crème

Sunscreen

full 360° spectrum

Oil-Free Anti-Pollution UVA/UVB/IR/HEV **Broad Spectrum SPF 30**

1.5 FL OZ / 44 mL



Beach to Boaldloom"

Meet your mineral match! This multi-tasking modern masterpiece does it all. Our oil-free, airy-light formula gently glides on to form a transparent veil, ideal for everyday use. Non-nano Zinc Oxide provides broad spectrum UVA/UVB protection while our plant-derived Full Spectrum 360° complex helps mitigate the effects of today's modern-world skin-aggressors - High Energy Visible light (which includes blue light emitted from digital devices), IR (Infrared) and pollution. A proprietary blend of supercharged antioxidants helps defend against free radicals while a bouquet of plant stem cells and niacinamide helps promote skin radiance and youthful-looking skin.

Finally - full spectrum organic skincare that keeps up with your everyday modern lifestyle.

> let's get social! tag your photos #coolasuncare





Drug Facts

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Enriched

dermatologist tested, gluten free & non-gm

featuring plant cell cultures, non-nano zinc axide & niacinamide







COOLA MINERAL SUN SILK CREME SUNSCREEN SPF 30

zinc oxide lotion

Pro	duct	Information	
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:21839-550

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 150 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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COCOA (UNII: D9108TZ9KG)

SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)

POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)

POLYHYDRO XYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)

NIACINAMIDE (UNII: 25X51I8RD4)

METHYLPRO PANEDIO L (UNII: N8 F53B3R4R)

JASMINUM SAMBAC FLOWER (UNII: 2S686I937F)

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)

SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)

PROPANEDIOL (UNII: 5965N8W85T)

DIDECYLDIMO NIUM CHLO RIDE (UNII: JXN40 O 9 Y 9 B)

ALOE VERA LEAF (UNII: ZY81Z83H0X)

WATER (UNII: 059QF0KO0R)

HYDRO XYETHYL ACRYLATE/SO DIUM ACRYLO YLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)

(UNII: 86FQE96TZ4)

DIMETHICO NE (UNII: 92RU3N3Y10)

CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)

GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)

GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)

Packaging

#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21839-550-01	1 in 1 BOX	12/11/20 18	
1	NDC:21839-550-02	44 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 not final	part352	12/11/2018	

Labeler - GORDON LABORATORIES, INC (008328619)

Registrant - GORDON LABORATORIES, INC (008328619)

Establishment					
Name	Address	ID/FEI	Business Operations		
GORDON LABORATORIES,INC		008328619	manufacture(21839-550)		

Revised: 12/2019 GORDON LABORATORIES,INC