

MINERAL SUNSCREEN- zinc oxide emulsion
CA-Botana International

DS Mineral Sunscreen SPF 50 Gabriel

Active Ingredient

Zinc Oxide 21%..... Sunscreen

Purpose

Sunscreen

Ask Doctor

Stop use and ask a doctor if rash occurs

Keep out of reach of children

Keep out of reach of children

Inactive Ingredients

Water (Aqua), Coco-Caprylate/Caprata, Cetearyl Alcohol, Propanediol, Stearyl Alcohol, Polyhydroxystearic Acid, Mica, Butyrospermun parki (Shea butter), Cetearyl Oliviate, Sorbitan Oliviate, Caaprylhydroxamic acid. GlycerylCaprylate, Glycerin, Xanthan Gum, Equisetum arvense (Horsetail) extract, Rosmarinus officinalis (Rosemary) extract, Centella asiatica(Gotu-kola) extract, Aesculus hippocastanum (Horse chestnut) extract, Camellia sinensis(Green tea) extract, Olea europaea (Olive) extract, Tocopheryl Acetate, Potassium Acetate, Sodium Phytate, Citrus nobilis/Mandarinorange) Peel oil, Coconut oil, Helianthus annuus (Sunflower) Seed oil, Silica, Triethpxycapryylsilane, OXY CA (Rosmarinus officinalis (Leaf)CO2 Extract& Ascorbyl Palmitate & Caprylic/Capric Triglyceride & Ascorbic Acid & Tocopherol & Citric Acid)

Safety information

Protect this product from excessive heat and direct sun

Dosage & Administration

Helps prevent sunburn. If used as directed with other sun protection measured decreases the risk of skin cancer and early skin aging caused by the sun. Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply : at least 2 hours. Children under 6 months: Ask a doctor. Sun protection measurements. 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 othe sun protection measures including: limit time in the sun, specially from 10 a.m.- 2 p.m Wear long-sleeveshirts, pants, hats, and sunglasses. Protect this product from excessive heat and direct 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. If product is swallowed get medical help or contact a poison Control Center right away.

Indications & Usage

Apply liberally 15 minutes before exposure, use water resistant sunscreen, if swimming or sweating. reapply at least every 2 hours. Children under 6 months: ask a doctor

PACKAGE LABEL PRINCIPAL

113 mm

109.90 mm

86 mm

GABRIEL

REEF SAFE

Mineral Sunscreen
Transparent

Broad Spectrum SPF 50
Water Resistant (80 Minutes)

Sun Care

Lotion | lotion

2.1 oz. | net 61 g

Drug Facts

Active Ingredients: Zinc Oxide 21% Purpose: Sunscreen

Uses: • 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 • When using this product keep out of eyes. Rinse with water to remove. Do not use on damaged or broken skin. Stop use and ask a doctor if 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 • use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • children under 6 months; ask a doctor • 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 • limit time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses.

Inactive Ingredients: Water (Aqua), Caprylic/Capric Acid, Cetearyl Alcohol, Propanediol, Stearyl Alcohol, Polyhydroxybutyrate, Mica, Butyrospermum Parkii (Shea) Butter, Cetearyl Olivate, Sorbitan Olivate, Caprylyl Glycol, Glyceryl Caprylate, Xanthan Gum, Equisetum Arvense (Horsetail) Extract, Rosmarinus officinalis (Rosemary) Extract, Centella Asiatica (Gotu Kola) Extract, Ascorulus Hippocastanum (Horse Chestnut) Extract, Camellia Sinensis (Green Tea) Extract, Olea Europaea (Olive) Extract, Tocopheryl Acetate, Potassium Sorbate, Sodium Phytate, Citrus Nobilis (Mandarin/Orange) Peel Oil, Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Oil, Silica, Triethoxycaprylylsilane, Dry CA (Rosmarinus officinalis Leaf CO2 Extract and Ascorbyl Palmate and Caprylic/Capric Triglyceride and Ascorbic Acid and Tocopherol and Citric Acid).

NDC 35192-044-01 WWW.GABRIELCOSMETICSINC.COM

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MINERAL SUNSCREEN

zinc oxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35192-044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12.81 g in 12.81 g

Inactive Ingredients

Ingredient Name	Strength
SORBITAN OLIVATE (UNII: MDL271E3GR)	
EQUISETUM ARVENSE WHOLE (UNII: 73DM367W4P)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
DIMETHICONOL TRIETHOXYCAPRYLYLSILANE TETRAETHYL SILICATE CROSSPOLYMER (4000000 MW) (UNII: 6CA31A9P15)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ALLANTOIN (UNII: 344S277G0Z)	
ROSEMARY (UNII: IJ67X351P9)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

ETHYL FERULATE (UNII: 5B8915UELW)
TOCOPHEROL (UNII: R0ZB2556P8)
XANTHAN GUM (UNII: TTV12P4NEE)
GLYCERIN (UNII: PDC6A3C0OX)
PROPANEDIOL (UNII: 5965N8W85T)
WATER (UNII: 059QF0KO0R)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
GLYCERYL CAPRATE (UNII: 197M6VFC1W)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
GREEN OLIVE (UNII: 6HD2W46UEG)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
ORANGE PEEL (UNII: TI9T76XD44)
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
MICA (UNII: V8A1AW0880)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HORSE CHESTNUT (UNII: 3C18L6RJAZ)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
SHEA BUTTER (UNII: K49155WL9Y)

Product Characteristics

Color	white (white yellowish)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-044-01	61 g in 1 TUBE; Type 0: Not a Combination Product	08/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/15/2021	

Labeler - CA-Botana International (106276728)

Establishment

Name	Address	ID/FEI	Business Operations
CA-Botana International		106276728	manufacture(35192-044)

Revised: 10/2023

CA-Botana International