

**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



# MINERAL SUNSCREEN

zinc oxide emulsion

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

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

### Product Characteristics

<b>Color</b>	white (white yellowish)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-044-15	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**

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

Revised: 12/2024

CA-Botana International