

**SUNSCREEN- zinc oxide emulsion**  
**CA-Botana International**

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**Elixir SPF50 Tinted**

**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, Ceteary Alcohol, Propanediol, Stearyl Alcohol, Polyhydroxystearic Acid, Mica, Cetearyl Oliviate, Sorbitan Oliviate, Caprylhydroxamic 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 Sorbate, Sodium Phytate, Carthamus tinctorius (Safflower ) Seed oil, Silica, Triethoxycaprylsilane, OXY CA (Rosmarinus officinalis (Leaf)CO2 Extract& Ascorbyl Palmitate & Caprylic/Capric Triglyceride & Ascorbic Acid & Tocopherol & Citric Acid ), Glyceryl Stearate, Iron Oxide.

**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 other 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



**SUNSCREEN**  
zinc oxide emulsion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:35192-050
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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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PEG-8 CAPRYLIC/CAPRIC GLYCERIDES (UNII: 00BT03FSO2)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
EQUISETUM ARVENSE WHOLE (UNII: 73DM367W4P)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ROSEMARY (UNII: IJ67X351P9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
WATER (UNII: 059QF0KO0R)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
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)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
MICA (UNII: V8A1AW0880)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

### Product Characteristics

Color	brown (light brownish)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35192-050-17	61 g in 1 PACKAGE; Type 0: Not a Combination Product	07/31/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/31/2022	

**Labeler** - CA-Botana International (106276728)

## Establishment

Name	Address	ID/FEI	Business Operations
CA-Botana International		106276728	manufacture(35192-050)

Revised: 11/2023

CA-Botana International