

**SKIN TONE DEFENDER 20% ZINC OXIDE- zinc oxide cream**  
**Cali Skin Care LLC**

-----

**Active Ingredients:**

Zinc Oxide 20%

**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 aging caused by the sun.

**Warnings:**

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

**Directions:**

- Apply liberally 15 minutes before sun exposure
- Reapply: • After 40 minutes of swimming or sweating
- Immediately after towel drying
- 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 value of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 am- 2 pm
  - Wear long sleeve shirts and hats and sunglasses

**Inactive Ingredients:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

**Other Information:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

## Warnings:

Keep out of reach of children

**DRUG FACTS (cont)**  
**INACTIVE INGREDIENTS:** C<sub>12-15</sub> Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

**OTHER INFORMATION:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

Clinically Clear® Skin Rehab Center  
San Leandro, California 94577  
clinicallyclear.com



**Skin Tone Defender**  
20% Zinc Oxide

Advanced Mineral Protection

SPF 40  
Broad Spectrum  
Water Resistant (40 Minutes)

Net. Wt. 4 oz/115g

**DRUG FACTS**  
**ACTIVE INGREDIENTS:** Zinc Oxide 20%  
**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 aging caused by the sun.  
**WARNINGS:** For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.  
**DIRECTIONS:**

- Apply liberally 15 minutes before sun exposure
- Reapply:
  - After 40 minutes of swimming or sweating
  - Immediately after towel drying
  - 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 value of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 am- 2 pm
  - Wear long sleeve shirts and hats and sunglasses



## SKIN TONE DEFENDER 20% ZINC OXIDE

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85298-205
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>WATER</b> (UNII: 059QF0K00R)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85298-205-04	115 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/10/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/10/2020	

**Labeler** - Cali Skin Care LLC (040952420)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85298-205)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85298-205)

