

**PROTECTION E AND C LIGHTLY TINTED- zinc oxide cream**  
**CLEAR SKIN SOLUTIONS, LLC**

**DRUG FACTS**

**ACTIVE INGREDIENTS:**

Zinc Oxide 16%

**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. 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 the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**DIRECTIONS:**

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant product 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 value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10 am-2 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

**INACTIVE INGREDIENTS:** Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer

**OTHER INFORMATION:**

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

Clear Skin Solutions  
 Ardmore, OK  
 580-798-3950  
 clearskinsolutions.com



CLEAR SKIN SOLUTIONS



Protection E & C  
 Lightly Tinted  
 SPF 40 BROAD SPECTRUM  
 with Ceramides

1.75 oz | 50 g

PROTECTION E AND C LIGHTLY TINTED			
zinc oxide cream			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85563-208(NDC:58892-208)
<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	160 mg in 1 g	
Inactive Ingredients			
Ingredient Name	Strength		

<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>CERAMIDE 3</b> (UNII: 4370DF050B)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85563-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/30/2021	

**Labeler** - CLEAR SKIN SOLUTIONS, LLC (076140083)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85563-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85563-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85563-208)