

**MINERAL LIP PROTECTION- titanium dioxide, zinc oxide stick**  
**CLEAR SKIN SOLUTIONS, LLC**

Acne Safe  
 Mineral Lip Protection  
 SPF 45 BROAD SPECTRUM | WATER RESISTANT (80 MINS)  
 .14 oz | 4.5 g






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**DRUG FACTS:**  
 ACTIVE INGREDIENTS/PURPOSE: Titanium Dioxide 4.0%, Sunscreen, Zinc Oxide 5.5%, 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. Reapply after 80 minutes of swimming or sweating, immediately after towel drying, and 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  
 Clear Skin Solutions 580-798-3950 clearskinsolutions.com  
 NDC 385563212450



**MINERAL LIP PROTECTION**

titanium dioxide, zinc oxide stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85563-212(NDC:58892-212)
<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	55 mg in 1 g

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | **TITANIUM DIOXIDE** | 40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALUMINA</b> (UNII: LMI26O6933)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CITRIC ACID</b> (UNII: 2968PHW8QP)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ZINGIBER OFFICINALE (GINGER) ROOT OIL</b> (UNII: SAS9Z1SVUK)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>PEG-8</b> (UNII: B6978945GQ)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>CETEARYL ISONONANOATE</b> (UNII: P5O01U99NI)	
<b>DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER</b> (UNII: R6G12EY23X)	
<b>HEXYLDECYL LAURATE</b> (UNII: 0V595C1P6M)	
<b>SOYBEAN LECITHIN</b> (UNII: 1DI56QDM62)	
<b>PEG/PPG-15/15 DIMETHICONE</b> (UNII: 184IZ28A2G)	
<b>CI 77499</b> (UNII: XM0M87F357)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HEXYLDECANOL</b> (UNII: 151Z7P1317)	
<b>CETYL DIMETHYLBUTYL ETHER</b> (UNII: 7LAB1GXG9G)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	LIME, KIWI	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85563-212-45	4.5 g in 1 CYLINDER; Type 0: Not a Combination Product	07/11/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/11/2019	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85563-212)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85563-212)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85563-212)

Revised: 12/2025

CLEAR SKIN SOLUTIONS, LLC