

**AGE DEFYING MINERAL PROTECTION- titanium dioxide, zinc oxide cream  
MARK SCHWARTZ CLINICAL SKINCARE, INC.**

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**Active Ingredients:**

Titanium Dioxide 8%

Zinc Oxide 3.8%

**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 broken or damaged 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.

**Warnings:**

Keep out of reach of children

**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 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

**Inactive Ingredients:**

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

**Other Information:**

- Protect this product from excessive heat and direct sun
- PA++++

<b>DRUG FACTS (cont)</b>
<p>• <b>Sun Protection Measures:</b> 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:</p> <ul style="list-style-type: none"> <li>• Limit time in the sun, especially from 10 am-2 pm</li> <li>• Wear long-sleeved shirts, pants, hats, and sunglasses</li> </ul>
<p><b>INACTIVE INGREDIENTS:</b> Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate</p>
<p><b>OTHER INFORMATION:</b></p> <ul style="list-style-type: none"> <li>• Protect this product from excessive heat and direct sun</li> <li>• PA++++</li> </ul>
<p>MANUFACTURED FOR: MARK SCHWARTZ CLINICAL SKINCARE INC. NY, NY 10075 Made in USA www.schwartzmdskincare.com</p>

CLINICALSKINCARE



**SUNSCREEN**  
**AGE DEFYING MINERAL PROTECTION**

**CLEAR ZINC & TITANIUM BROAD SPECTRUM SPF 40 WATER RESISTANT (80 MINUTES)**

Net Wt. 1.8 OZ / 53 G

<b>DRUG FACTS</b>	
<b>ACTIVE INGREDIENTS:</b> Titanium Dioxide 8% Zinc Oxide 3.8%	<b>PURPOSE:</b> Sunscreen Sunscreen
<p><b>USES:</b> 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.</p>	
<p><b>WARNINGS:</b> 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. <b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	
<p><b>DIRECTIONS:</b> Apply liberally 15 minutes before sun exposure.</p> <ul style="list-style-type: none"> <li>• Reapply: <ul style="list-style-type: none"> <li>• After 80 minutes of swimming or sweating</li> <li>• Immediately after towel drying</li> <li>• At least every 2 hours</li> </ul> </li> <li>• Children under 6 months: Ask a doctor</li> </ul>	

**AGE DEFYING MINERAL PROTECTION**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85715-202(NDC:58892-202)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	38 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
ALUMINA (UNII: LMI26O6933)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85715-202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/06/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/06/2021	

**Labeler** - MARK SCHWARTZ CLINICAL SKINCARE, INC. (115548819)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85715-202)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85715-202)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85715-202)

Revised: 12/2025

MARK SCHWARTZ CLINICAL SKINCARE, INC.