

**TINTED MINERAL SUNSCREEN 20% ZINC OXIDE- zinc oxide cream**  
**INTEGRATIVE AESTHETICS BOSTON, LLC**

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Zinc Oxide 20%

Sunscreen

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.

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.

Keep out of reach of children

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.

Bismuth Oxychloride, 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, Iron Oxides, Mica, 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

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

**DRUG FACTS (cont)**

**INACTIVE INGREDIENTS:** Bismuth Oxychloride, 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, Iron Oxides, Hydrogren Dimethicone, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexydecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

**OTHER INFORMATION:**

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



**TINTED  
MINERAL SUNSCREEN  
20% ZINC OXIDE**

**SPF 40 BROAD SPECTRUM  
WATER RESISTANT (40 MINS)**

NET WT. 2.1 OZ / 60 G

**DRUG**  
**ACTIVE**  
Zinc Oxide  
**USES:**  
direct measurement of risk of by the **WARNING** use on and as this product is for children contact **DIRECTIONS:**  
• Apply and reapply as directed.  
• Avoid direct sunlight.  
• Children: Use only as directed.  
• Sunburn: Sunburn increases the risk of skin cancer and other skin conditions.  
• Use: Use as directed.

Distributed by  
ClearDermaceuticals, Inc  
Watertown, MA 02472  
www.cleardermaceuticals.com



**TINTED MINERAL SUNSCREEN 20% ZINC OXIDE**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85306-204(NDC:58892-204)
<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
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>MICA</b> (UNII: V8A1AW0880)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>CI 77491</b> (UNII: 1K09F3G675)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85306-204-21	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/04/2024	

**Labeler** - INTEGRATIVE AESTHETICS BOSTON, LLC (053676863)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85306-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85306-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals LTD		958388357	relabel(85306-204)

Revised: 5/2026

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