

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

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**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 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.

**Warnings:**

Keep out of reach of children

**Directions:**

- Apply liberally 15 minutes before sun exposure.
- Reapply: • After 80 minutes of swimming or sweating • Immediately after towel drying • 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:**

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, Triethoxycaprylsilane,

Water

**Other Information:**

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 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

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



<b>TINTED MINERAL SUNSCREEN 20% ZINC OXIDE</b>			
zinc oxide cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85306-204(NDC:58892-204)
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	200 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)	
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)	
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CI 77492</b> (UNII: EX438O2MRT)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CI 77491</b> (UNII: 1K09F3G675)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>CI 77499</b> (UNII: XM0M87F357)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85306-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/12/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/12/2023	

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

**Establishment**

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

**Establishment**

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(85306-204)

Revised: 12/2025

INTEGRATIVE AESTHETICS BOSTON, LLC