

# TINTED MINERAL SUNSCREEN- zinc oxide cream

## Gentlehomme LLC

### DRUG FACTS

**ACTIVE INGREDIENT:**  
ZINC OXIDE 20%

**PURPOSE:**  
SUNSCREEN

**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
  - 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, IRON OXIDES, HYDROGEN DIMETHICONE, 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

**OTHER INFORMATION:**

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN
- MAY STAIN SOME FABRICS.

MANUFACTURED FOR GENTLEHOMME LLC  
5620 WASHINGTON BLVD LOS ANGELES, CA 90016  
SUPPORT@GENTLEHOMME.COM  
WWW.GENTLEHOMME.COM

MADE IN THE USA WITH US AND IMPORTED MATERIALS

    NDC 385366208506



# GENTLEHOMME®

MADE FOR MEN

## TINTED MINERAL SUNSCREEN 20% ZINC OXIDE

**BROAD SPECTRUM SPF 40**

Gentle, moisturizing, lightly tinted mineral sunscreen suitable for all skin types. Virtually vanishes even on darker skin tones. Dries quickly, leaving an elegant, dewy finish. 20% Zinc Oxide calms and soothes; perfect for all skin types.



Net Wt. 2.1 oz /60 g

## TINTED MINERAL SUNSCREEN

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85366-204(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
-----------------	----------

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85366-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/02/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/02/2023	

**Labeler** - Gentlehomme LLC (064612699)

**Establishment**

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85366-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85366-204)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85366-204)

Revised: 12/2025

Gentlehomme LLC