

# THE TINTED MINERAL SUNSCREEN- zinc oxide cream

## The Hue Solution L.L.C.

### DRUG FACTS (continued)

#### INACTIVE INGREDIENTS:

Bismuth Oxochloride, 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, 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.

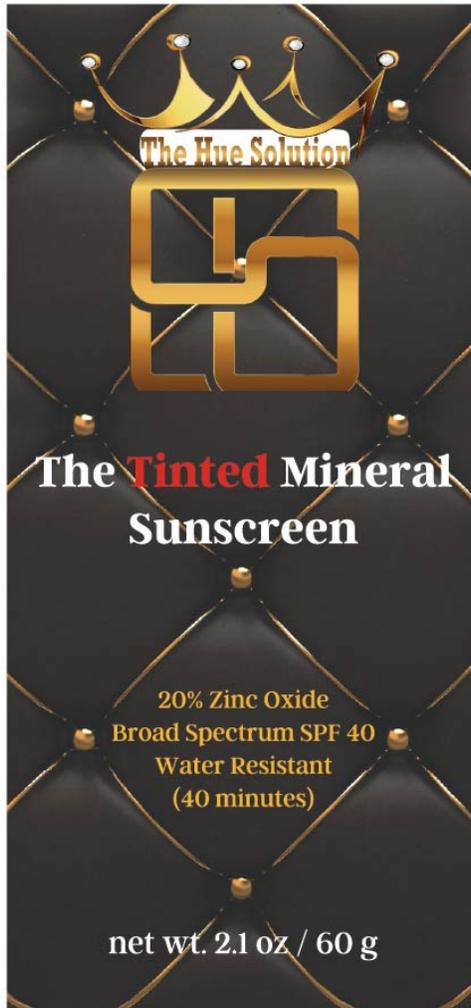
**TREAT YOURSELF LIKE ROYALTY!™**

Professional Skincare for all Hues.™

#### MANUFACTURED FOR:

The Hue Solution™  
Division of the Hue Solution LLC,  
Durham, NC 27706

[www.thehuesolution.com](http://www.thehuesolution.com)



### DRUG FACTS

#### ACTIVE INGREDIENT:

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
  - 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

## THE TINTED MINERAL SUNSCREEN

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85412-204(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
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<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>MICA</b> (UNII: V8A1AW0880)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85412-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/23/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/23/2022	

**Labeler** - The Hue Solution L.L.C. (097144488)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Custom Analytics LLC		144949372	analysis(85412-204)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fragrance Manufacturing Inc		793406000	manufacture(85412-204)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(85412-204)

Revised: 12/2025

The Hue Solution L.L.C.