

NON-TINTED SHEER MATTE MINERAL- titanium dioxide, zinc oxide cream  
NEXTEX CORPORATION

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**DRUG FACTS**  
**ACTIVE INGREDIENTS:**  
Titanium Dioxide 8%  
Zinc Oxide 3.8%  
**PURPOSE:**  
Sunscreen  
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.  
**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 am-2 pm  
• 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-Hydrogen Dimethicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate  
**OTHER INFORMATION:**  
• Protect this product from excessive heat and direct sun  
• May stain some fabrics  
• Cleanse thoroughly at nighttime  
• PA ++++

3634 Long Prairie Road #132, Flower Mound, TX 75022



over

SKINCARE

SOCY

Titanium Dioxide

Zinc Oxide

Vitamins C & E

non-tinted sheer

matte mineral

1.8 oz / 53 g

SUNSCREEN

spf 40 broad spectrum

ACNE SAFE

water resistant (80 mins)

NON-COMEDOGENIC.

NON-TINTED SHEER MATTE MINERAL			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85575-202
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
Inactive Ingredients			

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85575-202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/22/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/22/2020	

**Labeler -** NEXTEX CORPORATION (006596095)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85575-202)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85575-202)

Revised: 5/2025

NEXTEX CORPORATION