

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

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. 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: Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI 44791), 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



Titanium Dioxide
Zinc Oxide
Vitamins C & E

sheer tinted
matte mineral

1.8 oz / 53 g

SUNSCREEN

ACNE SAFE
spf 40 broad spectrum
water resistant (80 mins)
NON-COMEDOGENIC,
GOOD FOR ALL SKIN SHADES.

SHEER TINTED MATTE MINERAL

titanium dioxide, zinc oxide cream

Product Information

Table with 4 columns: Product Type, HUMAN OTC DRUG, Item Code (Source), NDC:85575-203. Row 2: Route of Administration, TOPICAL.

Active Ingredient/Active Moiety

Table with 3 columns: Ingredient Name, Basis of Strength, Strength. Rows for TITANIUM DIOXIDE and ZINC OXIDE.

Inactive Ingredients

Ingredient Name	Strength
ALUMINA (UNII: LMI26O6933)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CI 77492 (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85575-203-50	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(85575-203)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85575-203)