

TINTED MINERAL SUNSCREEN BROAD SPECTRUM SPF 40- titanium dioxide, zinc oxide cream

WECARE FRISCO PLLC

CRUELTY FREE • NON-COMEDOGENIC • PARABEN FREE

DRUG FACTS

ACTIVE INGREDIENTS:

Titanium Dioxide 89%

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 77491), Lauryl PEG/PPG-18/18 Methicone, 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

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MANUFACTURED FOR:

WeCareFrisco

Frisco, TX 75035

3 85747 20350 2

WECARE FRISCO

TINTED MINERAL SUNSCREEN BROAD SPECTRUM SPF 40

BROAD SPECTRUM

WATER RESISTANT

net wt. 1.35 oz (38.1 g)

TINTED MINERAL SUNSCREEN BROAD SPECTRUM SPF 40			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85747-203(NDC:58892-203)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85747-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/16/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/16/2022	

Labeler - WECARE FRISCO PLLC (069012846)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85747-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85747-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85747-203)