

MATTIFYING MINERAL SPF 40 TINTED- titanium dioxide, zinc oxide cream

ELIZA ARAKELIAN

DRUG FACTS

ACTIVE INGREDIENT:

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 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 80 minutes of swimming or sweating
- Immediately after towel drying
- 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 sleeve shirts and 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, Tetrahexydecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun

- May stain some fabrics

- Cleanse thoroughly at nighttime

BLUE ORCHID BEAUTY

14567 BIG BASIN WAY D2, SARATOGA, CA 95070 | 408-867-2001







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ELIZA ARAKELIAN

BY ELIZA ARAKELIAN

SPF 40 BROAD SPECTRUM

WATER RESISTANT

ANTIOXIDANT

MATTIFYING MINERAL

TINTED | NON-FLUORINATED

3 OZ (85.35g)

MATTIFYING MINERAL SPF 40 TINTED

titanium dioxide, zinc oxide cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85555-201(NDC:58892-201)		
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		
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)					

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85555-201-85	85 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/27/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/27/2020	

Labeler - ELIZA ARAKELIAN (125207466)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85555-201)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85555-201)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85555-201)