# MINERAL SUNSCREEN TINTED- titanium dioxide, zinc oxide cream YUMA ACNE CLINIC, L.L.C.

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# **Active Ingredients:**

Titanium Dioxide 8% Zinc Oxide 3.8%

# **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 skin aging caused by the sun.

# **Warnings:**

For external use only. Do not use on broken or damaged 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.

## Warnings:

Keep out of reach of children

#### **Directions:**

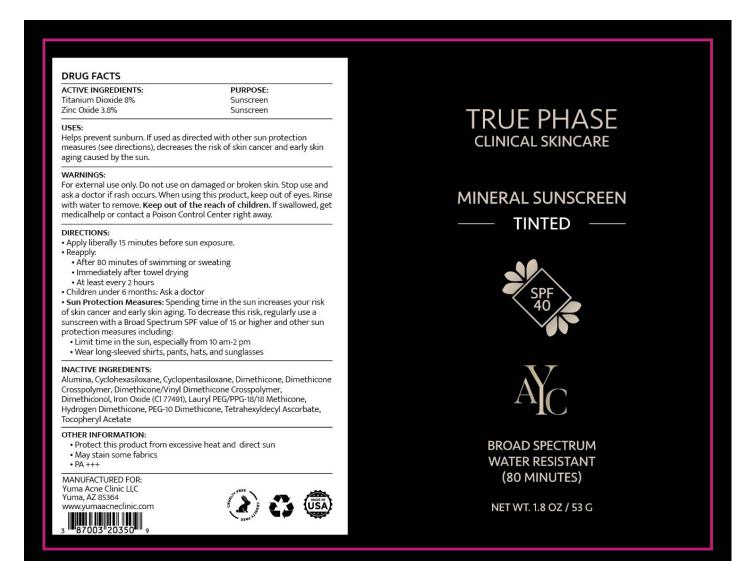
Apply liberally 15 minutes before sun exposure. Use a water-resistant product if swimming or sweating. Reapply at least every 2 hours. Children under 6 months: Ask a doctor. Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, 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 a.m. - 2 p.m. 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 fabircs
- PA +++



### MINERAL SUNSCREEN TINTED

titanium dioxide, zinc oxide cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87003-203(NDC:58892-203)	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	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
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CI 77499 (UNII: XM0M87F357)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CI 77491 (UNII: 1K09F3G675)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CI 77492 (UNII: EX43802MRT)	
DIMETHICONE (UNII: 92RU3N3Y10)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	

l	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:87003- 203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/14/2025	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	08/14/2025		

# Labeler - YUMA ACNE CLINIC, L.L.C. (121029619)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Custom Analytics LLC		144949372	analys is (87003-203)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fragrance Manufacturing Inc.		793406000	manufacture(87003-203)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(87003-203)

Revised: 12/2025 YUMA ACNE CLINIC, L.L.C.