PRIME AND PROTECT- titanium dioxide, zinc oxide cream Shannon Cornelsen-Lewandowski

DRUG FACTS

ACTIVE INGREDIENTS: PURPOSE:
Titanium Dioxide 8% Sunscreen
Zinc Oxide 3.8% 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
- PA +++



MANUFACTURED FOR:

Beauty Blend Studio | Auburn, CA 95603

Silky Texture * Chemical Free * Reef Friendly * Non-Comedogenic

www.beautyblendstudio.com



PRIME + PROTECT



MINERAL SUNSCREEN

*
MAKEUP PRIMER

Broad Spectrum SPF 40 Water Resistant (80 minutes)

SOFTLY TINTED • ACNE SAFE OIL FREE • CHEMICAL FREE

Net Wt. 1.8 oz / 53 g

PRIME AND PROTECT

titanium dioxide, zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85557-203(NDC:58892-203)

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

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:85557- 203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/03/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/03/2021	

Labeler - Shannon Cornelsen-Lewandowski (115198317)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis (85557-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85557-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85557-203)

Revised: 12/2025 Shannon Cornelsen-Lewandowski