

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

DRUG FACTS
ACTIVE INGREDIENTS: Titanium Dioxide 8%, Zinc Oxide 3.8%
PURPOSE: Sunscreen
USES: Helps prevent sunburn.
WARNINGS: For external use only.
DIRECTIONS: Apply liberally 15 minutes before sun exposure.
INACTIVE INGREDIENTS: Alumina, Cyclohexasiloxane, Dimethicone, etc.
OTHER INFORMATION: Protect this product from excessive heat and direct sun.
MANUFACTURED FOR: Beauty Blend Studio | Auburn, CA 95603
www.beautyblendstudio.com

BEAUTY BLEND studio
PRIME + PROTECT
SPF 40
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: EX438O2MRT)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
ALUMINA (UNII: LMI26O6933)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CI 77491 (UNII: 1K09F3G675)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

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)