

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



MANUFACTURED FOR: Beauty Blend Studio | Auburn | CA | 95603

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	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
CI 77499 (UNII: XM0M87F357)				
CI 77491 (UNII: 1K09F3G675)				
CI 77492 (UNII: EX438O2MRT)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
ALUMINA (UNII: LMI26O6933)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85557-203-15	1.5 g in 1 PACKET; 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

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