

TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
The Essential Brazilian Spa LLC



TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85492-203(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
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
CI 77492 (UNII: EX438O2MRT)	
CI 77499 (UNII: XM0M87F357)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CI 77491 (UNII: 1K09F3G675)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85492-203-15	1.5 g in 1 PACKET; Type 0: Not a Combination Product	04/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/17/2023	

Labeler - The Essential Brazilian Spa LLC (106993754)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85492-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85492-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85492-203)

Revised: 12/2025

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