

MINERAL SUNSCREEN TINTED- titanium dioxide, zinc oxide cream
LOTUS SKINCARE AND MAKE-UP STUDIO

Product packaging for Lotus Mineral Sunscreen Tinted. The box features a black background with pink and white text. The front panel displays the Lotus logo, product name, SPF 40, and water resistance. The back panel contains detailed drug facts, ingredients, and usage instructions.

MINERAL SUNSCREEN TINTED			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85558-203(NDC:58892-203)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALUMINA (UNII: LMI26O6933)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CI 77492 (UNII: EX438O2MRT)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85558-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/28/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/28/2022	

**Labeler -** LOTUS SKINCARE AND MAKE-UP STUDIO (049251066)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85558-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85558-203)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85558-203)