

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

Product packaging for Lotus Mineral Sunscreen Non-Tinted. The box features a pink border and contains detailed drug facts, usage instructions, and the Lotus brand logo. The back of the box lists ingredients, warnings, and directions.

MINERAL SUNSCREEN NON-TINTED

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85558-202(NDC:58892-202)
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)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
ALUMINA (UNII: LMI26O6933)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85558-202-50	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(85558-202)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85558-202)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85558-202)