

SPF 101 LIGHTLY TINTED- zinc oxide cream
The Acne Lab LLC



wash tone hydrate moisturize spf



Broad Spectrum SPF 40 · Lightly Tinted
Sunscreen 101™



MANUFACTURED FOR | TheLAB. Skincare | Lafayette | CO | 80026

SPF 101 LIGHTLY TINTED
zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85415-208(NDC:58892-208)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	160 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)				
CERAMIDE 3 (UNII: 4370DF050B)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
CI 77491 (UNII: 1K09F3G675)				
CI 77492 (UNII: EX438O2MRT)				
CI 77499 (UNII: XM0M87F357)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85415-208-15	15 g in 1 PACKET; Type 0: Not a Combination Product	07/15/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020		07/15/2024	

Labeler
- The Acne Lab LLC (070842990)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85415-208)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85415-208)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85415-208)

Revised: 12/2025

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