# SPF 101 NON-TINTED- zinc oxide cream The Acne Lab LLC

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#### DRUG FACTS (continued)

#### · Sun Protection Measures:

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:

- · Limit time in the sun, especially from 10 am - 2 pm · Wear long-sleeved shirts,
- Wear long-sleeved shirts, pants, hats, and sunglasses

#### **INACTIVE INGREDIENTS:**

Capric/Caprylic Triglyceride,
Ceramide 3, Cyclohexasiloxane,
Cyclopentasiloxane, Dimethicone,
Dimethicone Crosspolymer,
Dimethicone/Vinyl Dimethicone
Crosspolymer, Dimethiconol,
Hydrogen Dimethicone, PEG-10
Dimethicone, Polyhydroxystearic
Acid, Tetrahexyldecyl Ascorbate,
Tocopheryl Acetate, Vinyl
Dimethicone/Methicone
Silsesquioxane Crosspolymer

#### OTHER INFORMATION:

· Protect this product from excessive heat and direct sun

MANUFACTURED FOR: TheLAB. Skincare IOI E Chester St Lafayette, CO 80026 303-600-8361





wash tone hydrate moisturize

spf



#### **DRUG FACTS**

ACTIVE INGREDIENT: PURPOSE: Zinc Oxide 16% Sunscreen

#### USES:

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.

#### WARNINGS:

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

#### DIRECTIONS:

Apply liberally 15 minutes before sun exposure

- · Use a water resistant product if swimming or sweating
- · Reapply at least every 2 hours
- · Children under 6 months: Ask a doctor



FOR BEST RESULTS WATCH THE TUTORIAL

Strength

An essential daily skincare step for all skin types. This ceramide-rich mineral sunscreen protects against sun damage and moisture loss.

## **SPF 101 NON-TINTED**

zinc oxide cream

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85415-226(NDC:58892-226)

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

l	Ingredient Name	<b>Basis of Strength</b>	Strength
l	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

## **Inactive Ingredients**

Ingredient Name	
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CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CYCLOPENTASILOXANE (UNII: 0THT5PCIOR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:85415- 226-50	50 g in 1 BOTTLE, PUMP; 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 (85415-226)	

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fragrance Manufacturing INnc.		793406000	manufacture(85415-226)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(85415-226)

Revised: 12/2025 The Acne Lab LLC