

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

-----



wash   tone   hydrate   moisturize   spf



Broad Spectrum SPF 40  
Sunscreen 101™



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

|                            |  |  |
|----------------------------|--|--|
| <b>SPF 101 NON-TINTED</b>  |  |  |
| zinc oxide cream           |  |  |
| <b>Product Information</b> |  |  |

|                                                                               |                                          |                                                     |                              |                    |
|-------------------------------------------------------------------------------|------------------------------------------|-----------------------------------------------------|------------------------------|--------------------|
| Product Type                                                                  | HUMAN OTC DRUG                           | Item Code (Source)                                  | NDC:85415-226(NDC:58892-226) |                    |
| 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                     |                    |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)                                         |                                          |                                                     |                              |                    |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)                                   |                                          |                                                     |                              |                    |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) |                                          |                                                     |                              |                    |
| DIMETHICONE (UNII: 92RU3N3Y1O)                                                |                                          |                                                     |                              |                    |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)                                    |                                          |                                                     |                              |                    |
| CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)                               |                                          |                                                     |                              |                    |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                                   |                                          |                                                     |                              |                    |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA)                                          |                                          |                                                     |                              |                    |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)                          |                                          |                                                     |                              |                    |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)                              |                                          |                                                     |                              |                    |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)                               |                                          |                                                     |                              |                    |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)                                  |                                          |                                                     |                              |                    |
| CERAMIDE 3 (UNII: 4370DF050B)                                                 |                                          |                                                     |                              |                    |
| VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)    |                                          |                                                     |                              |                    |
|                                                                               |                                          |                                                     |                              |                    |
| Packaging                                                                     |                                          |                                                     |                              |                    |
| #                                                                             | Item Code                                | Package Description                                 | Marketing Start Date         | Marketing End Date |
| 1                                                                             | NDC:85415-226-15                         | 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(85415-226) |

**Establishment**

| Name                         | Address | ID/FEI    | Business Operations    |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. |         | 793406000 | manufacture(85415-226) |

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

Revised: 12/2025

The Acne Lab LLC