

**PRIME AND PROTECT DEWY- zinc oxide cream**  
**Kalon Skin Studio, LLC**



**PRIME & PROTECT**  
**DEWY**

**TINTED MINERAL SUNSCREEN**  
**20% zinc oxide**

**broad spectrum spf 40**  
**water resistant (40 minutes)**

**STEP 7 | AM**

**net wt. 2.1 oz /60 g**

**DRUG FACTS**

**ACTIVE INGREDIENT:**  
 Zinc Oxide 20%

**USES:** Helps prevent sunburn. If used measures (see Directions), decreases the by the sun.

**WARNINGS:** For external use only. Do use and ask a doctor if rash occurs. Wt Rinse with water to remove. Keep out medical help or contact a Poison Contr

**DIRECTIONS:**

- Apply liberally 15 minutes before sun e
- Reapply:
  - After 40 minutes of swimming or s
  - Immediately after towel drying
  - At least every 2 hours
- Children under 6 months: Ask a docto
- Sun Protection Measures: Spending tir cancer and early skin aging. To decrease broad spectrum SPF value of 15 or hig including:
  - Limit time in the sun, especially fro
  - Wear long-sleeved shirts, pants, hat

**INACTIVE INGREDIENTS:** Bismuth Caprylhydroxamic Acid, Caprylyl Glyc Cyclohexasiloxane, Cyclopentasiloxane, I Dimethicone/Vinyl Dimethicone Crossp Glycerin, Iron Oxides, Hydrogren Di PEG-10 Dimethicone, PEG-30 Dipolyhy Polyhydroxystearic Acid, Polysorbate 20 Tetrahexyldecyl Ascorbate, Tocopheryl / lysilane, Water

**OTHER INFORMATION:**

- Protect this product from excessiv
- May stain some fabrics.



Vegan



Reef friendly

Exclusively Mfg. for Kalon Skin Studio, LLC  
 2743 Smith Ranch Rd. Suite 804  
 Pearland, TX 77584  
[www.kalonskinstudio.com](http://www.kalonskinstudio.com)

**PRIME AND PROTECT DEWY**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85363-204(NDC:58892-204)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>MICA</b> (UNII: V8A1AW0880)
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>PEG-30 DIPOLYHYDROXYSTEARATE</b> (UNII: 9713Q0S7FO)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>TRIETHANOLAMINE</b> (UNII: 9O3K93S3TK)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>STEARYL DIMETHICONE (400 MPA.S AT 50C)</b> (UNII: R327X197HY)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85363-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/25/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/25/2023	

**Labeler** - Kalon Skin Studio, LLC (118331568)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Custom Analytics LLC		144949372	analysis(85363-204)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fragrance Manufacturing INC		793406000	manufacture(85363-204)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fallien Cosmeceuticals Ltd.		958388357	relabel(85363-204)

Revised: 12/2025

Kalon Skin Studio, LLC