

**MINERAL TINTED SPF40 WITH CERAMIDES- zinc oxide cream**  
**Spalina LLC.**

**DRUG FACTS**

**ACTIVE INGREDIENTS:**  
 Zinc Oxide 20%

**PURPOSE:**  
 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
- Reapply:
  - After 40 minutes of swimming or sweating
  - Immediately after towel drying
  - Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- 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 sleeve shirts and hats and sunglasses

**INACTIVE INGREDIENTS:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylsilane, Water

**OTHER INFORMATION:**

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

Made for: Spalina Inc., Irvine CA 92620

spelaskincareandwaxing.com | customer service: 949-500-7785



**SPALINA**  
 SKINCARE BY SPELA HERNANDEZ

**Hydrating Mineral  
 Zinc Oxide SPF 40**  
 non-tinted

non-comedogenic • safe for sensitive skin  
 chemical sunscreen free  
 cruelty free • reef friendly



**SPF 40** broad spectrum  
 water resistant (40 mins)

4 oz | 113 g

**MINERAL TINTED SPF40 WITH CERAMIDES**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85360-208(NDC:58892-208)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)	

<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>CI 77491</b> (UNII: 1K09F3G675)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>CI 77499</b> (UNII: XM0M87F357)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>CERAMIDE 3</b> (UNII: 4370DF050B)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85360-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/04/2020	

**Labeler** - Spalina LLC. (105212651)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85360-208)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85360-208)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85360-208)