

# SHIELD AND PROTECT TINTED- zinc oxide cream

## TRILGY LABORATORIES, LLC

DRUG FACTS	
<b>ACTIVE INGREDIENT:</b> Zinc Oxide 16%	<b>PURPOSE:</b> Sunscreen
<b>USES:</b> 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.	
<b>WARNINGS:</b> 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. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>DIRECTIONS:</b> <ul style="list-style-type: none"> <li>Apply liberally 15 minutes before sun exposure</li> <li>Use a water resistant product if swimming or sweating.</li> <li>Reapply at least every 2 hours</li> <li>Children under 6 months: Ask a doctor</li> <li><b>Sun Protection Measures:</b> 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: <ul style="list-style-type: none"> <li>Limit time in the sun, especially from 10 am - 2 pm</li> <li>Wear long-sleeved shirts, pants, hats, and sunglasses</li> </ul> </li> </ul>	
<b>INACTIVE INGREDIENTS:</b> Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer	
<b>OTHER INFORMATION:</b> <ul style="list-style-type: none"> <li>Protect this product from excessive heat and direct sun</li> <li>May stain some fabrics.</li> </ul>	



Vitamin C · Ceramides · Antioxidants

Manufactured for: Trilog Laboratories  
Fort Myers, FL 33913 USA  
www.idskinpro.com  
239-939-5454



Broad Spectrum SPF 40

Net Wt. 1.75 oz / 50 g

## SHIELD AND PROTECT TINTED

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69487-208(NDC:58892-208)
<b>Route of Administration</b>	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
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<b>CI 77499</b> (UNII: XM0M87F357)
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)
<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)
<b>CYCLOHEXASILOXANE</b> (UNII: XHK3U310BA)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>DIMETHICONE CROSSPOLYMER</b> (UNII: UF7620L1W6)
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)
<b>CERAMIDE 3</b> (UNII: 4370DF050B)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>CI 77492</b> (UNII: EX438O2MRT)
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)
<b>CYCLOPENTASILOXANE</b> (UNII: 0THT5PCI0R)
<b>DIMETHICONOL (2000 CST)</b> (UNII: T74O12AN6Y)
<b>CI 77491</b> (UNII: 1K09F3G675)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69487-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/20/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/20/2025	

**Labeler** - TRILOGY LABORATORIES, LLC (079652958)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(69487-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(69487-208)

### Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(69487-208)