

SHIELD AND PROTECT- zinc oxide cream
TRILOGY LABORATORIES, LLC

DRUG FACTS	
ACTIVE INGREDIENT: Zinc Oxide 16%	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: <ul style="list-style-type: none"> 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 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: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 am - 2 pm 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: <ul style="list-style-type: none"> Protect this product from excessive heat and direct sun 	



Vitamin C · Ceramides · Antioxidants

Manufactured for: Trilogy 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			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69487-226(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		

DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
DIMETHICONE (UNII: 92RU3N3Y1O)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
CERAMIDE 3 (UNII: 4370DF050B)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69487-226-50	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(69487-226)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(69487-226)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(69487-226)