

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: • 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: • 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: • 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

3 69487 22650 2

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 |
| 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) | |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| CERAMIDE 3 (UNII: 4370DF050B) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U) | |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |

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 |
|-----------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing INC | | 793406000 | manufacture(69487-226) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(69487-226) |

Revised: 6/2025

TRILOGY LABORATORIES, LLC