

SUNSCREEN- zinc oxide, titanium dioxide lotion giggle

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

giggle sunscreen for early 2016

Active Ingredients

| Active Ingredients | Purpose |
|------------------------|-----------|
| Titanium Dioxide: 7.0% | Sunscreen |
| Zinc Oxide: 9.0% | Sunscreen |

Warnings

For external use only.

When using this product - avoid damaged/broken skin - avoid contact with eyes. Rinse well with cool water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Directions Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming/sweating, immediately after towel drying, and at least every 2 hours. Children under 6 months: ask a doctor.

Sun Protection Measures: Spending time in sun increases risk of skin cancer and early skin aging. To decrease risk, use sunscreen with Broad Spectrum SPF 15 or higher and limit time in sun especially 10am-2pm, and wear long-sleeved shirts, pants, hats, sunglasses.

Inactive Ingredients

Inactive Ingredients Water, Coconut Alkanes, Caprylic/Capric Triglyceride, Isoamyl Laurate, Aloe Barbadensis Leaf Juice ⁽¹⁾, Crambe Abyssinica Seed Oil, Glycerin, Polyglyceryl-2 Sesquioleate, Polyglyceryl-3 Ricinoleate, Polyhydroxystearic Acid, Tocopheryl Acetate, Butyrospermum Parkii (Shea) Butter, Coco-Caprylate/Caprates, Stearic Acid, Magnesium Sulfate, Sodium Chloride, Sorbitan Sesquioleate, Alumina, Phenoxyethanol, Benzyl Alcohol, Brassica Campestris (Rapeseed) Oil, Camilla Sinesis Leaf Extract ⁽¹⁾, Echinacea Purpurea Extract, Ginkgo Biloba Leaf Extract ⁽¹⁾, Polygonum Aviculare Extract ⁽¹⁾ Certified Organic Ingredient

Questions? Visit giggle.com or call 800-495-8577.



SUNSCREEN

zinc oxide, titanium dioxide lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70306-5357 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 9 g in 100 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 7 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| COCONUT ALKANES (UNII: 1E5KJY107T) | |
| ECHINACEA PURPUREA (UNII: QI7G114Y98) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| POLYGLYCERYL-2 SESQUISO STEARATE (UNII: LA272Q68GQ) | |
| POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W) | |
| CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL (UNII: 0QW9S92J3K) | |

| | |
|--|--|
| POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| GINKGO (UNII: 19FUJ2C58T) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| WATER (UNII: 059QF0KO0R) | |
| ISOAMYL LAURATE (UNII: M1SLX00M3M) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626) | |
| COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H) | |
| MAGNESIUM SULFATE (UNII: DE08037SAB) | |
| SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |

Product Characteristics

| | | | |
|----------|-------------------|--------------|--|
| Color | white (Off-white) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70306-5357-4 | 118 mL in 1 TUBE; Type 0: Not a Combination Product | 03/15/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 03/15/2016 | |

Labeler - giggle (194045402)