SUNSCREEN- titanium dioxide 6.8% liquid Baxter of California, LLC

Active Ingredients

Octisalate 3.2%

Octocrylene 6%

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 skin aging caused by the sun

Warnings

For external use only

Do not use

on damamged skin or broken skin

When using this product

Keep out of eyes.

Rinse with water to remove

Stop use and ask doctor if

rash occurs

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- 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 10am-2pm
- wear long sleeved shirts, pants, hats, and sunglasses
- o children under 6 months of age: Ask a doctor

Other information

protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, undecane, dimethicone, glycerin, tridecane, polyglyceryl-4 isostearate, pentylene glycol, cetyl PEG/PPG-10/1, hexyl laurate, magnesium sulfate, disteardimonium hectorite, trihydroxystearin, cellulose gum, aluminum hydroxide, disodium stearoyl glutamate, acetylated glycol stearate, acrylates copolymer, ethylhexylglyceerin; may contain: titanium dioxide, iron oxides

Questions or Comments?

1-877-900-6700 Monday - Friday (9 a.m. - 5 p.m. EST)



Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:84203-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) TITANIUM DIOXIDE 0.068 g in 1 mL

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| WATER (UNII: 059QF0KO0R) | |
| UNDECANE (UNII: JV0QT00NUE) | |
| DIMETHICONE (UNII: 92RU3N3Y10) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TRIDECANE (UNII: A3LZ F0L939) | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | |
| PENTYLENE GLYCOL (UNII: 50C1307PZG) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| TRIHYDROXYSTEARIN (UNII: 06YD7896S3) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M) | |
| ACETYLATED GLYCOL STEARATE (UNII: K71M6R9N7E) | |

Packaging

| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
|------------------------|--|-------------------------|-----------------------|
| 1 NDC:84203-001- 01 | 30 mL in 1 TUBE; Type 0: Not a Combination Product | 03/25/2024 | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|--------------------|---------------------------------|-----------------|---------------|
| Category | Citation | Date | Date |
| OTC Monograph Drug | M020 | 03/25/2024 | |

Labeler - Baxter of California, LLC (031183172)

| Establishment | | | | | |
|--------------------------------|---------|-----------|----------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Dimensional Merchandising, Inc | | 076693183 | manufacture(84203-001) | | |

Revised: 3/2024 Baxter of California, LLC