CREAM- titanium dioxide, zinc oxide lotion OXYGEN DEVELOPMENT, LLC

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.

BB TINTED TREATMENT PRIMER BROAD SPECTRUM SPF 30 SUNSCREEN - FAIR

Active Ingredients

Titanium Dioxide 4.55% Zinc Oxide 3.5%

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

Stop use and ask doctor if rash occurs.

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

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

Directions

- Shake before use.
- Apply liberally 15 minutes before sun exposure.
- Use a water-resistant sunscreen of 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 our 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 a.m.- 2p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

Other information

- Protect the product in this container from excessive heat and direct sunlight.
- You may report a serious adverse reaction to: tarte c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, NJ 08536-0222.

Inactive Ingredients

Cyclopentasiloxane, Isododecane, Mica, Polysilicone-11, Polymethylsilsesquioxane, Hexyl Laurate, PEG-10 Dimethicone, Polyglyceryl-4 Isostearate, Stearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Alumina, Triethoxycaprylylsilane, Dipalmitoyl Hydroxyproline, Diamond Powder, Iron Oxides.

Primary Package (Inner)

tarte™

B

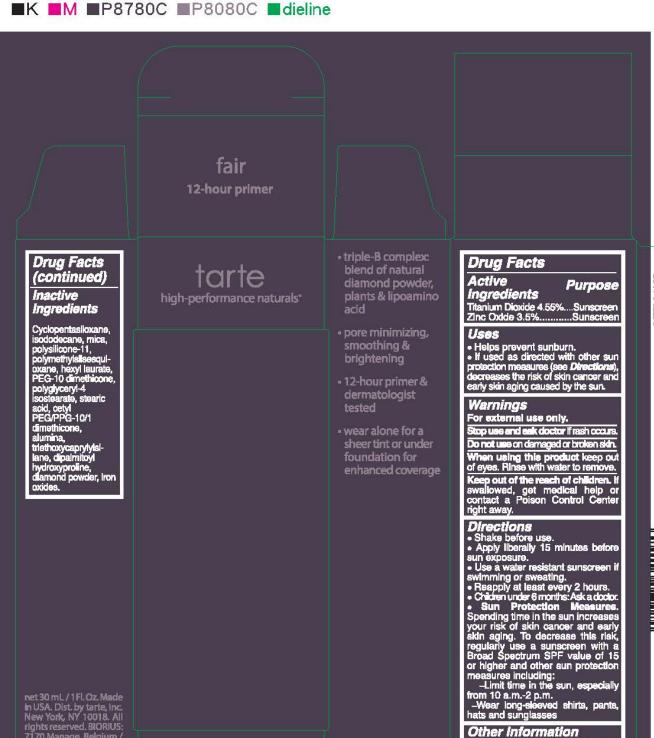
BB tinted treatment primer Broad Spectrum SPF 30 Sunscreen



Secondary Package (Outer)

30ml, 61354-051-01





net 30 mL / 1FLOz Made in USA. Dist. by tarte, Inc. New York, NY 10018. All rights reserved. BIORIUS 7170 Manage, Belgium / London WC2H 9JQ, UK.

#claypowered

@tartecosmetics

www.tarte.com

BB tinted treatment primer **Broad Spectrum** SPF 30 Sunscreen

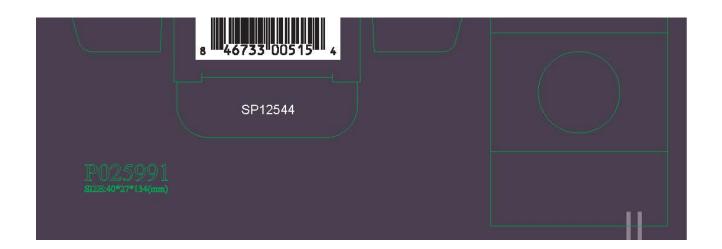


- Other Information
 Protect the product in this container from excessive heat and direct sunlight.
 You may report a serious adverse reaction to: tarte c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, NJ 08538-0222 OR536-0222



FG01187-01





CREAM

titanium dioxide, zinc oxide lotion

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61354-051 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------|----------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 3.5 mg in 100 mg | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 4.55 mg in 100 mg | |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK) | | | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | | | |
| ISODODECANE (UNII: A8289P68Y2) | | | |
| MICA (UNII: V8A1AW0880) | | | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | | | |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | | | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCIOR) | | | |

| Packaging | | | | |
|-----------|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:61354-051- 02 | 1 in 1 CARTON | 02/22/2021 | |
| 1 | | 30 mg in 1 TUBE; Type 0: Not a Combination Product | | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part352 | 02/22/2021 | | |
| | | | | |

Labeler - OXYGEN DEVELOPMENT, LLC (137098492)

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| OXYGEN DEVELOPMENT, LLC | | 137098492 | manufacture(61354-051) | |

Revised: 2/2023 OXYGEN DEVELOPMENT, LLC