CREAM- zinc oxide, titanium dioxide 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.

SKIN TREAT TINTED MOISTURIZER BROAD SPECTRUM SPF 20 SUNSCREEN

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 aging caused by the sun.

Warnings

For external use only. Stop use and ask a doctor if rash occurs. Do not use on damage or broken skin.

When using this product

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 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 the 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. - 2 p.m.

- Wear long-sleeved shirts, pants, hats, and sunglasses

Other information

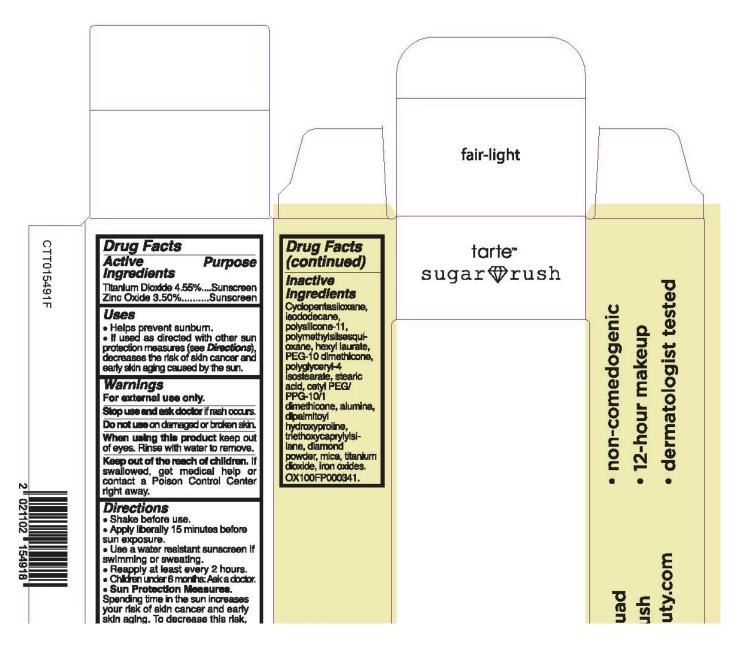
Protect the product in this container from excessive heat and direct sunlight.

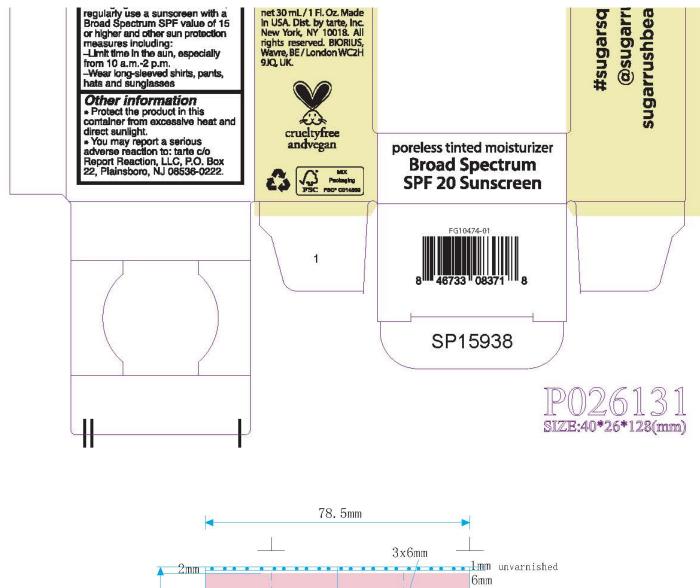
You may report a serious adverse reaction to: tarte c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, NJ 08536-0222

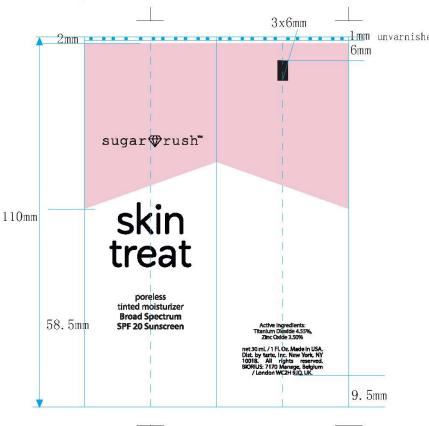
Inactive Ingredients

Cyclopentasiloxane, Isododecane, 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

Package Label







320469(2)|树脂印(Offset printing):black white(white offset underneath 705c)

| black | |
|--|-------|
| white(white offset underneath | 705c) |
| black | |
| 705c | |
| die line,does not print (边框,不印刷) •••• unvarnished area | |

| 产品编号 P/N | 320469(2) | 制作人 Processed by | Mary | 确认签字 Approval | |
|-----------------------|-----------|---------------------|------------|------------------|--|
| 打样/订单号 Sample/PO # | | 制作日期 Date | 2020/07/31 | 日期 Date | |
| 附加说明 Remarks | | | | | |

| CREAM | |
|-------|--|
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zinc oxide, titanium dioxide lotion

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61354-081 |
| Route of Administration | TOPICAL | | |
| | | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------|----------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 4.54 mg in 100 mg | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 3.49 mg in 100 mg | |
| | | | |
| Inactive Ingredients | | | |
| · · · · · · · · · · · · · · · · · · · | | | |

| Ingredient Name | Strength |
|--|-----------------------|
| DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) | 55.74 mg in 100 mg |
| ISODODECANE (UNII: A8289P68Y2) | 10.69 mg in 100 mg |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | 4.68 mg in 100 mg |

| HEXYL LAURATE (UNII: 4CG9F9W01Q) | | | | 1.76 mg in 100 mg |
|---|----------------------|---|-------------------------|-----------------------|
| POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69) | | | | 3.19 mg in 100 mg |
| PO | LYGLYCERYL-4 | ISOSTEARATE (UNII: 820DPX33S7) | | 1.5 mg in 100 mg |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | | | | 1.65 mg in 100 mg |
| | | | | |
| Pa | ackaging | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | | | | |
| | NDC:61354-081- 01 | 1 in 1 CARTON | 08/25/2022 | |
| | 01 | 1 in 1 CARTON 100 mg in 1 TUBE; Type 0: Not a Combination Product | 08/25/2022 | |
| 1 | 01 | 100 mg in 1 TUBE; Type 0: Not a Combination | 08/25/2022 | |
| 1 | 01 | 100 mg in 1 TUBE; Type 0: Not a Combination | 08/25/2022 | |
| 1 | 01 | 100 mg in 1 TUBE; Type 0: Not a Combination Product | 08/25/2022 | Marketing End Date |

Labeler - Oxygen Development LLC (137098492)

| Establishment | | | | |
|------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Oxygen Development LLC | | 137098492 | manufacture(61354-081) | |

Revised: 8/2022

Oxygen Development LLC