

**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

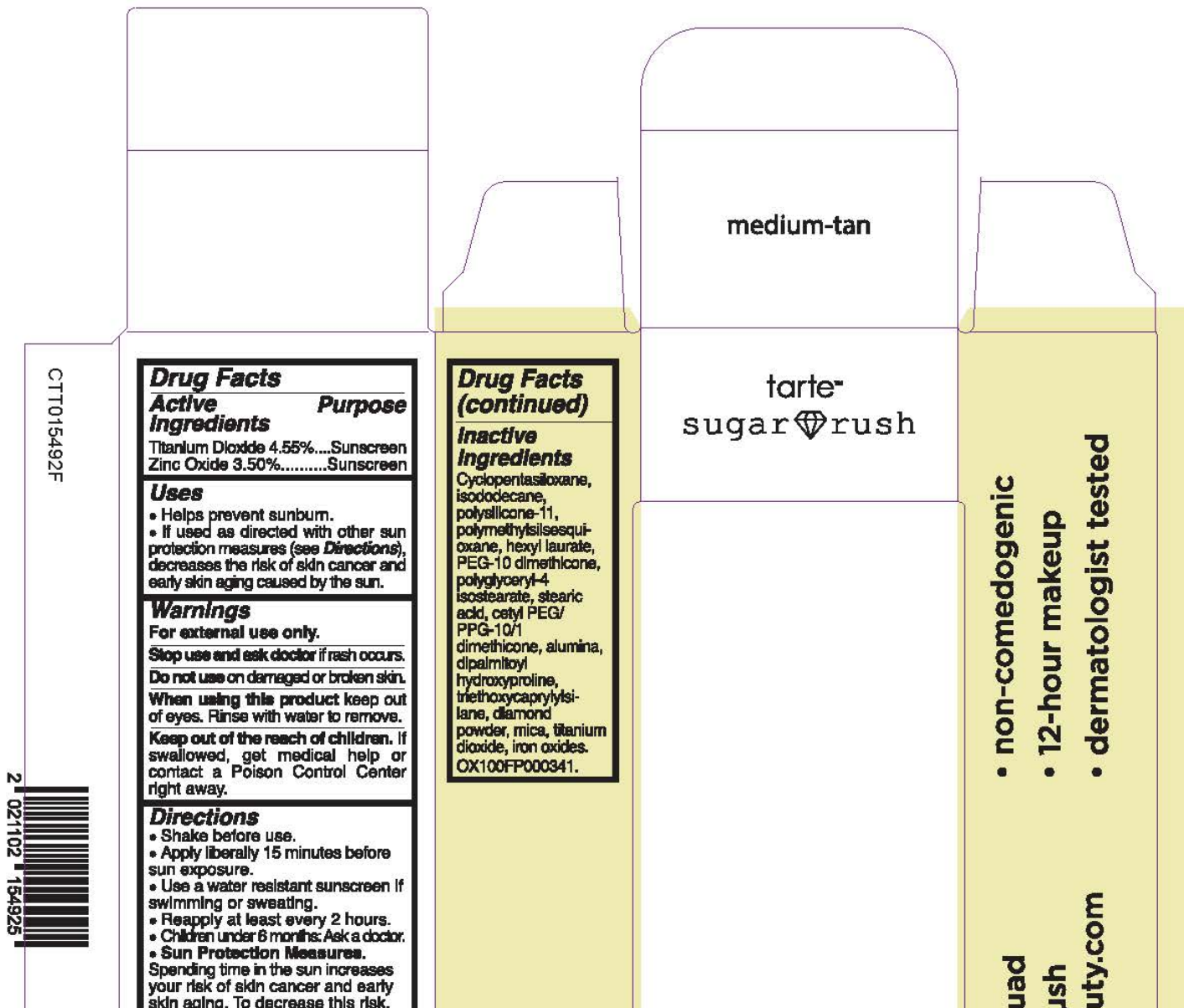
Protect the product in this container from excessive heat and direct sunlight.

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



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.

net 30 mL / 1 Fl. Oz. Made in USA. Dist. by tarte, Inc. New York, NY 10018. All rights reserved. BIORIUS, Wavre, BE / London WC2H 9JQ, UK.



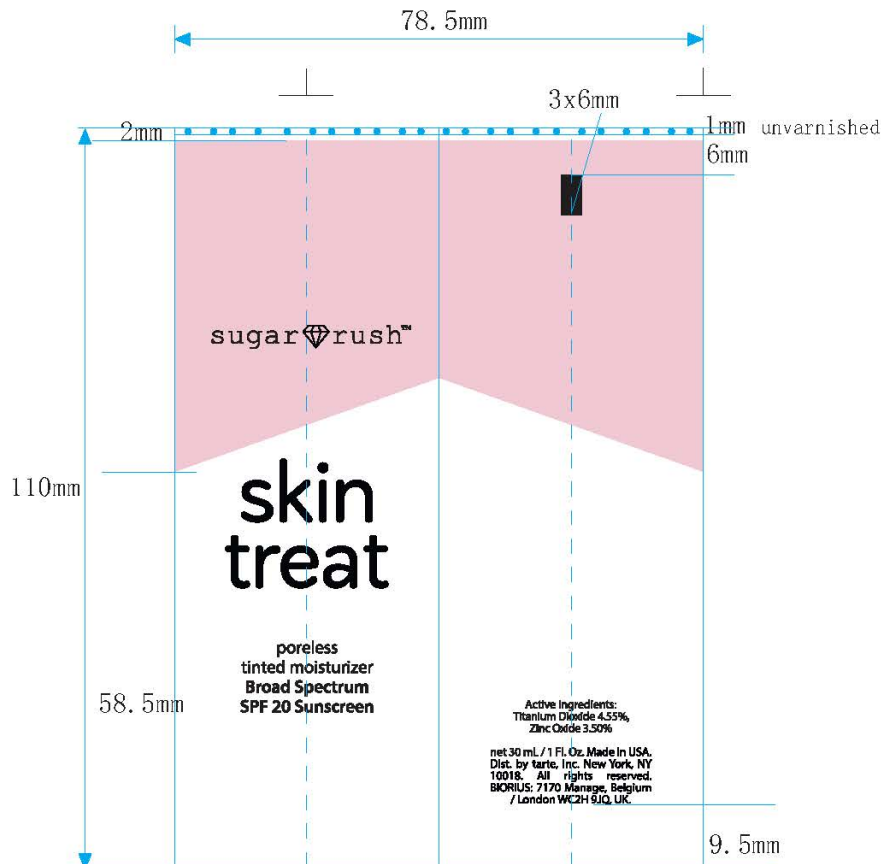
#sugarsq  
 @sugarr  
 sugarrushbea

poreless tinted moisturizer  
**Broad Spectrum  
 SPF 20 Sunscreen**



SP15939

P026131  
 SIZE:40\*26\*128(mm)



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

丝网印(Silkscreen) : black 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

zinc oxide, titanium dioxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-082
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.54 mg in 100 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.49 mg in 100 mg

### Inactive Ingredients

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

<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	1.76 mg in 100 mg
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	3.19 mg in 100 mg
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	1.5 mg in 100 mg
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	1.65 mg in 100 mg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-082-01	1 in 1 CARTON	08/26/2022	
1		100 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	M020	08/26/2022	

**Labeler** - Oxygen Development LLC (137098492)

### Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-082)

Revised: 8/2022

Oxygen Development LLC