# 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.

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# SUGAR RUSH SKIN TREAT PORELESS 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.

## 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

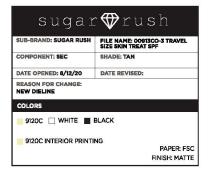
Protect the product in this container from excessive heat and direct sunlight.

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

## **Inactive Ingredients**

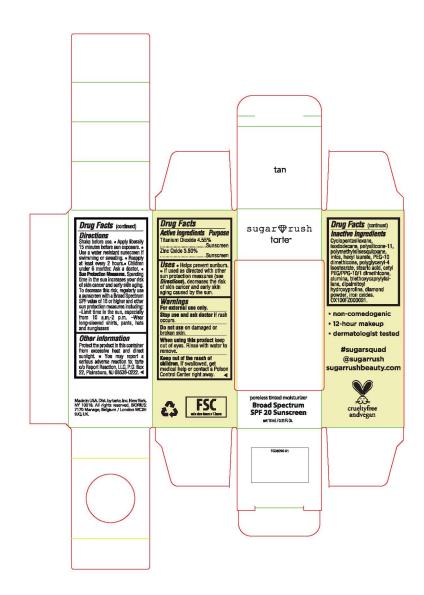
Cyclopentasiloxane, Isododecane, Polysilicone-11, Polymethylsilsesquioxane, Hexyl Laurate, PEG-10 Dimethicone, Polyglyceryl-4 Isostearate, Stearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Alumina, Triethoxycaprylylsilane, Dipalmitoyl Hydroxyproline, Diamond Powder

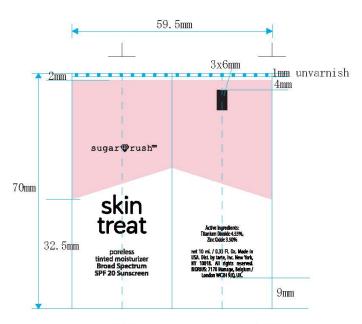
Package Label - Principal Display Panel



# P025709

SIZE:86\*33\*33(mm)





320479(3) 丝网印(Silkscreen): black 705c 树脂印(Offset printing): black white(white offset underneath 705c)



产品编号 P/N	320479(3)	制作人 Processed by	Mary	确认签字 Approval	
打样/订单号 Sample/PO#		制作日期 Date	2020/08/20	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:61354-057	
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		
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	1.65 mg in 100 mg		
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	4.68 mg in 100 mg		
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	3.19 mg in 100 mg		
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	1.5 mg in 100 mg		
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	55.74 mg in 100 mg		
HEXYL LAURATE (UNII: 4CG9F9W01Q)	1.76 mg in 100 mg		
ISODODECANE (UNII: A8289P68Y2)	10.69 mg in 100 mg		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61354-057- 01	1 in 1 CARTON	05/04/2022		
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	part352	05/04/2022	

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Oxygen Development LLC		137098492	manufacture(61354-057)		

Revised: 5/2022 Oxygen Development LLC