# 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.

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# LIGHT-SKIN TREAT BLURRING SKIN TINT 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 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.

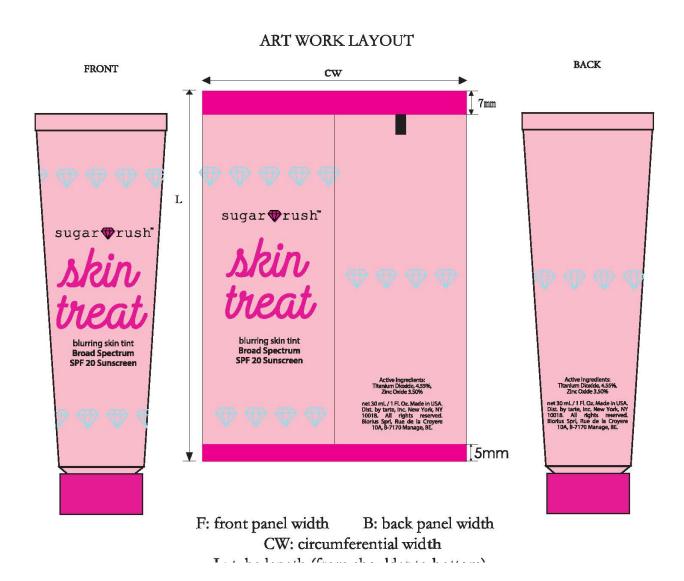
#### Other information

- 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)**



L: tupe length (from shoulder to bottom)

Eyemark (3 × 6mm):mark for end sealing

Upper edge(7mm): space for end sealing

Bottom edge(5mm): non-printing space

Dia 25×L110 shadow area:

F/B 39.25mm printing area CW 78.5mm

L(changeable)
110 mm

Attention of arwork: Use CorelDraw,Freehand or Illustrator, and do not compress or change the file's type, then outline the file and send us.

SUGAT TUSh

SUB-BRAND: SUGAR RUSH FILE NAME: SKIN TREAT

COMPONENT: PRIMARY SHADE: SPF

DATE OPENED: 5/4/18 DATE REVISED: 10/19/18

REASON FOR CHANGE:
PID REVISED

COLORS

BLACK 182C
225C 304C

## **Secondary Package (Outer)**

30ml, 61354-51-14



#### Drug Facts (continued)

Inactive Ingredients

cyclopentasiloxane, sododecane, polysilicone-11, polymethylsitesequi-oxane, hexyl laurale, PEG-10 dimethicone, polysilycani-4. PEG-10 dimethicone, polyglyceryl-isostearate, mica, stoaric acid, cetyl PEG/PPG-10/1 dimethicone, alumina, triechoxycapnyty's-iane, dipalmitoyl hydroxynoline. hydroxyproline, diamond powder, iron oxides. OX100FZ000081

LOT: 0H53 EXP: 05/21

net 30 mL / 1 FL Oz. Made in USA. Dist. by tarte, Inc. NY 10018. All rights reserved. Bior 10 A. P. 2170 de la Croyere 10A, B-7170 Manage, BE.







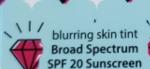
sugar rush tarte-

skin treat



asugarrush













11/



Purpose

## Uses

Helps prevent sunburn.
 If used as directed with other sunprotection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

## Warnings

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- 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

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## **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)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-051- 14	1 in 1 CARTON	02/23/2021	
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	02/23/2021	

# Labeler - OXYGEN DEVELOPMENT, LLC (137098492)

## **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
OXYGEN DEVELOPMENT, LLC		137098492	manufacture(61354-051)

Revised: 2/2023 OXYGEN DEVELOPMENT, LLC