

**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-MEDIUM- 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.

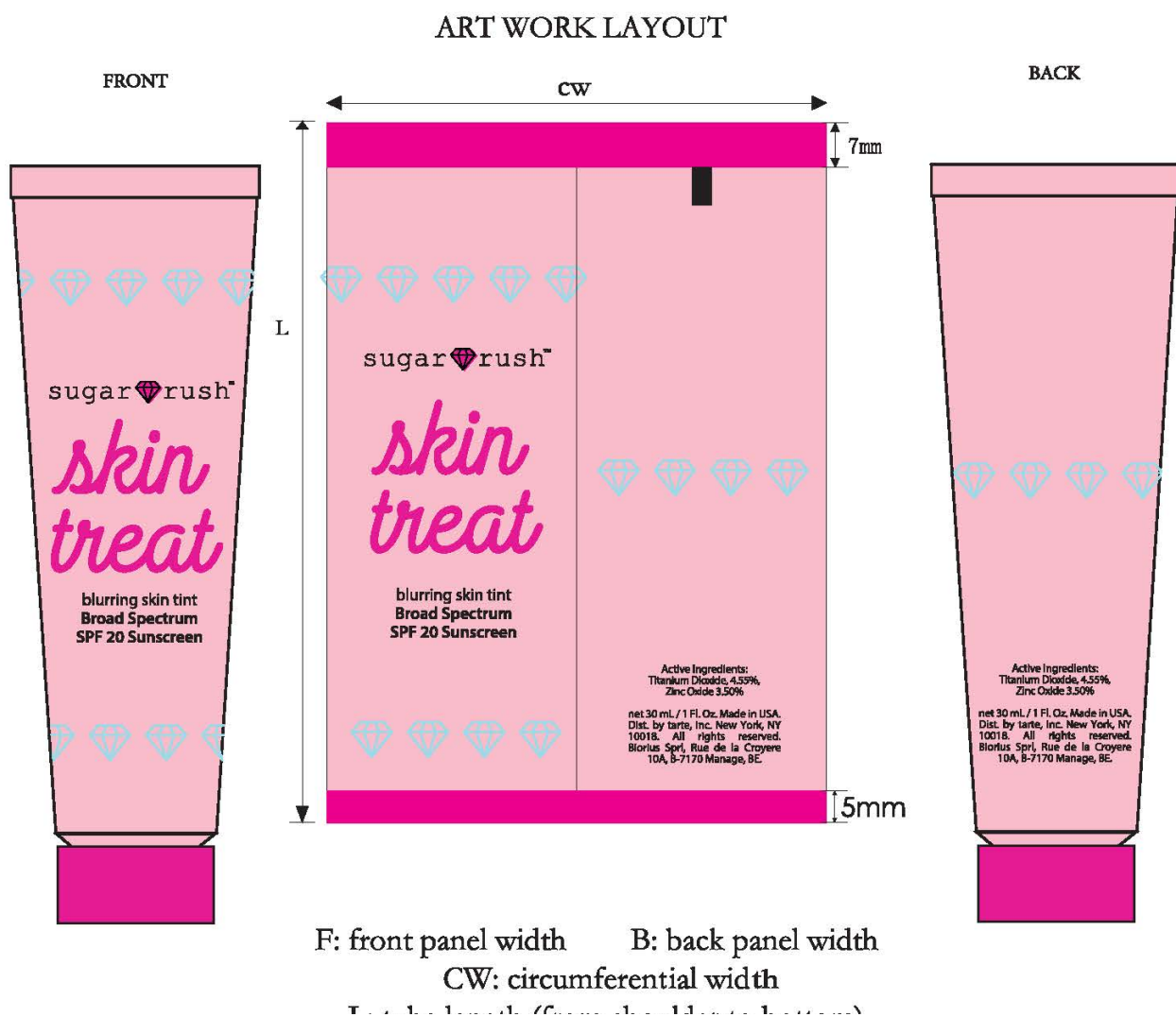
### Other information

- 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: tube 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

	F/B	CW	L(changeable)
Dia 25×L110	39.25mm	78.5mm	110mm
shadow area:	printing area		


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

sugar  rush	
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	
<div> <div>■</div> BLACK           <div>■</div> 182C         </div> <div> <div>■</div> 225C           <div>■</div> 304C         </div>	

## Secondary Package (Outer)

30ml, 61354-051-18

light-medium

sugar  rush  
tarte™

skin  
treat

@sugarrush  
sugarrushbeauty.com

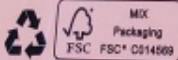
**Drug Facts**  
(continued)

**Inactive Ingredients**

Cyclopentasiloxane, isododecane, polysilicone-11, polymethylsilsesquioxane, mica, hexyl laurate, PEG-10 dimethicone, polyglyceryl-4 isostearate, stearic acid, cetyl PEG/PPG-10/1 dimethicone, alumina, triethoxycaprylylsilane, dipalmitoyl hydroxyproline, diamond powder, iron oxides.  
OX100FZ000091.

LOT OH21  
EXP: 02/21

net 30 mL / 1 FL Oz. Made in USA. Dist. by tarte, Inc. NY 10018. All rights reserved. Biorius Sprl, Rue de la Croeyere 10A, B-7170 Manage, BE.



blurring skin tint  
Broad Spectrum  
SPF 20 Sunscreen

**Drug Facts**

**Active Ingredients**

Active Ingredients	Purpose
Titanium Dioxide 4.55%	Sunscreen
Zinc Oxide 3.50%	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**

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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 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 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.-2 p.m.
- Wear long-sleeved shirts, pants, hats and sunglasses

**Other information**

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FG05240-01



SP08823

# 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
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.5 mg in 100 mg
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.55 mg in 100 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYMETHYLSILSESQUIOXANE (11 MICRONS)</b> (UNII: Z570VEV8XK)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-051-18	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	Business Operations
OXYGEN DEVELOPMENT, LLC		137098492	manufacture(61354-051)

Revised: 2/2023

OXYGEN DEVELOPMENT, LLC