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.

TAN_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.

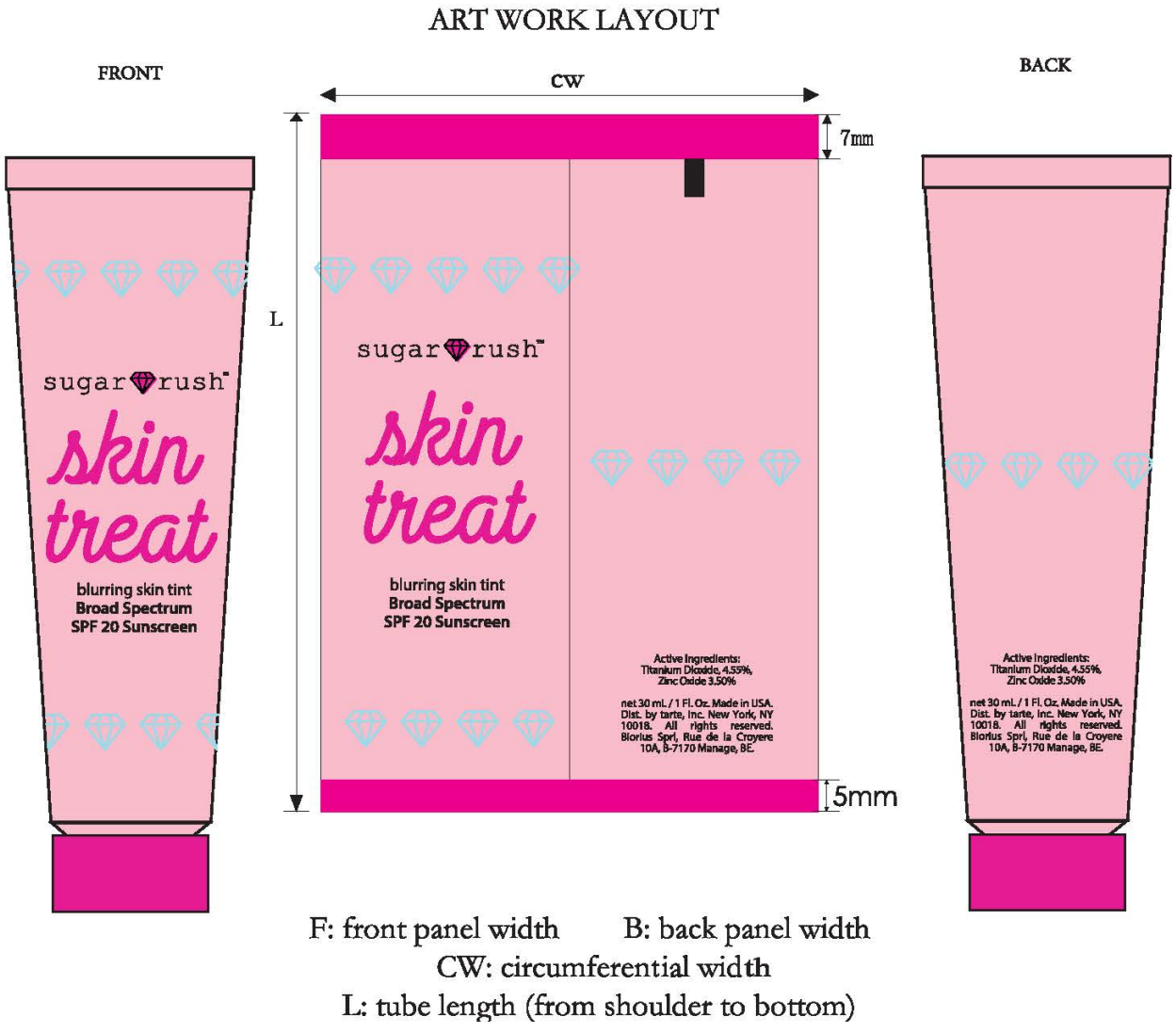
Other information

- 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)



F: front panel width B: back panel width
CW: circumferential width
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 arwork: Use CorelDraw,Freehand or Illustrator, and do not compress or change the file's type, then outline the file and send us.

sugar rush

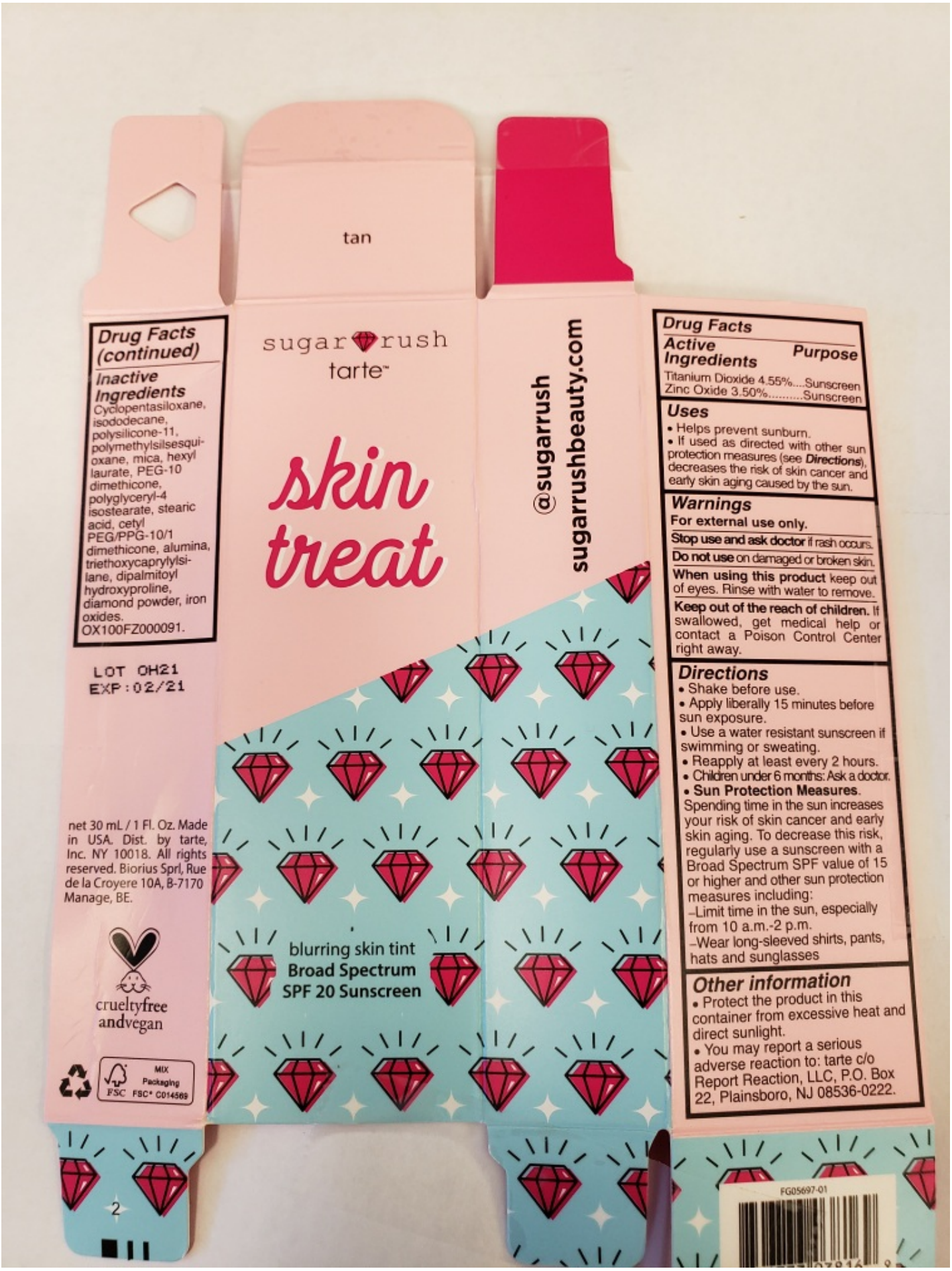
SUB-BRAND: SUGAR RUSH	FILE NAME: SKIN TREAT
COMPONENT: PRIMARY	SHADE: SPF
DATE OPENED: 5/4/18	DATE REVISED: 10/19/18
REASON FOR CHANGE: PID REVISED	

COLORS

BLACK 182C
225C 304C

Secondary Package (Outer)

30ml, 61354-051-17


tan
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 Croyere 10A, B-7170 Manage, BE.
crueltyfree andvegan
MIX
Packaging
FSC FSC® C014569
blurring skin tint
Broad Spectrum
SPF 20 Sunscreen
Drug Facts
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
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 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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• You may report a serious adverse reaction to: tarte c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, NJ 08536-0222.
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FG05697-01

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: 0THT5PCI0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61354-051-17	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