# 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.

-----

## DEEP- 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

L(changeable)

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.

	change the	
sugar	rwsh	
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)** 



## **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	
<b>TITANIUM DIOXIDE</b> (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)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61354-051- 15	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