

**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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**BB TINTED TREATMENT PRIMER BROAD SPECTRUM SPF 30 SUNSCREEN - FAIR**

***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.

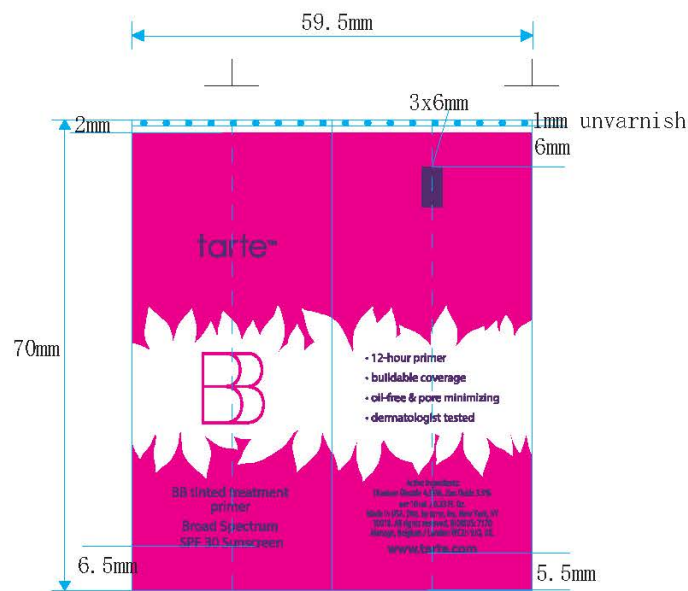
### **Other information**

- 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)**



- white
- 269c
- die line, does not print  
(边框, 不印刷)
- unvarnished area

产品编号 P/N	320477(2)	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					

10 ML 61354-051-33

### Secondary Package (Outer)

P025709

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

fair

12-hour primer

tarte

high-performance naturals™

- triple-B complex: blend of natural diamond powder, plants & lipoamino acid
- pore minimizing, smoothing & brightening
- 12-hour primer & dermatologist

CTT014203

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Titanium Dioxide 4.55%.....Sunscreen	
Zinc Oxide 3.6%.....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.

**Drug Facts (continued)**

**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, Plainboro, NJ 08536-0222.

**Inactive Ingredients**

Cyclopentasiloxane, Isododecane, mica, polyallcane-11, polymethylsilsesquioxane, hexyl laurate, PEG-10 dimethicone, polyglyceryl-4 isostearate, stearic acid, poly PEG/PPG-10/1



10 ml 61354-051-33

## CREAM

titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61354-051
<b>Route of Administration</b>	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)	

**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:61354-051-33	1 in 1 CARTON	02/25/2021	
1		10 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	02/25/2021	

**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