

**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 - DEEP**

***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.

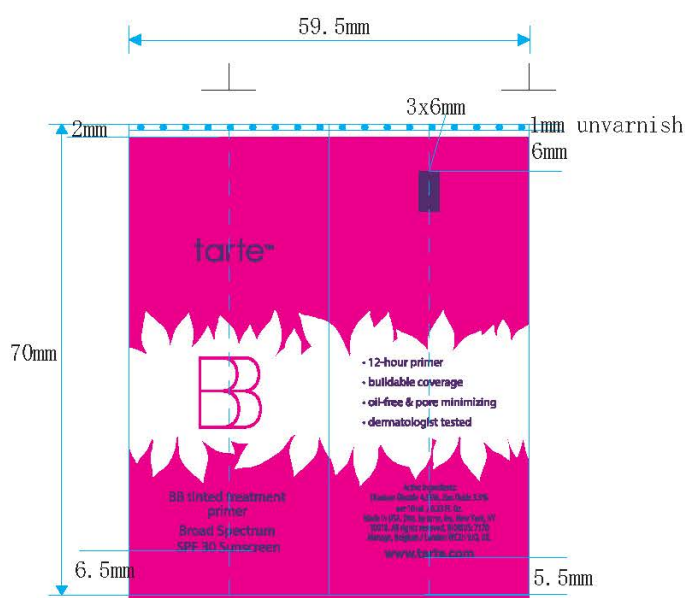
### **Other information**

- 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, 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.

### **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 61354-051-38

**Secondary Package (Outer)**

10 ml 61354-051-38

P025709  
SIZE:33\*33\*86(mm)

deep  
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  
tested

• wear alone for a  
sheer tint or under  
foundation for  
enhanced coverage

**Drug Facts**  
**Active Ingredients**  
Titanium Dioxide 4.65%.....Sunscreen  
Zinc Oxide 3.5%.....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 seek 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.  
• Check for or 6 months after 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**  
• Protect the product in this container from excessive heat and direct sunlight.  
• You may report a serious adverse reaction to this product to the FDA, U.S. Food and Drug Administration, P.O. Box 22, Plainsboro, NJ 08836-0022.

**Inactive Ingredients**  
Cyclopentasiloxane, Isododecane, polydimethylsiloxane, mica, heptyl laurate, PEG-10 dimethicone, polyglyceryl-4 isostearate, stearic acid, cetyl PEG/PPG-10/1 dimethicone, alumina, bis(1,2-dimethylamino)ethylamine, dipalmitoyl hydroxyproline, diamond powder, iron oxides.

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#claypowered  
@tartecosmetics  
www.tarte.com

BB tinted treatment primer  
Broad Spectrum  
SPF 30 Sunscreen  
net 10 ml / 0.33 fl. Oz.



SP12513

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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)	
<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:61354-051-38	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)

