

CREAM- zinc oxide, titanium dioxide cream
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.

TARTE high-performance naturals BB tinted treatment primer Broad Spectrum SPF 30 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 aging caused by the sun.

Warnings

For external use only. Stop use and ask a 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 the 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: tarte c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, NJ 08536-0222

Inactive Ingredients

Cyclopentasiloxane, Isododecane, Polysilicone-11, Polymethylsilsesquioxane, Hexyl Laurate, PEG-10 Dimethicone, Polyglyceryl-4 Isostearate, Stearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Alumina, Dipalmitoyl Hydroxyproline, Triethoxycaprylylsilane,, Mica, Titanium dioxide (CI 77891), Iron oxides (CI 77491, CI 77492, CI 77499, OX100FP000371

Package Label

■ K ■ M ■ P878oC ■ P8o8oC ■ dieline

light-medium
12-hour primer

tarte
high-performance naturals™

Drug Facts (continued)
Inactive Ingredients
Cyclopentasiloxane, isododecane, polysilicone-11, polymethylsilsesquioxane, hexyl laurate, PEG-10 dimethicone, polyglyceryl-4 isostearate, diamond powder, stearic acid, cetyl PEG/PPG-10/1 dimethicone, alumina, dipalmitoyl hydroxyproline, triethoxycaprylylsilane, mica, titanium dioxide (CI 77891), iron oxides (CI 77491, CI 77492, CI 77499, OX100FP000371.

• 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 4.55%.....Sunscreen
Zinc Oxide 3.5%.....Sunscreen

Purpose

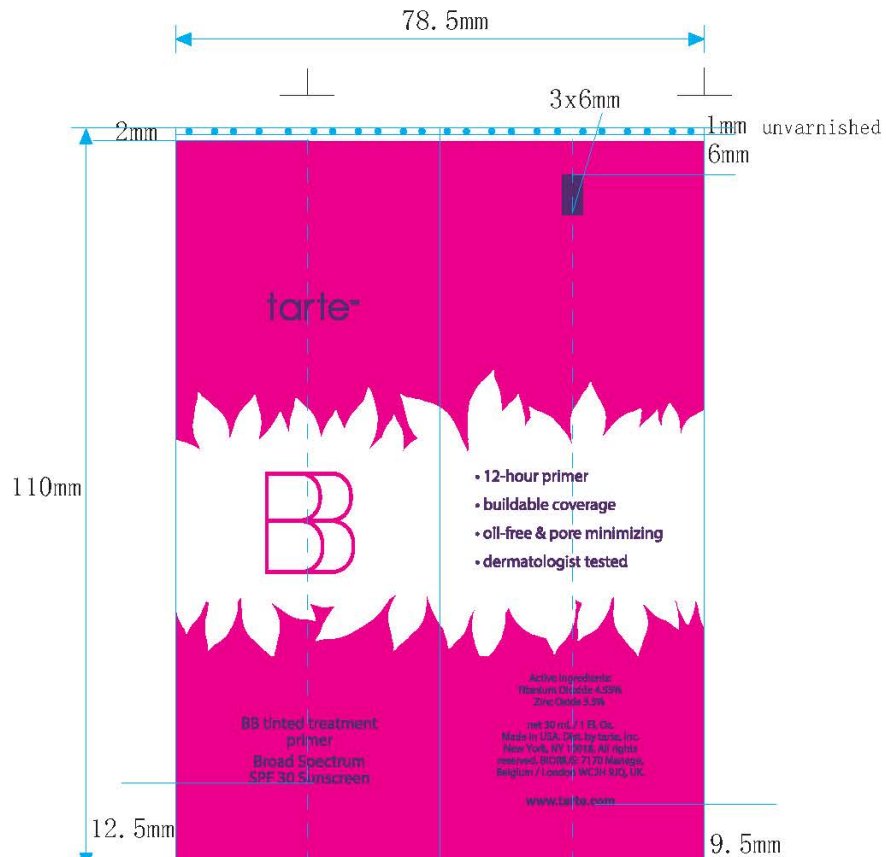
Uses
• Helps prevent sunburn.
• If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun.

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,

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320471 (2) 丝网印 (Silkscreen) : white 269c

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

产品编号 P/N	320471 (2)	制作人 Processed by	Mary	确认签字 Approval	
打样/订单号 Sample/PO #		制作日期 Date	2020/07/27	日期 Date	
附加说明 Remarks					

CREAM

zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-084
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.54 mg in 100 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.49 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
ISODODECANE (UNII: A8289P68Y2)	10.69 mg in 100 mg

POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	3.19 mg in 100 mg
HEXYL LAURATE (UNII: 4CG9F9W01Q)	1.76 mg in 100 mg
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	55.74 mg in 100 mg
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	1.65 mg in 100 mg
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	1.5 mg in 100 mg
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	4.68 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-084-01	1 in 1 CARTON	08/30/2022	
1		100 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	M020	08/30/2022	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-084)

Revised: 8/2022

Oxygen Development LLC