ZINC OXIDE- cream 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.

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tarte BB blur tinted moisturizer Broad Spectrum SPF 30 Sunscreen

Active ingredient

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 damage or broken skin.

When using

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 Ingredient

Cyclopentasiloxane, Isododecane, 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

tarte™	
SUB-BRAND: TARTE	FILE NAME: 00028CO-12 BB BLUE TINTED MOISTRUIZER SPF
COMPONENT: PRI	SHADE: N/A
DATE OPENED: 8/30/22	DATE REVISED:
REASON FOR CHANGE: NAME CHANGE	
COLORS	
CLEAR ■ 269C □ WHITE	

ART WORK LAYOUT

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.

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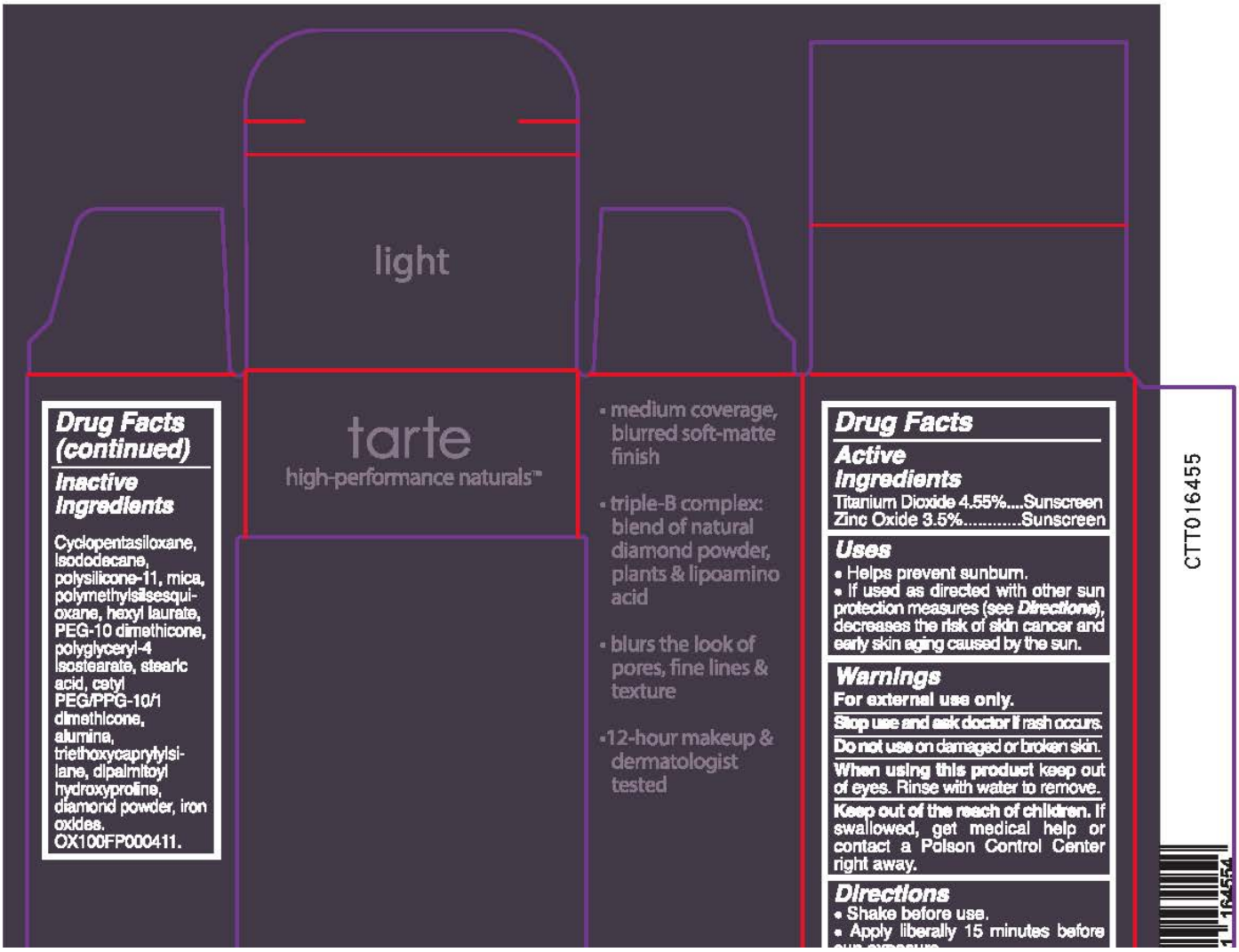
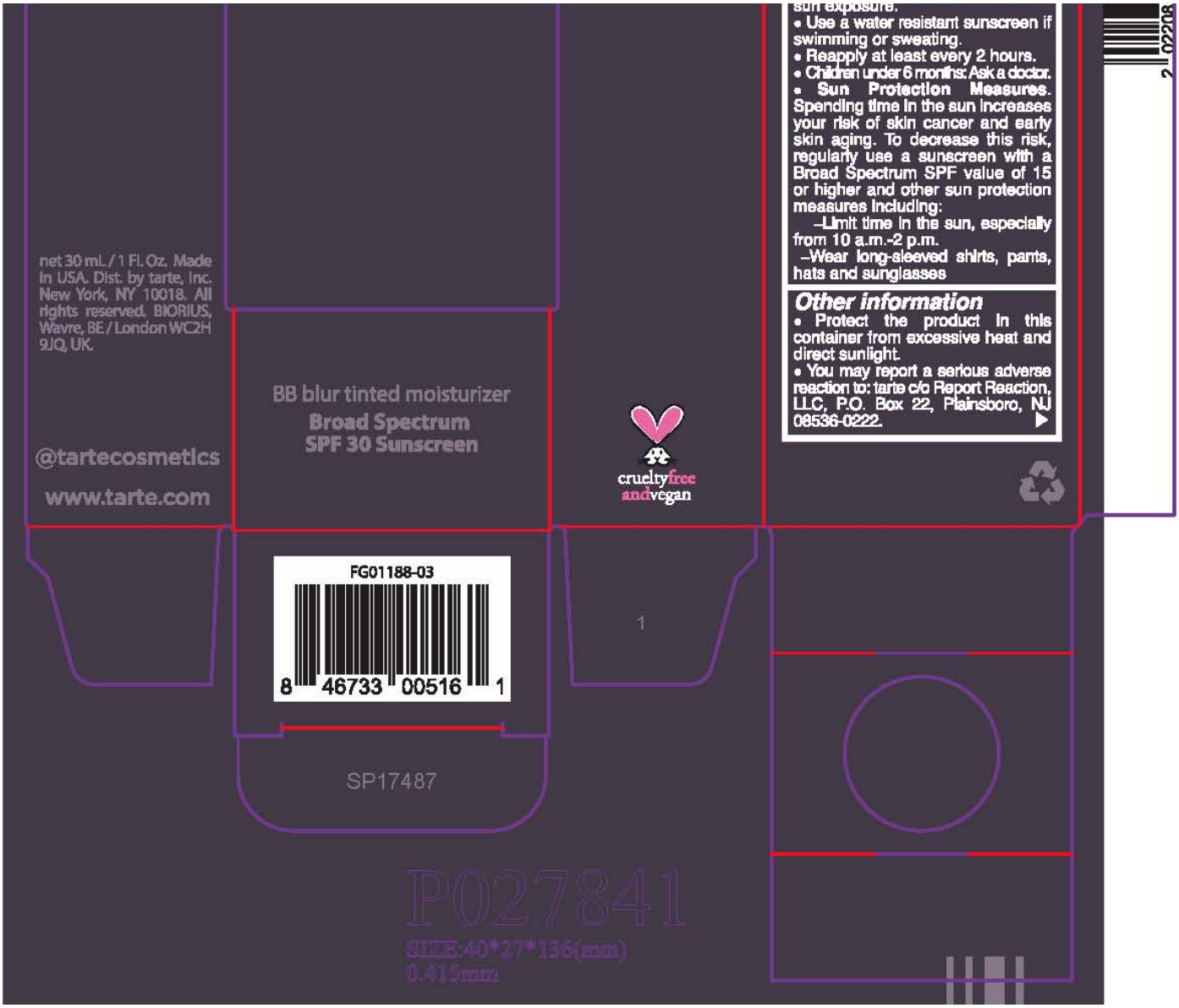
Secondary package

K M P878oC P8o8oC dieline





ZINC OXIDE

cream cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-095
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	3.498 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
ISODODECANE (UNII: A8289P68Y2)	10.69 mg in 100 mg
HEXYL LAURATE (UNII: 4CG9F9W01Q)	1.76 mg in 100 mg
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	4.68 mg in 100 mg
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	3.19 mg in 100 mg
PEG-10 DIMETHICONE (220 CST) (UNII: 287GF3Y3WC)	1.65 mg in 100 mg
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	55.74 mg in 100 mg
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	1.5 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-095-02	1 in 1 CARTON	06/23/2023	
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	06/23/2023	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-095)

Revised: 6/2023 Oxygen Development LLC