

CREAM- zinc oxide, titanium dioxide 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.

**SUGAR RUSH SKIN TREAT PORELESS TINTED MOISTURIZER 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 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 this product

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.

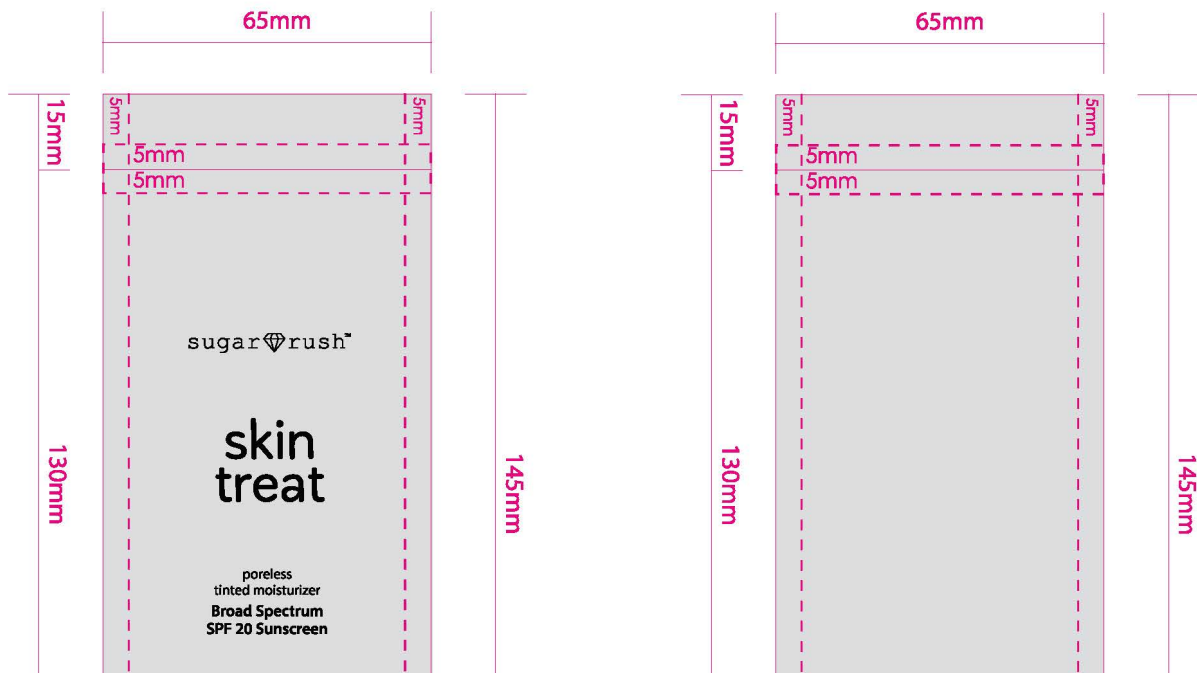
You may report a serious adverse reaction to: tarte c/o Report Reaction, LLC, P.O. Box 22, Plainsboro, NJ 08536-0222

Inactive Ingredients

Cyclopentasiloxane, Isododecane, Polysilicone-11, Polymethylsilsesquioxane, Hexyl Laurate, PEG-10 Dimethicone, Polyglyceryl-4 Isostearate, Stearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Alumina, Triethoxycaprylylsilane, Dipalmitoyl Hydroxyproline, Diamond Powder

Package Label - Principal Display Panel

sugar  rush	
SUB-BRAND: SUGAR RUSH	FILE NAME: 01541CO-2 GG SKIN TREAT SPF
COMPONENT: ZIP BAG	SHADE: TAN
DATE OPENED: 9/1/20	DATE REVISED:
REASON FOR CHANGE:	
COLORS	
<input checked="" type="checkbox"/> 9120C <input type="checkbox"/> WHITE <input type="checkbox"/> BLACK <input type="checkbox"/> CLEAR	
FINISH: GLOSSY	





F: front panel width B: back panel width
 CW: circumferential width
 L: tube length (from shoulder to bottom)
 Eyemark (2×4 mm): mark for end sealing
 Upper edge(7mm): space for end sealing
 Bottom edge(5mm): non-printing space

Dia 13xL50
 shadow area:

F/B
 20mm

CW
 40mm

L(changeable)
 50mm

printing area

CREAM

zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-059
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
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	1.5 mg in 100 mg

DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	55.74 mg in 100 mg
ISODODECANE (UNII: A8289P68Y2)	10.69 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
HEXYL LAURATE (UNII: 4CG9F9W01Q)	1.76 mg in 100 mg
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	1.65 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-059-01	1 in 1 BAG	05/04/2022	
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	part352	05/04/2022	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-059)

Revised: 5/2022

Oxygen Development LLC