POWDER- zinc oxide, titanium dioxide powder
Oxygen development

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.

SEA SET & PROTECT MINERAL POWDER SUNSCREEN BROAD SPECTRUM SPF 30 TRANSLUCENT

Active ingredients

Titanium Dioxide 8.6%

Zinc Oxide 10.0%

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 again caused by the sun.

Warnings

For external use only

Stop Use

Stop use and ask doctor if rash occurs

Do not use

Do not use on damaged 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

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control center rigth away

Directions

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at lease every 2 hours.
- Children under 6 months: ask a doctor.
- Optional: apply to all skin exposed to the sun.
- Sun Protection measures. Spending time in the sin increases your risk ofg 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.

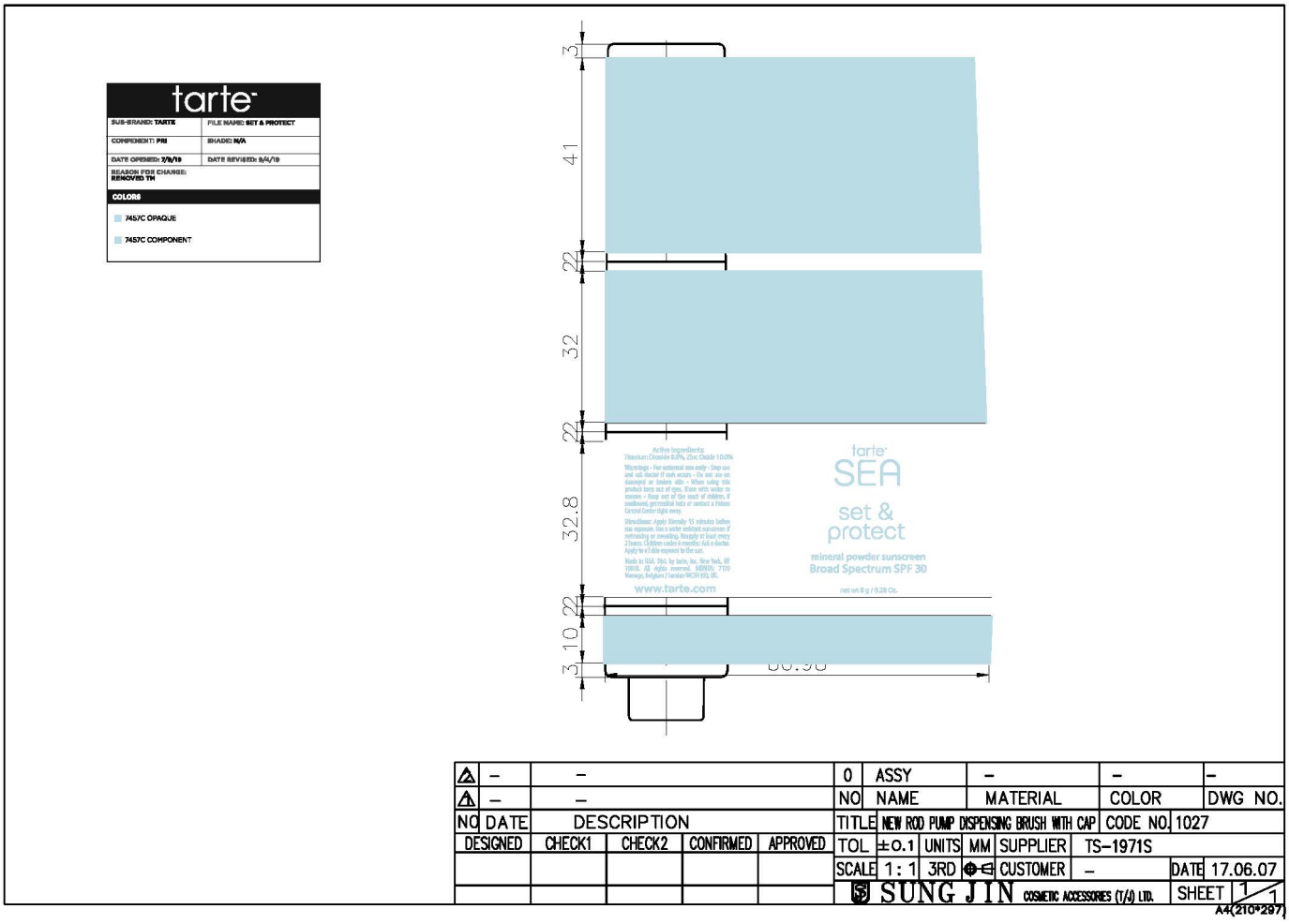
Other information

- 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, New Jersey 08536-0222.

Inactive Ingredients

Polymethylsilsesquioxane, silica, jojoba esters, caprylyl glycol, alumina, sodium dehydroacetate, phenoxyethanol, vanillin, caprylic/capric triglyceride, hexylene glycol, vanilla planifolia fruit extract, aluminum dimyristate, triethoxycaprylylsilane, disodium stearoyl glutamate, mica, iron oxides. OX100FW000041.

Primary package



8g 61354-052-02

Secondary Package

8g

61354-052-02

POWDER

zinc oxide, titanium dioxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	8.6 mg in 100 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
JOJOBA OIL (UNII: 724GKU717M)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-052-02	1 in 1 CARTON	02/25/2021	
1		8 mg in 1 BOTTLE, PLASTIC; 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 (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development		137098492	manufacture(61354-052)

Revised: 2/2023 Oxygen development