

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 TRASLUCENT

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 aging 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 right away

Directions

- 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.
- Optional: apply to all skin exposed to the sun.
- 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-2p.m. - Wear long-sleeved shirts, pants, hats and sunglasses.

Other information

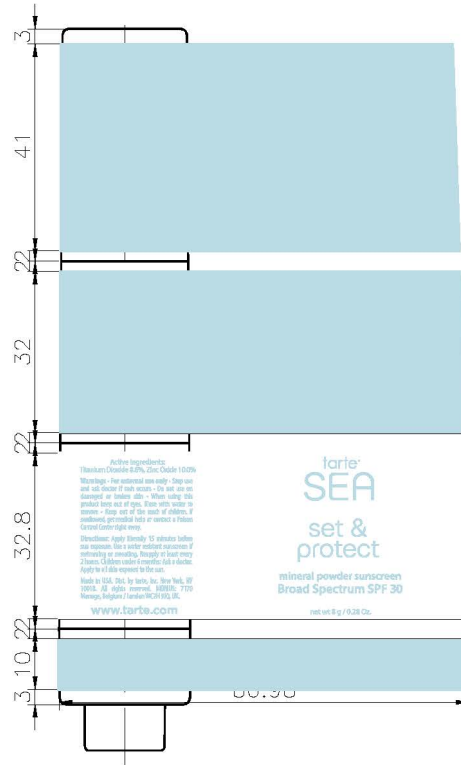
- Protect the product in this container from excessive heat and direct sunlight.
- You may report a serious adverse reaction to: tarte c/o report Reaction, LLC, P.O. Box 22, Plainsboro, New Jersey 08536-0222.

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 stearyl glutamate, mica, iron oxides. OX100FW000041.

Primary package

tarte	
SUB-BRAND: TARTÉ	FILE NAME: SET & PROTECT
COMPONENT: PR	SHADE: NA
DATE OPENED: 12/19	DATE REVISED: 04/19
REASON FOR CHANGE: REWORK IN	
COLORS	
■ 7457C OPAQUE	
■ 7457C COMPONENT	



▲	-	-	0	ASSY	-	-	-	-
▲	-	-	NO	NAME	MATERIAL	COLOR	DWG NO.	
NO	DATE	DESCRIPTION			TITLE	NEW ROD PUMP DISPENSING BRUSH WITH CAP CODE NO. 1027		
DESIGNED	CHECK1	CHECK2	CONFIRMED	APPROVED	TOL	±0.1	UNITS	MM
					SCALE	1: 1	3RD	CUSTOMER
								TS-1971S
								DATE 17.06.07
					SUNG JIN COSMETIC ACCESSORIES (U/A) LTD.			SHEET 1/1

8g 61354-052-03

Secondary Package

■ K ■ P7457C ■ P7711C
 ■ sand varnish ■ dieline

Secondary packaging design for tarte SEA set & protect sunscreen. The design features a light blue background with a white brush illustration. Text includes: 'P025064 SIZE:35*35*145(mm)', 'translucent', 'tarte SEA', 'SPF protection', 'sets makeup for 15 min', and 'TT014052F'. Two 'Drug Facts' panels are included:

Drug Facts
Active Ingredients Purpose
 Titanium Dioxide 8.6%.....Sunscreen
 Zinc Oxide 10.0%.....Sunscreen

Uses
 • Helps prevent sunburn.
 • If used as directed with other sun protection measures (see **Directions**), decreases the risk

Drug Facts (continued)
 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

of skin cancer and early skin aging caused by the sun.

Warnings

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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

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• Use a water resistant sunscreen if swimming or sweating.

• Reapply at least 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 sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a ▶

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

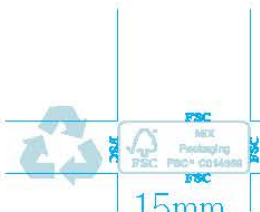
Polymethylsilsesquioxane, silica, jojoba esters, caprylyl glycol, alumina, sodium dehydroacetate, phenoxyethanol, vanillin, caprylic/capric triglyceride, hexylene glycol, vanilla planifolia fruit extract, aluminum dimyristate, triethoxycaprylylsilane, disodium stearoyl glutamate, mica, iron oxides. OX100FW000041.

Made in USA. Dist. by tarte, Inc. New York, NY 10018. All rights reserved. BIORIUS: 7170 Manage, Belgium / London WC2H 9JQ, UK.

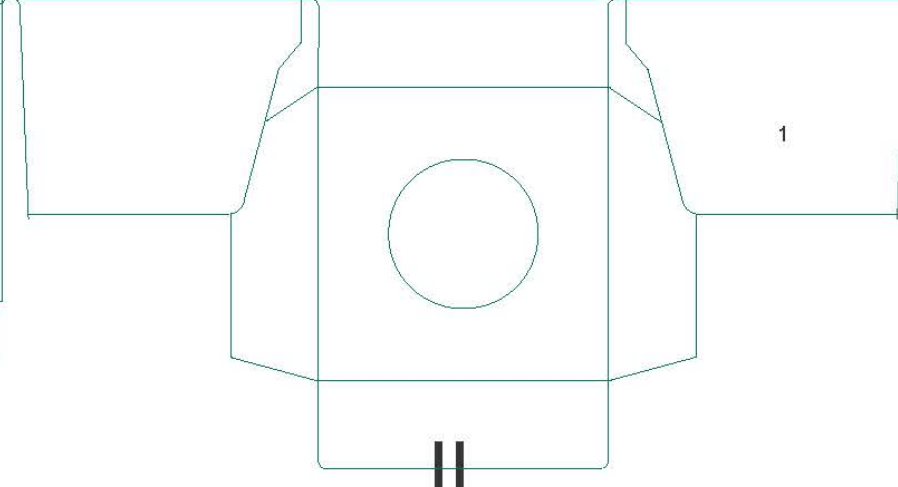


set & protect mineral powder sunscreen Broad Spectrum SPF 30 net wt 8 g / 0.28 Oz.

12 hours mineral pigments jojoba dermatologist tested



#tartesea @tartecosmetics www.tarte.com



8g 61354-052-03

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:61354-052-03	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