POWDER- zinc oxide powder
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.

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

When using

When using this product keep out of eyes. Rinse with water to remove.

Keep out of 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 unther 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 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.

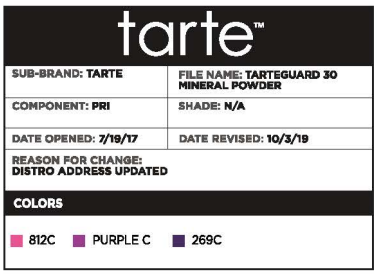
Wear long - sleeved shirts, pants, hats and sunglasses.

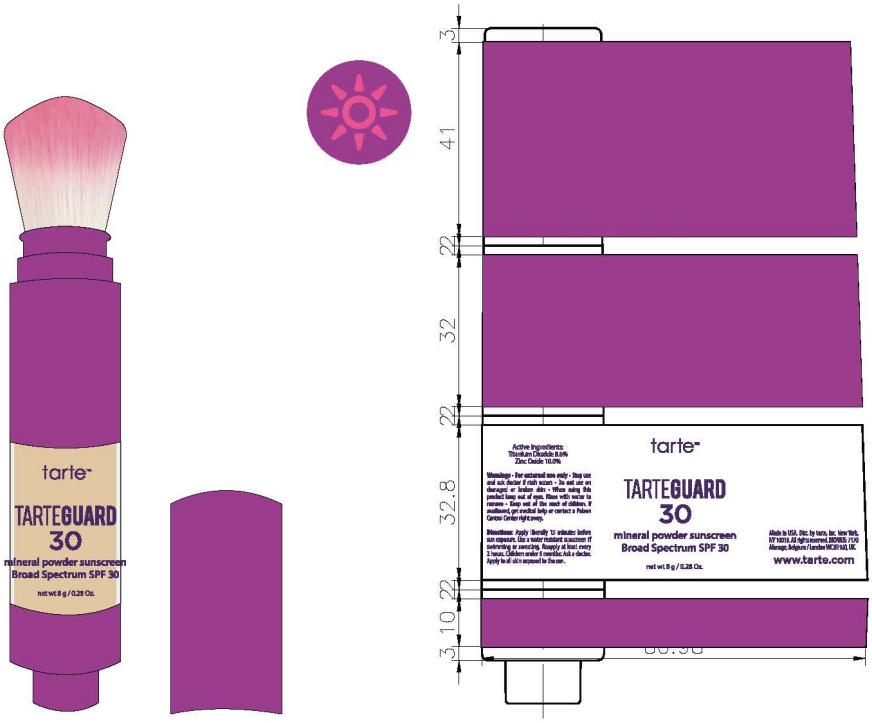
Other information

Protect the prodcut in this container from excessive heat and direct sunlight.

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

Package





Package

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TARTEGUARD 30

mineral powder sunscreen
Broad Spectrum SPF 30

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 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

- 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.-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, New Jersey 08536-0222.

Drug Facts (continued)

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, iron oxides, mica. OX100FW000041.

tarte
high-performance naturals™

TARTEGUARD 30

mineral powder sunscreen
Broad Spectrum SPF 30

@tartecosmetics
www.tarte.com

net wt 8 g / 0.28 Oz.

crueltyfree andvegan

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POWDER

zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-043
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	73 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	5.35 g in 100 g
POTASSIUM HYDROLYZED JOJOBA ESTERS (UNII: CH428W5O62)	0.55 g in 100 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61354-043-02	1 in 1 CARTON	01/11/2022	
1	NDC:61354-043-01	8 g in 1 BOTTLE; 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	01/11/2022	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-043)

Revised: 1/2022