PERFECTLY POSH THROWING SHADE SPF30 BROAD SPECTRUM FACIAL SUNSCREEN- zinc oxide, titanium dioxide cream Perfectly Posh, 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.

Perfectly Posh THROWING SHADE SPF30 Broad Spectrum Facial Sunscreen

Drug Facts

Active Ingredient

Zinc Oxide 6%

Titanium Dioxide 4.6%

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

Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs.

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

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Children under 6 months of age: ask a doctor.
- Reapply at least every 2 hours.
- Use a water-resistant sunscreen if swimming or sweating.

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 10am-2pm.
 - Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Water (Aqua), Carthamus Tinctorius (Safflower) Oleosomes, Butyrospermum Parkii (Shea) Butter,

Caprylic/Capric Triglyceride, Diheptyl Succinate, Glycerin, Cetearyl Alcohol, Hydroxypropyl Starch Phosphate, Methylcellulose, Phenylpropanol, Alumina, Stearic Acid, Propanediol, Polyhydroxystearic Acid, Caprylyl Glycol, Gluconolactone, Lavandula Hybrida Oil, Capryloyl Glycerin/Sebacic Acid Copolymer, Triethoxycaprylylsilane, Sodium Benzoate, Sodium Phytate, Rhizobian Gum, Sodium Chloride, Sodium Hyaluronate, Phenoxyethanol, Tocopherol, Chlorphenesin, Citric Acid.

Other Information

Protect this product from excessive heat and sun.

PRINCIPAL DISPLAY PANEL

Broad Spectrum

Facial Sunscreen

SPF 30

1.6 oz/45 g



PERFECTLY POSH THROWING SHADE SPF30 BROAD SPECTRUM FACIAL SUNSCREEN

zinc oxide, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71140-0332
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 g
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	4.6 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
ALUMINUM O XIDE (UNII: LMI26 O 6933)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
GLYCERIN (UNII: PDC6A3C0OX)		
PHENYLPROPANOL (UNII: 0F897O3O4M)		
CHLORPHENESIN (UNII: 1670 DAL4SZ)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)		
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
LAVENDER OIL (UNII: ZBP1YXW0H8)		
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
TOCOPHEROL (UNII: R0ZB2556P8)		
STEARIC ACID D7 (UNII: T3B081197X)		
PROPANEDIOL (UNII: 5965N8W85T)		
HYDRO XYPRO PYL DISTARCH PHO SPHATE, HIGH AMYLO SE CORN (UNII: 9F8 ET54T05)		
WATER (UNII: 059QF0KO0R)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
GLUCONOLACTONE (UNII: WQ29KQ9POT)		
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)		
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)		
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)		
PHYTATE SO DIUM (UNII: 88496G1ERL)		
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)		
RHIZOBIAN GUM (UNII: 0 XNZ14VU7K)		

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:71140-0332-3	45 g in 1 TUBE; Type 0: Not a Combination Product	02/15/2017		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	02/15/2017		

Labeler - Perfectly Posh, LLC (063537897)

Revised: 2/2017 Perfectly Posh, LLC