

PURE HAVEN ESSENTIALS- titanium dioxide, zinc oxide cream
Pure Haven LLC

Pure Haven Essentials SPF-30

Drug Facts

Active Ingredient

Titanium Dioxide (6.00%) Zinc Oxide (6.00%)

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

- For external use only.

Do not use

on damaged or broken skin.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and consult physician

if irritation or rash develops.

Keep out of reach of children.

If product is swallowed, get medical attention or contact poison control center immediately.

Directions:

- Apply liberally 15-minutes before sun exposure.
- Reapply:

- At least every tow-hours.

- Immediately after swimming, sweating or towel drying.

Spending time in the sun increase your risk of skin cancer and early skin aging . To decrease this risk, regularly use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including: **Sun protection measures.**

- Limit time in the sun, especially between 10am and 2pm.

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

- For childre under 6-months, consult with a physician.

Other Ingredients

Aloe Barbadensis (Aloe vera) Juice, Aqua (Deionized Water), Camellia Sinensis (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Oliviate, Cucurbita Pepo (Pumpkin) Seed Oil, Ethylhexyl Palmitate, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Leuconostoc/Radish Root Ferment Filtrate, Prunus Amygdalus Dulcis (Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Sodium Laurylglucosides Hydroxypropylsulfonate, Sorbitan Oliviate, Theobroma Cacao (Cocoa) Butter, Xanthan Gum

Other Information:

- Protect this product from excessive heat and direct sunlight.

Package Labeling:

SUN



PUREhaven
ESSENTIALS

safe. effective. trustworthy.

Sunscreen
SPF 30

Protects Skin



3 oz net wt

Eye Mark

2mm

OUR PRODUCT PROMISE

To offer safe, effective, and trustworthy products without harmful ingredients.

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purehaven.com
Pure Haven LLC

99 Main St., Warren, RI 02885

PURE HAVEN ESSENTIALS

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71355-819
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
PUMPKIN SEED OIL (UNII: 6E5QR5USSP)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)	
ALMOND (UNII: 3Z252A2K9G)	
SESAME OIL (UNII: QX10HYY4QV)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
COCOA (UNII: D9108TZ9KG)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71355-819-03	90 mL in 1 TUBE; Type 0: Not a Combination Product	03/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/28/2017	

